



Hello,

Great News! I understand you are interested in starting COVID-19 testing in your school district.

Here is the **COVID-19 Testing Guidance for Alaska School Districts**, a packet of applications, guidelines, and procedures to get you ready for school COVID-19 testing.

**Step 1. Apply for a Clinical Laboratory Improvement Amendments (CLIA waiver)**

- [CLIA Application](#)
- [CLIA Waiver Sample](#)

Contact: Katherine Ross  
Katherine.Ross@alaska.gov (O) 907.334.2112

**Step 2. Order testing supplies from your Borough Office of Emergency Management.**

For more information view [Resource Request Presentation](#).

- a. Complete the [Resource Request Message \(ICS 213RR\)](#) form
- b. Complete the [Entity Demographics for IMATS](#) form
- c. Email completed forms/request to [2020\\_COVID-19@ak-prepared.com](mailto:2020_COVID-19@ak-prepared.com)

Contact: Collin Johanknecht  
(O) 907.754.3559 (C) 907.351.5197

**Step 3. Testing Procedures & Guidelines**

- [COVID-19 Antigen Testing Consent Form Sample](#)
- [BinexNow Testing procedures](#)
- [Antigen Testing instructions \(short form\)](#)
- [Antigen Testing Preparation at School Clinics](#)
- [Guidelines for screening with antigen testing in K-12 schools](#)
- [Cue COVID-19 Test Advisement](#)

#### Step 4. Apply for a Reporting Portal Access

- [Lab Online Facility Request Form](#)
- [Lab Online User Agreement](#)

Contact: Megan Tompkins, MPH

[Megan.Tompkins@alaska.gov](mailto:Megan.Tompkins@alaska.gov)

Direct line: (907)269-8014 or Section of Epidemiology: (907)269-8000

#### Step 5. Reporting Procedures

- [Confidential Infectious Disease Report Form](#)
- [COVID Reporting Requirements for State of Alaska](#)
- [Download Flat File State of Alaska Spreadsheet Guide \(Excel\)](#)

I suggest downloading the full packet and save electronically.

If you have any questions or need assistance, please contact me at

[wendy.degraffenried@alaska.gov](mailto:wendy.degraffenried@alaska.gov).

Kind regards,

Wendy

Wendy DeGraffenried BSN, RN, NCSN, HN-BC School Health Nurse Consultant I State of Alaska | Dept of Health and Social Services

Dept of Public Health | Women, Children, and Family Health

Phone: 907-891-1263



**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)  
APPLICATION FOR CERTIFICATION****ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.****I. GENERAL INFORMATION**

<input type="checkbox"/> Initial Application      Anticipated Start Date _____			CLIA IDENTIFICATION NUMBER		
<input type="checkbox"/> Survey			_____ D _____		
<input type="checkbox"/> Change in Certificate Type			(If an initial application leave blank, a number will be assigned)		
<input type="checkbox"/> Other Changes (Specify) _____					
Effective Date _____					
FACILITY NAME			FEDERAL TAX IDENTIFICATION NUMBER		
EMAIL ADDRESS			TELEPHONE NO. (Include area code)		FAX NO. (Include area code)
<input type="checkbox"/> RECEIVE FUTURE NOTIFICATIONS VIA EMAIL					
FACILITY ADDRESS — <i>Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified</i>			MAILING/BILLING ADDRESS (If different from facility address) send Fee Coupon or certificate		
NUMBER, STREET (No P.O. Boxes)			NUMBER, STREET		
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE
SEND FEE COUPON TO THIS ADDRESS		SEND CERTIFICATE TO THIS ADDRESS	CORPORATE ADDRESS (If different from facility) send Fee Coupon or certificate		NUMBER, STREET
PICK ONE:		PICK ONE:			
<input type="checkbox"/> Physical		<input type="checkbox"/> Physical	CITY		STATE
<input type="checkbox"/> Mailing		<input type="checkbox"/> Mailing			ZIP CODE
<input type="checkbox"/> Corporate		<input type="checkbox"/> Corporate			
NAME OF DIRECTOR (Last, First, Middle Initial)			Laboratory Director's Phone Number		
CREDENTIALS			FOR OFFICE USE ONLY		
			Date Received		

**II. TYPE OF CERTIFICATE REQUESTED** (Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)☐ Certificate of Waiver (Complete Sections I – VI and IX – X)**NOTE:** Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.☐ Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I-VII and IX-X)☐ Certificate of Compliance (Complete Sections I – X)☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.☐ The Joint Commission      ☐ AAHHS/HFAP      ☐ AABB      ☐ A2LA☐ CAP      ☐ COLA      ☐ ASHI**If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.****PRA Disclosure Statement**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 03/31/2024. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. \*\*\*\*\*CMS Disclaimer\*\*\*\*\*Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact [LabExcellence@cms.hhs.gov](mailto:LabExcellence@cms.hhs.gov).

**III. TYPE OF LABORATORY** (Check the one most descriptive of facility type)

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> 01 Ambulance                                      | <input type="checkbox"/> 11 Health Main. Organization   | <input type="checkbox"/> 22 Practitioner Other (Specify) _____            |
| <input type="checkbox"/> 02 Ambulatory Surgery Center                      | <input type="checkbox"/> 12 Home Health Agency  |   |
| <input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility | <input type="checkbox"/> 13 Hospice   | <input type="checkbox"/> 23 Prison  |
| <input type="checkbox"/> 04 Assisted Living Facility                       | <input type="checkbox"/> 14 Hospital  | <input type="checkbox"/> 24 Public Health Laboratories                    |
| <input type="checkbox"/> 05 Blood Bank                                     | <input type="checkbox"/> 15 Independent   | <input type="checkbox"/> 25 Rural Health Clinic                           |
| <input type="checkbox"/> 06 Community Clinic                               | <input type="checkbox"/> 16 Industrial  | <input type="checkbox"/> 26 School/Student Health Service                 |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab Facility                | <input type="checkbox"/> 17 Insurance   | <input type="checkbox"/> 27 Skilled Nursing Facility/<br>Nursing Facility |
| <input type="checkbox"/> 08 End Stage Renal Disease<br>Dialysis Facility   | <input type="checkbox"/> 18 Intermediate Care Facilities for<br>Individuals with Intellectual<br>Disabilities | <input type="checkbox"/> 28 Tissue Bank/Repositories                      |
| <input type="checkbox"/> 09 Federally Qualified<br>Health Center           | <input type="checkbox"/> 19 Mobile Laboratory   | <input type="checkbox"/> 29 Other (Specify) _____                         |
| <input type="checkbox"/> 10 Health Fair                                    | <input type="checkbox"/> 20 Pharmacy  |   |
|  | <input type="checkbox"/> 21 Physician Office  |   |

**IV. HOURS OF LABORATORY TESTING** (List times during which laboratory testing is performed in HH:MM format) If testing 24/7 Check Here ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

**V. MULTIPLE SITES** (must meet one of the regulatory exceptions to apply for this provision in 1-3 below)**Are you applying for a single site CLIA certificate to cover multiple testing locations?**

- ☐
- No. If no, go to section VI.
- ☐
- Yes. If yes, complete remainder of this section.

**Indicate which of the following regulatory exceptions applies to your facility's operation.**

- Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?  
☐ Yes ☐ No  
If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.
- Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?  
☐ Yes ☐ No  
If yes, provide the number of sites under the certificate \_\_\_\_\_ and list name, address and test performed for each site below.
- Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?  
☐ Yes ☐ No  
If yes, provide the number of sites under this certificate \_\_\_\_\_ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.  
**If additional space is needed, check here ☐ and attach the additional information using the same format.**

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)	

In the next three sections, indicate testing performed and estimated annual test volume.

**VI. WAIVED TESTING** *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed \_\_\_\_\_

☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

**VII. PPM TESTING** *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.

- ☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ☐ Potassium hydroxide (KOH) preparations
- ☐ Pinworm examinations
- ☐ Fern tests
- ☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ☐ Urine sediment examinations
- ☐ Nasal smears for granulocytes
- ☐ Fecal leukocyte examinations
- ☐ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed \_\_\_\_\_

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

**VIII. NON-WAIVED TESTING** (Including PPM testing if applying for a Certificate of Compliance or Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

If additional space is needed, check here ☐ and attach additional information using the same format.

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

If additional space is needed, check here and attach additional information using the same format.” Include text box similar to Section VII.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/ subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AAHHS/HFAP, AABB, A2LA ,CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			HEMATOLOGY 400		
<input type="checkbox"/> Transplant			<input type="checkbox"/> Hematology		
<input type="checkbox"/> Nontransplant			IMMUNOHEMATOLOGY		
MICROBIOLOGY			<input type="checkbox"/> ABO Group & Rh Group 510		
<input type="checkbox"/> Bacteriology 110			<input type="checkbox"/> Antibody Detection (transfusion) 520		
<input type="checkbox"/> Mycobacteriology 115			<input type="checkbox"/> Antibody Detection (nontransfusion) 530		
<input type="checkbox"/> Mycology 120			<input type="checkbox"/> Antibody Identification 540		
<input type="checkbox"/> Parasitology 130			<input type="checkbox"/> Compatibility Testing 550		
<input type="checkbox"/> Virology 140			PATHOLOGY		
DIAGNOSTIC IMMUNOLOGY			<input type="checkbox"/> Histopathology 610		
<input type="checkbox"/> Syphilis Serology 210			<input type="checkbox"/> Oral Pathology 620		
<input type="checkbox"/> General Immunology 220			<input type="checkbox"/> Cytology 630		
CHEMISTRY			RADIOBIOASSAY 800		
<input type="checkbox"/> Routine 310			<input type="checkbox"/> Radiobioassay		
<input type="checkbox"/> Urinalysis 320			CLINICAL CYTOGENETICS 900		
<input type="checkbox"/> Endocrinology 330			<input type="checkbox"/> Clinical Cytogenetics		
<input type="checkbox"/> Toxicology 340			TOTAL ESTIMATED ANNUAL TEST VOLUME:		

**IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)****VOLUNTARY NONPROFIT**

- ☐ 01 Religious Affiliation  
☐ 02 Private Nonprofit  
☐ 03 Other Nonprofit

\_\_\_\_\_  
(Specify)

**FOR PROFIT**

- ☐ 04 Proprietary

**GOVERNMENT**

- ☐ 05 City  
☐ 06 County  
☐ 07 State  
☐ 08 Federal  
☐ 09 Other Government

\_\_\_\_\_  
(If 09 is selected, please specify the country or the province.)

Does this facility have partial or full ownership by a foreign entity or foreign government?

☐ Yes ☐ No

If Yes, what is the country of origin for the foreign entity? \_\_\_\_\_

**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

**ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION**

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF DIRECTOR OF LABORATORY

PRINT NAME OF OWNER OF LABORATORY

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE)

DATE

**NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.**

**STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:**

**<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>**



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# THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

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## INSTRUCTIONS FOR COMPLETION

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CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

**NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.**

**NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M (42 CFR PART 493) of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:**

- Verification of State Licensure, as applicable
- Documentation of qualifications:
  - Education (copy of Diploma, transcript from accredited institution, CMEs),
  - Credentials, and
  - Laboratory experience.

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

**ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.**

### I. GENERAL INFORMATION

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "change in certificate type" and provide the effective

date of the change. For all other changes, including change in location, director, lab closure, etc., check "other changes" and provide the effective date of the change.

**CLIA Identification Number:** For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10 digit CLIA identification number already assigned and listed on your CLIA certificate.

**Facility Name:** Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. NOTE: the information provided is what will appear on your certificate.

**Email Address:** A valid Email Address is optional and will be used for communications between the CLIA program and the laboratory. Selecting the RECEIVE NOTIFICATIONS VIA EMAIL checkbox, requires the laboratory to enter a valid Email Address.

**Physical Facility Address:** This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.

**Mailing Address:** This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this section.

**Corporate Address:** This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as, the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.

**Form Mailing:** Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.

**For Office Use Only:** The date received is the date the form is received by the state agency or CMS regional office for processing.

### II. TYPE OF CERTIFICATE REQUESTED

Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory.

When completing this section, please remember that a facility holding a:



- **Certificate of Waiver** can only perform tests categorized as waived;\*
- **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;\*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met following a CLIA survey; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.)

\*A current list of waived and PPM tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm>.

### III. TYPE OF LABORATORY

Select the type that is most descriptive of the location where the laboratory testing is performed.

If selecting 'mobile laboratory' (code 19), a mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINs) of all vehicles used for mobile laboratory testing.

If selecting 'Practitioner Other' (code 22), this type includes practitioners such as, dentists, chiropractors, etc.

### IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM

format and check box marked '24/7' if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.

### V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493.493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3). Hospice and HHA could qualify for an exception.

### VI. WAIVED TESTING

Indicate the estimated total annual test volume for all waived tests performed. List can be found at: <https://www.cms.gov/CLIA/downloads/waivetbl.pdf>

### VII. PPM TESTING

Indicate the estimated total annual test volume for all PPM tests performed. List can be found at: <https://www.cms.gov/CLIA/downloads/ppmplist.pdf>

### VIII. NON-WAIVED TESTING (INCLUDING PPM)

The total Estimated Annual Test volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section for test counting information. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

### IX. TYPE OF CONTROL

Select the type of ownership or control which most appropriately describes your facility.

### X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible and that are under different certificates. Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

#### Reminders - Before submitting the Form CMS-116:

1. Include the current or estimated annual test volume.
2. For Certificate for PPM, Certificate of Compliance, or Certificate of Accreditation, include the laboratory director qualifications.
3. Do not send any money with your application.
4. Send the completed Form CMS-116 to the appropriate State Agency (<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>).

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency. State agency contact information can be found at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

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**VIII. NON-WAIVED TESTING**

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**TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING  
LABORATORY SPECIALTIES/SUBSPECIALITIES**

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**HISTOCOMPATIBILITY (010)**

HLA Typing (disease associated antigens)

**MICROBIOLOGY****Bacteriology (110)**

Gram Stain

Culture

Susceptibility

Strep screen

Antigen assays (H.pylori, Chlamydia, etc.)

**Mycobacteriology (115)**

Acid Fast Smear

Mycobacterial culture

Mycobacterial susceptibility

**Mycology (120)**

Fungal Culture

DTM

KOH Preps

**Parasitology (130)**

Direct Preps

Ova and Parasite Preps

Wet Preps

**Virology (140)**

RSV (Not including waived kits)

HPV assay

Cell culture

**DIAGNOSTIC IMMUNOLOGY****Syphilis Serology (210)**

RPR

FTA, MHATP

**General Immunology (220)**

Allergen testing

ANA

Antistreptolysin O

Antigen/Antibody (hepatitis, herpes, rubella, etc.)

Complement (C3, C4)

Immunoglobulin

HIV

Mononucleosis assay

Rheumatoid factor

Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)\*

\*Tumor markers can alternatively be listed under  
Routine Chemistry instead of General Immunology.

**HEMATOLOGY (400)**

Complete Blood Count (CBC)

WBC count

RBC count

Hemoglobin

Hematocrit (Not including spun micro)

Platelet count

Differential

Activated Clotting Time

Prothrombin time (Not including waived instruments)

Partial thromboplastin time

Fibrinogen

Reticulocyte count

Manual WBC by hemocytometer

Manual platelet by hemocytometer

Manual RBC by hemocytometer

Sperm count

**IMMUNOHEMATOLOGY**

ABO group (510)

Rh(D) type (510)

Antibody screening

Antibody identification (540)

Compatibility testing (550)

**PATHOLOGY**

Dermatopathology

Oral Pathology (620)

PAP smear interpretations (630)

Other Cytology tests (630)

Histopathology (610)

**RADIOBIOASSAY (800)**

Red cell volume

Schilling test

**CLINICAL CYTOGENETICS (900)**

Fragile X

Buccal smear

Prader-Willi syndrome

FISH studies for: neoplastic disorders, congenital disorders  
or solid tumors.

## **CHEMISTRY**

### **Routine Chemistry (310)**

Albumin  
Ammonia  
Alk Phos  
ALT/SGPT  
AST/SGOT  
Amylase  
Bilirubin  
Blood gas (pH, pO<sub>2</sub>, pCO<sub>2</sub>)  
BUN  
Calcium  
Chloride  
Cholesterol  
Cholesterol, HDL  
CK/CK isoenzymes  
CO<sub>2</sub>  
Creatinine  
Ferritin  
Folate  
GGT  
Glucose (Not fingerstick)  
Iron  
LDH/LDH isoenzymes  
Magnesium  
Potassium  
Protein, electrophoresis  
Protein, total  
PSA  
Sodium  
Triglycerides  
Troponin  
Uric acid  
Vitamin B12

### **Endocrinology (330)**

Cortisol  
HCG (serum pregnancy test)  
T3  
T3 Uptake  
T4  
T4, free  
TSH

### **Toxicology (340)**

Acetaminophen  
Blood alcohol  
Blood lead (Not waived)  
Carbamazepine  
Digoxin  
Ethosuximide  
Gentamicin  
Lithium  
Phenobarbital  
Phenytoin  
Primidone  
Procainamide  
NAPA  
Quinidine  
Salicylates  
Theophylline  
Tobramycin  
Therapeutic Drug Monitoring

### **Urinalysis\*\* (320)**

Automated Urinalysis (Not including waived instruments)  
Microscopic Urinalysis  
Urine specific gravity by refractometer  
Urine specific gravity by urinometer  
Urine protein by sulfosalicylic acid

\*\* Dipstick urinalysis is counted in Section VI. WAIVED TESTING

**NOTE:** This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/ subspecialties can be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf> and <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/lccodes.pdf>. You may also call your State agency for further information. State agency contact information can be found at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>.

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## GUIDELINES FOR COUNTING TESTS FOR CLIA

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- For **chemistry**, each non-calculated analyte is counted separately (e.g., Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals 4 tests).
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests. NOTE: For all other genetic tests, the number of tests is determined by the number of results reported in the final report.
- For manual gynecologic and nongynecologic **cytology**, each slide (not case) is counted as one test.
- For **flow cytometry**, each measured individual analyte (e.g. T cells, B cells, CD4, etc.) that is ordered and reported should be counted separately.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- **Genetics tests** should be placed in the specialty or subspecialty where they fit best, according to the methodology of the test.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **histocompatibility**, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA cross match is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as 3 tests.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialties**, do not count calculations (e.g., A/G ratio, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your State agency.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)  
APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

## I. GENERAL INFORMATION

<input type="checkbox"/> Initial Application      Anticipated Start Date _____			CLIA IDENTIFICATION NUMBER		
<input type="checkbox"/> Survey			_____ D _____		
<input type="checkbox"/> Change in Certificate Type			(If an initial application leave blank, a number will be assigned)		
<input type="checkbox"/> Other Changes (Specify) _____					
Effective Date _____					
FACILITY NAME			FEDERAL TAX IDENTIFICATION NUMBER		
EMAIL ADDRESS			TELEPHONE NO. (Include area code)		FAX NO. (Include area code)
<input type="checkbox"/> RECEIVE FUTURE NOTIFICATIONS VIA EMAIL					
FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified			MAILING/BILLING ADDRESS (If different from facility address) send Fee Coupon or certificate		
NUMBER, STREET (No P.O. Boxes)			NUMBER, STREET		
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE
SEND FEE COUPON TO THIS ADDRESS		SEND CERTIFICATE TO THIS ADDRESS	CORPORATE ADDRESS (If different from facility) send Fee Coupon or certificate		NUMBER, STREET
PICK ONE:		PICK ONE:			
<input type="checkbox"/> Physical		<input type="checkbox"/> Physical	CITY		STATE
<input type="checkbox"/> Mailing		<input type="checkbox"/> Mailing			ZIP CODE
<input type="checkbox"/> Corporate		<input type="checkbox"/> Corporate			
NAME OF DIRECTOR (Last, First, Middle Initial)			Laboratory Director's Phone Number		
CREDENTIALS			FOR OFFICE USE ONLY		
			Date Received		

## II. TYPE OF CERTIFICATE REQUESTED (Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

☐ Certificate of Waiver (Complete Sections I – VI and IX – X)**NOTE:** Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.☐ Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I-VII and IX-X)☐ Certificate of Compliance (Complete Sections I – X)☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.☐ The Joint Commission☐ AAHHS/HFAP☐ AABB☐ A2LA☐ CAP☐ COLA☐ ASHI**If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.**

## PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 03/31/2024. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. \*\*\*\*\*CMS Disclaimer\*\*\*\*\*Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact [LabExcellence@cms.hhs.gov](mailto:LabExcellence@cms.hhs.gov).

### III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> 01 Ambulance                                      | <input type="checkbox"/> 11 Health Main. Organization   | <input type="checkbox"/> 22 Practitioner Other (Specify) _____         |
| <input type="checkbox"/> 02 Ambulatory Surgery Center                      | <input type="checkbox"/> 12 Home Health Agency  |  |
| <input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility | <input type="checkbox"/> 13 Hospice   | <input type="checkbox"/> 23 Prison                                     |
| <input type="checkbox"/> 04 Assisted Living Facility                       | <input type="checkbox"/> 14 Hospital  | <input type="checkbox"/> 24 Public Health Laboratories                 |
| <input type="checkbox"/> 05 Blood Bank                                     | <input type="checkbox"/> 15 Independent   | <input type="checkbox"/> 25 Rural Health Clinic                        |
| <input type="checkbox"/> 06 Community Clinic                               | <input type="checkbox"/> 16 Industrial  | <input type="checkbox"/> 26 School/Student Health Service              |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab Facility                | <input type="checkbox"/> 17 Insurance   | <input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility |
| <input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility      | <input type="checkbox"/> 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities | <input type="checkbox"/> 28 Tissue Bank/Repositories                   |
| <input type="checkbox"/> 09 Federally Qualified Health Center              | <input type="checkbox"/> 19 Mobile Laboratory   | <input type="checkbox"/> 29 Other (Specify) _____                      |
| <input type="checkbox"/> 10 Health Fair                                    | <input type="checkbox"/> 20 Pharmacy  |  |
|  | <input type="checkbox"/> 21 Physician Office  |  |

### IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format) If testing 24/7 Check Here ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

### V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision in 1-3 below)

#### Are you applying for a single site CLIA certificate to cover multiple testing locations?

- ☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

#### Indicate which of the following regulatory exceptions applies to your facility's operation.

- Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?  
☐ Yes ☐ No  
If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.
- Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?  
☐ Yes ☐ No  
If yes, provide the number of sites under the certificate \_\_\_\_\_ and list name, address and test performed for each site below.
- Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?  
☐ Yes ☐ No  
If yes, provide the number of sites under this certificate \_\_\_\_\_ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.  
If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)	

In the next three sections, indicate testing performed and estimated annual test volume.

**VI. WAIVED TESTING** *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed \_\_\_\_\_

☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

**VII. PPM TESTING** *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.

- ☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ☐ Potassium hydroxide (KOH) preparations
- ☐ Pinworm examinations
- ☐ Fern tests
- ☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ☐ Urine sediment examinations
- ☐ Nasal smears for granulocytes
- ☐ Fecal leukocyte examinations
- ☐ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed \_\_\_\_\_

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.



**VIII. NON-WAIVED TESTING** (Including PPM testing if applying for a Certificate of Compliance or Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

If additional space is needed, check here ☐ and attach additional information using the same format.

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

If additional space is needed, check here and attach additional information using the same format.” Include text box similar to Section VII.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/ subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AAHHS/HFAP, AABB, A2LA ,CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			HEMATOLOGY 400		
<input type="checkbox"/> Transplant			<input type="checkbox"/> Hematology		
<input type="checkbox"/> Nontransplant			IMMUNOHEMATOLOGY		
MICROBIOLOGY			<input type="checkbox"/> ABO Group & Rh Group 510		
<input type="checkbox"/> Bacteriology 110			<input type="checkbox"/> Antibody Detection (transfusion) 520		
<input type="checkbox"/> Mycobacteriology 115			<input type="checkbox"/> Antibody Detection (nontransfusion) 530		
<input type="checkbox"/> Mycology 120			<input type="checkbox"/> Antibody Identification 540		
<input type="checkbox"/> Parasitology 130			<input type="checkbox"/> Compatibility Testing 550		
<input type="checkbox"/> Virology 140			PATHOLOGY		
DIAGNOSTIC IMMUNOLOGY				<input type="checkbox"/> Histopathology 610	
<input type="checkbox"/> Syphilis Serology 210			<input type="checkbox"/> Oral Pathology 620		
<input type="checkbox"/> General Immunology 220			<input type="checkbox"/> Cytology 630		
CHEMISTRY			RADIOBIOASSAY 800		
<input type="checkbox"/> Routine 310			<input type="checkbox"/> Radiobioassay		
<input type="checkbox"/> Urinalysis 320			CLINICAL CYTOGENETICS 900		
<input type="checkbox"/> Endocrinology 330			<input type="checkbox"/> Clinical Cytogenetics		
<input type="checkbox"/> Toxicology 340			TOTAL ESTIMATED ANNUAL TEST VOLUME:		

**IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)****VOLUNTARY NONPROFIT**

- ☐ 01 Religious Affiliation  
☐ 02 Private Nonprofit  
☐ 03 Other Nonprofit

\_\_\_\_\_  
(Specify)

**FOR PROFIT**

- ☐ 04 Proprietary

**GOVERNMENT**

- ☐ 05 City  
☐ 06 County  
☐ 07 State  
☐ 08 Federal  
☐ 09 Other Government

\_\_\_\_\_  
(If 09 is selected, please specify the country or the province.)

Does this facility have partial or full ownership by a foreign entity or foreign government?

☐ Yes ☒ No

If Yes, what is the country of origin for the foreign entity? \_\_\_\_\_

**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

**ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION**

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF DIRECTOR OF LABORATORY

PRINT NAME OF OWNER OF LABORATORY

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE)

DATE

**NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.**

**STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:**

**<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>**

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# THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

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## INSTRUCTIONS FOR COMPLETION

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CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

**NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.**

**NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M (42 CFR PART 493) of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:**

- Verification of State Licensure, as applicable
- Documentation of qualifications:
  - Education (copy of Diploma, transcript from accredited institution, CMEs),
  - Credentials, and
  - Laboratory experience.

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

**ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.**

### I. GENERAL INFORMATION

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "change in certificate type" and provide the effective

date of the change. For all other changes, including change in location, director, lab closure, etc., check "other changes" and provide the effective date of the change.

**CLIA Identification Number:** For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10 digit CLIA identification number already assigned and listed on your CLIA certificate.

**Facility Name:** Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. NOTE: the information provided is what will appear on your certificate.

**Email Address:** A valid Email Address is optional and will be used for communications between the CLIA program and the laboratory. Selecting the RECEIVE NOTIFICATIONS VIA EMAIL checkbox, requires the laboratory to enter a valid Email Address.

**Physical Facility Address:** This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.

**Mailing Address:** This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this section.

**Corporate Address:** This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as, the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.

**Form Mailing:** Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.

**For Office Use Only:** The date received is the date the form is received by the state agency or CMS regional office for processing.

### II. TYPE OF CERTIFICATE REQUESTED

Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory.

When completing this section, please remember that a facility holding a:

- **Certificate of Waiver** can only perform tests categorized as waived;\*
- **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;\*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met following a CLIA survey; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.)

\*A current list of waived and PPM tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm>.

### III. TYPE OF LABORATORY

Select the type that is most descriptive of the location where the laboratory testing is performed.

If selecting 'mobile laboratory' (code 19), a mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINs) of all vehicles used for mobile laboratory testing.

If selecting 'Practitioner Other' (code 22), this type includes practitioners such as, dentists, chiropractors, etc.

### IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM

format and check box marked '24/7' if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.

### V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493.493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3). Hospice and HHA could qualify for an exception.

### VI. WAIVED TESTING

Indicate the estimated total annual test volume for all waived tests performed. List can be found at: <https://www.cms.gov/CLIA/downloads/waivetbl.pdf>

### VII. PPM TESTING

Indicate the estimated total annual test volume for all PPM tests performed. List can be found at: <https://www.cms.gov/CLIA/downloads/ppmplist.pdf>

### VIII. NON-WAIVED TESTING (INCLUDING PPM)

The total Estimated Annual Test volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section for test counting information. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

### IX. TYPE OF CONTROL

Select the type of ownership or control which most appropriately describes your facility.

### X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible and that are under different certificates. Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

#### Reminders - Before submitting the Form CMS-116:

1. Include the current or estimated annual test volume.
2. For Certificate for PPM, Certificate of Compliance, or Certificate of Accreditation, include the laboratory director qualifications.
3. Do not send any money with your application.
4. Send the completed Form CMS-116 to the appropriate State Agency (<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>).

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency. State agency contact information can be found at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

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**VIII. NON-WAIVED TESTING**

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**TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING  
LABORATORY SPECIALTIES/SUBSPECIALITIES**

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**HISTOCOMPATIBILITY (010)**

HLA Typing (disease associated antigens)

**MICROBIOLOGY****Bacteriology (110)**

Gram Stain

Culture

Susceptibility

Strep screen

Antigen assays (H.pylori, Chlamydia, etc.)

**Mycobacteriology (115)**

Acid Fast Smear

Mycobacterial culture

Mycobacterial susceptibility

**Mycology (120)**

Fungal Culture

DTM

KOH Preps

**Parasitology (130)**

Direct Preps

Ova and Parasite Preps

Wet Preps

**Virology (140)**

RSV (Not including waived kits)

HPV assay

Cell culture

**DIAGNOSTIC IMMUNOLOGY****Syphilis Serology (210)**

RPR

FTA, MHATP

**General Immunology (220)**

Allergen testing

ANA

Antistreptolysin O

Antigen/Antibody (hepatitis, herpes, rubella, etc.)

Complement (C3, C4)

Immunoglobulin

HIV

Mononucleosis assay

Rheumatoid factor

Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)\*

\*Tumor markers can alternatively be listed under  
Routine Chemistry instead of General Immunology.

**HEMATOLOGY (400)**

Complete Blood Count (CBC)

WBC count

RBC count

Hemoglobin

Hematocrit (Not including spun micro)

Platelet count

Differential

Activated Clotting Time

Prothrombin time (Not including waived instruments)

Partial thromboplastin time

Fibrinogen

Reticulocyte count

Manual WBC by hemocytometer

Manual platelet by hemocytometer

Manual RBC by hemocytometer

Sperm count

**IMMUNOHEMATOLOGY**

ABO group (510)

Rh(D) type (510)

Antibody screening

Antibody identification (540)

Compatibility testing (550)

**PATHOLOGY**

Dermatopathology

Oral Pathology (620)

PAP smear interpretations (630)

Other Cytology tests (630)

Histopathology (610)

**RADIOBIOASSAY (800)**

Red cell volume

Schilling test

**CLINICAL CYTOGENETICS (900)**

Fragile X

Buccal smear

Prader-Willi syndrome

FISH studies for: neoplastic disorders, congenital disorders  
or solid tumors.

## **CHEMISTRY**

### **Routine Chemistry (310)**

Albumin  
Ammonia  
Alk Phos  
ALT/SGPT  
AST/SGOT  
Amylase  
Bilirubin  
Blood gas (pH, pO<sub>2</sub>, pCO<sub>2</sub>)  
BUN  
Calcium  
Chloride  
Cholesterol  
Cholesterol, HDL  
CK/CK isoenzymes  
CO<sub>2</sub>  
Creatinine  
Ferritin  
Folate  
GGT  
Glucose (Not fingerstick)  
Iron  
LDH/LDH isoenzymes  
Magnesium  
Potassium  
Protein, electrophoresis  
Protein, total  
PSA  
Sodium  
Triglycerides  
Troponin  
Uric acid  
Vitamin B12

### **Endocrinology (330)**

Cortisol  
HCG (serum pregnancy test)  
T3  
T3 Uptake  
T4  
T4, free  
TSH

### **Toxicology (340)**

Acetaminophen  
Blood alcohol  
Blood lead (Not waived)  
Carbamazepine  
Digoxin  
Ethosuximide  
Gentamicin  
Lithium  
Phenobarbital  
Phenytoin  
Primidone  
Procainamide  
NAPA  
Quinidine  
Salicylates  
Theophylline  
Tobramycin  
Therapeutic Drug Monitoring

### **Urinalysis\*\* (320)**

Automated Urinalysis (Not including waived instruments)  
Microscopic Urinalysis  
Urine specific gravity by refractometer  
Urine specific gravity by urinometer  
Urine protein by sulfosalicylic acid

\*\* Dipstick urinalysis is counted in Section VI. WAIVED TESTING

**NOTE:** This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/ subspecialties can be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf> and <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/lccodes.pdf>. You may also call your State agency for further information. State agency contact information can be found at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>.



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## GUIDELINES FOR COUNTING TESTS FOR CLIA

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- For **chemistry**, each non-calculated analyte is counted separately (e.g., Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals 4 tests).
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests. NOTE: For all other genetic tests, the number of tests is determined by the number of results reported in the final report.
- For manual gynecologic and nongynecologic **cytology**, each slide (not case) is counted as one test.
- For **flow cytometry**, each measured individual analyte (e.g. T cells, B cells, CD4, etc.) that is ordered and reported should be counted separately.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- **Genetics tests** should be placed in the specialty or subspecialty where they fit best, according to the methodology of the test.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **histocompatibility**, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA cross match is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as 3 tests.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialties**, do not count calculations (e.g., A/G ratio, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your State agency.



# Completing a Resource Request

Collin Johanknecht  
Health Program Associate  
Health Emergency Response Operations  
Division of Public Health

# ICS-213 Resource Request Form

ICS 213 RR – Resource Request					Alaska State Emergency Operations Center - For requesting tactical and non-tactical							
Incident Name:				Requested Date/Time:			Resource Request Number:					
ORDER (Use additional forms when requesting different resources of supply)												
Requestor	Qty	Kind	Type	*Priority Immediate High Medium Low	Detailed item/need/capability description (vital characteristics, brand, specs, experience, size, etc.) and if applicable, purpose/use, diagrams, and other info. that allows understanding of the capability/need requested	Requested Reporting Location & POC Info.		Date / Time	Order # (LSC)	ETA (LSC)	Cost	
Approval	Suggested source(s) of supply - Supplier and transportation contact information and suitable substitutes:					Requestor, ICS Position, and Signature:			Date/Time:			
						Operations Section Approver and Signature:			Date/Time:			
						Incident Command Approver and Signature:			Date/Time:			
Resources	Check box if: <input type="checkbox"/> Requisition contains tactical or personnel resources					RESL Review/Signature:			Date/Time:			
	Check box if: <input type="checkbox"/> Resources available <input type="checkbox"/> Resources not available											
Logistics	Notes:					Logistics Section Signature:					Date/Time:	
	Requisition/Purchase Order #:											
	Supplier Name/Phone/Fax/Email:											
Finance	Notes:					Finance Section Signature:					Date/Time:	
	Order Placed by (check box): <input type="checkbox"/> SPUL <input type="checkbox"/> PROC <input type="checkbox"/> OTHER _____											
Reply/Comments from Finance:												

\* **Priority Evaluation:**  
 Immediate - Life safety within next 24 hours  
 High - Life safety beyond 24 hours, life sustaining within 24 hours  
 Medium - Life sustaining beyond 24 hours  
 Low - Non-life sustaining

SEOC (907) 428-7100

ICS 213 RR – Resource Request				Alaska State Emergency Operations Center - For requesting tactical and non-tactical					
Incident Name: Your Facilities Name				Requested Date/Time: Date Request is Submitted		Resource Request Number:			
ORDER (Use additional forms when requesting different resources of supply)									
Qty	Kind	Type	Priority <small>Immediate High Medium Low</small>	Detailed item/need/capability description <small>(vital characteristics, brand, specs, experience, size, etc.) and if applicable, purpose/use, diagrams, and other info. that allows understanding of the capability/need requested</small>	Requested Reporting		Order # (LSC)	ETA (LSC)	Cost
					Location & POC Info.	Date / Time			
10	Boxes	Medium	High	Nitrile Gloves- Medium					
100	Tests		Medium	Abbott ID-Now Tests					
Suggested source(s) of supply - Supplier and transportation contact information and suitable substitutes:  Any additional information you need or want to include regarding the request.					Requestor, ICS Position, and Signature:			Date/Time:	
					Your Name, Signature & the Date				
					Operations Section Approver and Signature:			Date/Time:	
					Incident Command Approver and Signature:			Date/Time:	
Check box if: <input type="checkbox"/> Requisition contains tactical or personnel resources Check box if: <input type="checkbox"/> Resources available <input type="checkbox"/> Resources not available Notes:					RESL Review/Signature:			Date/Time:	
Requisition/Purchase Order #: _____ Supplier Name/Phone/Fax/Email: _____ Notes: Order Placed by (check box): <input type="checkbox"/> SPUL <input type="checkbox"/> PROC <input type="checkbox"/> OTHER _____					Logistics Section Signature:			Date/Time:	
Reply/Comments from Finance:					Finance Section Signature:			Date/Time:	
* Priority Evaluation: Immediate - Life safety within next 24 hours High - Life safety beyond 24 hours, life sustaining within 24 hours Medium - Life sustaining beyond 24 hours Low - Non-life sustaining					SEOC (907) 428-7100				

## What Information is Needed

- Incident name
- Date the request is made
- How much of each item do you need (Qty)
- Unit of measure for each item (Kind)
- How urgently do you need it (Priority)
- Item Description (Name of the item)
- Requestor's name, signature and the date

# Example of a Complete ICS-213 Form

ICS 213 RR – Resource Request				Alaska State Emergency Operations Center - For requesting tactical and non-tactical						
Incident Name: DHSS Warehouse				Requested Date/Time: 08/10/2021 12:00		Resource Request Number:				
ORDER (Use additional forms when requesting different resources of supply)										
Requestor	Qty	Kind	Type	*Priority Immediate High Medium Low	Detailed item/need/capability description (vital characteristics, brand, specs, experience, size, etc.) and if applicable, purpose/use, diagrams, and other info. that allows understanding of the capability/need requested	Requested Reporting Location & POC Info.	Date / Time	Order # (LSC)	ETA (LSC)	Cost
	100	Tests		High	Abbott ID-Now Tests					
	250	Each	Medium	High	Disposable Gowns- Medium					
	10	Boxes	Large	High	Nitrile Gloves- Large					
	60	Each		High	N-95, 3m 8000's					
Approval	Suggested source(s) of supply - Supplier and transportation contact information and suitable substitutes:					Requestor, ICS Position, and Signature:		Date/Time:		
						Collin Johanknecht, Collin Johanknecht		8/10/2021		
						Operations Section Approver and Signature:		Date/Time:		
Resources	Check box if: <input type="checkbox"/> Requisition contains tactical or personnel resources					RESL Review/Signature:		Date/Time:		
	Check box if: <input type="checkbox"/> Resources available <input type="checkbox"/> Resources not available									
	Notes:									
Logistics	Requisition/Purchase Order #:			Supplier Name/Phone/Fax/Email:			Logistics Section Signature:		Date/Time:	
	Notes:									
Finance	Order Placed by (check box): <input type="checkbox"/> SPUL <input type="checkbox"/> PROC <input type="checkbox"/> OTHER _____					Finance Section Signature:		Date/Time:		
	Reply/Comments from Finance:									

\* Priority Evaluation:  
 Immediate - Life safety within next 24 hours  
 High - Life safety beyond 24 hours, life sustaining within 24 hours  
 Medium - Life sustaining beyond 24 hours  
 Low - Non-life sustaining

SEOC (907) 428-7100

# IMATS Demographics Form

## Entity Demographics for IMATS

1	Facility Name (POD):						
2	Any Special Notes:						
3a	Ship to Address 1:						
3b	Ship to Address 2:						
5	Zip Code:						
6	Receiving Capabilities: (If known / optional)	Loadline Dock	Fork Lift Available	Accommodate 53-foot Trailer	Number of Loading Docks:	Lift Gate Available	Maximum Truck Size:
		Name	Telephone(s)	Cell Phone	Fax	Email	Comments
7	Primary Contact Info:						
8	Secondary Contact Info:						
<b>Additional Information</b>							
1	Expected Delivery Date/Time:				RSS Delivery Notes/Tracking		
2	Any Special Delivery Instructions:						
3							
<b>EOC and RSS Use</b>							
	Requested By (Date/Time):			Approved by (Date/Time):			
	Notes:			RSS Inputed by (Date/Time):			

File Name: Distribution Quantities - Demographics

### Entity Demographics for IMATS

1	Facility Name (POD):	Your Facilities Name					
2	Any Special Notes:	Laboratory					
3a	Ship to Address 1:	1234 100th Avenue, Suite 10					
3b	Ship to Address 2:	Anchorage, AK					
5	Zip Code:	99501					
6	Receiving Capabilities: (If known / optional)	Loadline Dock YES	Fork Lift Available YES	Accommodate 53-foot Trailer NO	Number of Loading Docks: 2	Lift Gate Available	Maximum Truck Size:
		Name	Telephone(s)	Cell Phone	Fax	Email	Comments
7	Primary Contact Info:	Your Name	Office Number	Cell Number		Email	
8	Secondary Contact Info:	Second Persons Name	Office Number	Cell Number		Email	
Additional Information							
1	Expected Delivery Date/Time:	When do you need this request by?			RSS Delivery Notes/Tracking		
2	Any Special Delivery Instructions:	Any additional information regarding shipping or delivery we need to know.					
3							
EOC and RSS Use							
	Requested By (Date/Time):			Approved by (Date/Time):			
	Notes:			RSS Inputed by (Date/Time):			

File Name: Distribution Quantities - Demographics

## What Information is Required

- Lines one through eight are required to be completed
- Line one of Additional Information also needs to be filled out

# Example of a Complete IMATS Form

## Entity Demographics for IMATS

1	Facility Name (POD):	DHSS Warehouse					
2	Any Special Notes:	Back Side of Building					
3a	Ship to Address 1:	3651 Penland Parkway, Anchorage, AK					
3b	Ship to Address 2:						
5	Zip Code:	99508					
6	Receiving Capabilities: (if known / optional)	Loadline Dock YES	Fork Lift Available YES	Accommodate 53-foot Trailer YES	Number of Loading Docks: 8	Lift Gate Available YES	Maximum Truck Size: 53'
		Name	Telephone(s)	Cell Phone	Fax	Email	Comments
7	Primary Contact Info:	Collin Johanknecht	(907) 754-3559	(907) 351-5197		collin.johanknecht@alaska.gov	
8	Secondary Contact Info:	Adrian Bennett	(907) 269-3023	N/A		adrian.bennett@alaska.gov	
<b>Additional Information</b>							
					RSS Delivery Notes/Tracking		
1	Expected Delivery Date/Time:	8/15/2021 13:45					
2	Any Special Delivery Instructions:	We are located on the back side of the building.					
3							
<b>EOC and RSS Use</b>							
	Requested By (Date/Time):				Approved by (Date/Time):		
	Notes:				RSS Input by (Date/Time):		

File Name: Distribution Quantities - Demographics



Email the Completed Documents to  
2020\_COVID-19@AK-Prepared.com

ICS 213 RR – Resource Request		Alaska State Emergency Operations Center - For requesting tactical and non-tactical							
Incident Name: DHSS Warehouse		Requested Date/Time: 08/10/2021 12:00				Resource Request Number:			
ORDER (Use additional forms when requesting different resources of supply)									
Qty	Kind	Type	Priority Immediate High Medium Low	Detailed Item/need/capability description (vital characteristics, brand, specs, experience, size, etc.) and if applicable, purpose/usage, diagrams, and other info. that allows understanding of the capability/need requested	Requested Location & POC Info.	Reporting Date / Time	Order # (LSC)	ETA (LSC)	Cost
100	Tests		High	Abbott ID-Now Tests					
250	Each	Medium	High	Disposable Gowns- Medium					
10	Boxes	Large	High	Nitrile Gloves- Large					
60	Each		High	N-95, 3m 8000's					
Suggested source(s) of supply - Supplier and transportation contact information and suitable substitutes:					Requestor, ICS Position, and Signature: Collin Johanknecht, Collin Johanknecht 8/10/2021				
					Operations Section Approver and Signature: _____ Date/Time: _____				
					Incident Command Approver and Signature: _____ Date/Time: _____				
Check box if: <input type="checkbox"/> Requisition contains tactical or personnel resources					RESL Review/Signature: _____ Date/Time: _____				
Check box if: <input type="checkbox"/> Resources available <input type="checkbox"/> Resources not available									
Notes:									
Requisition/Purchase Order #:					Supplier Name/Phone/Fax/Email:				
Notes:					Logistics Section Signature: _____ Date/Time: _____				
Order Placed by (check box): <input type="checkbox"/> SPUL <input type="checkbox"/> PROC <input type="checkbox"/> OTHER _____									
Reply/Comments from Finance:					Finance Section Signature: _____ Date/Time: _____				

\* Priority Evaluation:  
 Immediate - Life safety within next 24 hours  
 High - Life safety beyond 24 hours, life sustaining within 24 hours  
 Medium - Life sustaining beyond 24 hours  
 Low - Non-life sustaining

SEOC (907) 428-7100

Entity Demographics for IMATS							
1	Facility Name (POD):	DHSS Warehouse					
2	Any Special Notes:	Back Side of Building					
3a	Ship to Address 1:	3651 Penland Parkway, Anchorage, AK					
3b	Ship to Address 2:						
5	Zip Code:	99508					
6	Receiving Capabilities: (if known / optional)	Loadline Dock YES	Fork Lift Available YES	Accommodate 53-foot Trailer YES	Number of Loading Docks: 8	Lift Gate Available YES	Maximum Truck Size: 53'
		Name	Telephone(s)	Cell Phone	Fax	Email	Comments
7	Primary Contact Info:	Collin Johanknecht	(907) 754-3559	(907) 351-5197		collin.johanknecht@alaska.gov	
8	Secondary Contact Info:	Adrian Bennett	(907) 269-3023	N/A		adrian.bennett@alaska.gov	
Additional Information							
	Expected Delivery Date/Time:	8/15/2021 13:45				RSS Delivery Notes/Tracking	
2	Any Special Delivery Instructions:	We are located on the back side of the building.					
3							
EOC and RSS Use							
	Requested By (Date/Time):				Approved by (Date/Time):		
	Notes:				RSS input by (Date/Time):		

File Name: Distribution Quantities - Demographics

# Personal Protective Equipment Available for Request

- N-95 Masks ( 46767 Duck Bill, 3M 1860s, 3M 1870/9205, 3M 8210/8511/8200/8000, Moldex M/L, Gerson 1730, Cardinal Health S/M, Cardinal Health M/L, Honeywell N-95)
- Surgical Masks
- Disposable Face Shields
- Goggles
- Disposable Gowns ( Large, X-Large and XX-Large)
- Nitrile Gloves (X-Small, Small, Medium, Large, X-Large)
- Hand Sanitizer ( 1 Gallon, 2.5 Gallon, 5 Gallon)
- Disinfectant Wipes
- Shoe Covers
- Bouffant Caps
- Tyvek Suits ( Medium, Large, X-Large)
- Body Shippers
- Body Bags
- Infrared No Touch Thermometers
- Pulse Oximeters

# Durable Items Available for Request

- Ventilator- HT
- Ventilator- LTV
- Ventilator Circuits- LTV ( Infant, Pediatric, and Adult)
- High Flow Ventilator
- Oxygen Concentrator (5 Liter)
- PAPR- Maxair (Powered Air Purifying Respirator)
- PAPR Hoods- Maxair (Small/Medium and Medium/Large)
- PAPR- Airboss (Powered Air Purifying Respirator)
- PAPR Hoods- Airboss
- PAPR Filters- Airboss

# COVID-19 Testing Supplies Available for Request

- Swabs ( Nasal and Nasal Pharyngeal)
- Viral Transport Medium (Remel, BD)
- Basic Collection Kits (Copan E-Swab)
- Abbott ID-Now Test Kits
- Abbott ID-Now Controls
- Abbott ID-Now Analyzer (these are in high demand and requesters will likely be placed on a wait list till some are returned)
- Abbott Binax Now Test Cards (Antigen test)
- Cue Test Kits
- Cue Controls
- Cue Analyzers
- Specimen Collection Bags
- Band-Aids (for use with vaccine administration)
- Epinephrine 0.3 MG Auto Injectors (only for use with vaccine administration)

ICS 213 RR – Resource Request				Alaska State Emergency Operations Center - For requesting tactical and non-tactical						
Requestor	Incident Name:			Requested Date/Time:			Resource Request Number:			
	ORDER (Use additional forms when requesting different resources of supply)									
	Qty	Kind	Type	*Priority Immediate High Medium Low	Detailed item/need/capability description (vital characteristics, brand, specs, experience, size, etc.) and if applicable, purpose/use, diagrams, and other info. that allows understanding of the capability/need requested	Requested Reporting Location & POC info.      Date / Time		Order # (LSC)	ETA (LSC)	Cost
Approval	Suggested source(s) of supply - Supplier and transportation contact information and suitable substitutes:					Requestor, ICS Position, and Signature:      Date/Time:				
						Operations Section Approver and Signature:      Date/Time:				
						Incident Command Approver and Signature:      Date/Time:				
Resources	Check box if: <input type="checkbox"/> Requisition contains tactical or personnel resources					RESL Review/Signature:      Date/Time:				
	Check box if: <input type="checkbox"/> Resources available <input type="checkbox"/> Resources not available									
Logistics	Notes:					Logistics Section Signature:      Date/Time:				
	Requisition/Purchase Order #:		Supplier Name/Phone/Fax/Email:							
	Notes:									
Finance	Order Placed by (check box): <input type="checkbox"/> SPUL <input type="checkbox"/> PROC <input type="checkbox"/> OTHER _____					Finance Section Signature:      Date/Time:				
	Reply/Comments from Finance:									

**\* Priority Evaluation:**

**Immediate** - Life safety within next 24 hours

**High** - Life safety beyond 24 hours, life sustaining within 24 hours

**Medium** - Life sustaining beyond 24 hours

**Low** - Non-life sustaining

**SEOC (907) 428-7100**

## Entity Demographics for IMATS

1	Facility Name (POD):						
2	Any Special Notes:						
3a	Ship to Address 1:						
3b	Ship to Address 2:						
5	Zip Code:						
6	Receiving Capabilities: (If known / optional)	Loading Dock	Fork Lift Available	Accommodate 53-foot Trailer	Number of Loading Docks:	Lift Gate Available	Maximum Truck Size:
		<b>Name</b>	<b>Telephone(s)</b>	<b>Cell Phone</b>	<b>Fax</b>	<b>Email</b>	<b>Comments</b>
7	Primary Contact Info:						
8	Secondary Contact Info:						
<b>Additional Information</b>							
1	Expected Delivery Date/Time:				<b>RSS Delivery Notes/Tracking</b>		
2	Any Special Delivery Instructions:						
3							
<b>EOC and RSS Use</b>							
	Requested By (Date/Time):			Approved by (Date/Time):			
	Notes:			RSS Inputed by (Date/Time):			



## COVID-19 ANTIGEN TESTING CONSENT FORM

THIS FORM MUST BE SIGNED PRIOR TO TESTING

PLEASE COMPLETE THE INFORMATION BELOW

Full, Legal name of Staff Member ( <i>First, Middle Initial, Last Name</i> ) Please Print	Name of School
ETHNICITY (CIRCLE ONE)  Hispanic      Non-Hispanic      Other	RACE      Sex
Street Address      Email Address	Birth Date (MM/DD/YYYY)      Age
City      Zip Code	Home Phone #      Cell Phone #

This consent form acknowledges my permission to participate in Antigen testing for the purpose of screening.

### Why is the staff member being screened?

Regular screening of school staff is recommended by the CDC. Screening means testing staff who have no symptoms and no known exposure to COVID-19 (i.e. do not meet criteria to quarantine currently because of close contact with a person with COVID-19).

### How is the test conducted?

Samples for testing will be collected by using a nose swab (small swab put into the front part of the nose). The swab will then be placed in a folding card and the test administrator will apply reagent and set a timer. The test results will be read after 15 minutes.

### What to Do After Testing

If the result is positive, you will need to leave the building and contact your doctor for confirmatory PCR testing.

### By signing this form, I agree and attest to the following:

- I have signed this form freely and voluntarily.
- I consent to Covid19 Antigen testing for the purpose of screening.
- I authorize COVID-19 testing to be conducted via collection and testing through a nasal swab, as recommended by a medical provider, school nurse, or public health official. I understand that testing may happen several times a week and that I can refuse at any time. This consent extends to COVID-19 testing performed during the 2020-2021 academic year.



- I understand and authorize the test results and other information to be disclosed as permitted by law.
- I acknowledge that a positive test result is an indication of a requirement to self-isolate and wear a mask or face covering as directed.
- I understand that the School is not acting as a medical provider and that this testing does not replace treatment by a licensed medical professional.
- I assume complete and full responsibility to take appropriate action when I receive the test results. I agree I will seek medical advice, care and treatment.
- I understand that, as with any medical test, there is the potential for a false positive or a false negative COVID-19 test result.
- I understand that there will be no out-of-pocket cost for this testing.
- I understand that this consent form will be valid through August 15, 2021, unless I notify the District, **in writing**, that I revoke my consent.
- I freely give this consent and I do hereby release and hold harmless the Kenai Peninsula Borough School District from any and all liability or damage which may result from the disclosure of information herein authorized.

Signature of Staff member	Date
---------------------------	------

## PROCEDURE CARD

### For Use Under an Emergency Use Authorization (EUA) Only.

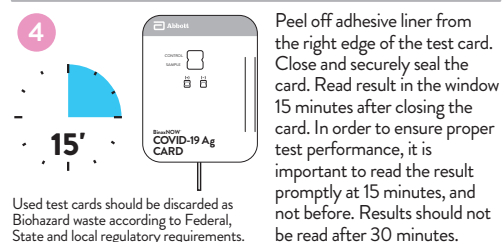
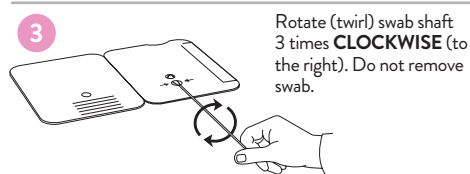
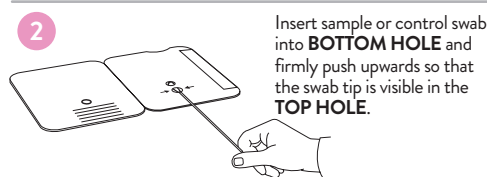
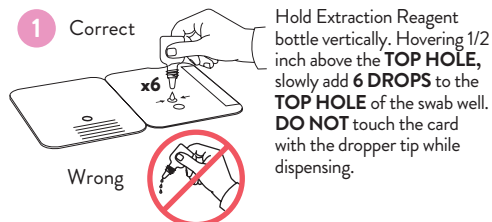
The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from anterior nasal (nares) swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms.

**IMPORTANT:** See Product Insert, including QC section, for complete use instructions, warnings, precautions and limitations.

**False negative results may occur if specimens are tested past 1 hour of collection. Specimens should be tested as quickly as possible after specimen collection.** Open the test card just prior to use, lay it flat, and perform assay as follows.

### Part 1 - Sample Test Procedure

#### Patient Samples require 6 drops of Extraction Reagent.



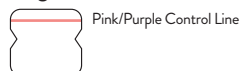
In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

### Part 2 - Result Interpretation

A **negative specimen** will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

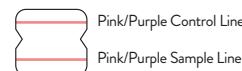
Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

#### Negative Result



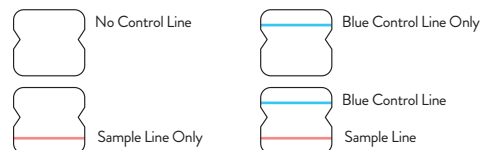
A **positive specimen** will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive.

#### Positive Result



If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated.

#### Invalid Result

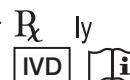


### Procedure for External Quality Control Testing

#### External Controls require 8 drops of Extraction Reagent

1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.
2. Follow Steps 2 – 4 of the Test Procedure shown.

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IN195001 Rev. 2 2020/12

**Abbott**  
**BinaxNOW**  
**COVID-19 Ag**

ProCard

**Size:**  
5.5" x 8.0"

#### Printed Colors



#### Incoming Inspection Colors (For Reference Only) Colors below are not used for printing



**PN:** IN195001  
**Rev:** 2

**Date of Last Revision:**  
2.2 2020/12/12

# BINAXNOW COVID-19 AG CARD (PN 195-000) – INSTRUCTIONS FOR USE

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## **BinaxNOW™ COVID-19 Ag CARD**

### **For Use Under an Emergency Use Authorization (EUA) Only**

For use with anterior nasal (nares) swab specimens

For *in vitro* Diagnostic Use Only

Rx Only

### **INTENDED USE**

The BinaxNOW™ COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The BinaxNOW™ COVID-19 Ag Card does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The BinaxNOW™ COVID-19 Ag Card is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests. BinaxNOW™ COVID-19 Ag Card is only for use under the Food and Drug Administration's Emergency Use Authorization.

### **SUMMARY AND EXPLANATION OF THE TEST**

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the  $\beta$  genus. The virus can cause mild to

severe respiratory illness and has spread globally, including the United States.

BinaxNOW™ COVID-19 Ag Card is a rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from nasal swabs, without viral transport media. The BinaxNOW™ COVID-19 Ag Card kit contains all components required to carry out an assay for SARS-CoV-2.

## PRINCIPLES OF THE PROCEDURE

The BinaxNOW™ COVID-19 Ag Card is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card.

To perform the test, a nasal swab specimen is collected from the patient, 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes.

## REAGENTS AND MATERIALS

### Materials Provided

**Test Cards (40):** A cardboard, book-shaped hinged test card containing the test strip

**Extraction Reagent (1):** Bottle containing 7.5 mL of extraction reagent

**Nasal Swabs (40):** Sterile swabs for use with BinaxNOW™ COVID-19 Ag Card test

**Positive Control Swab (1) :** Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab

**Negative Control Swab:** The use of a sterile patient swab ensures appropriate negative results are obtained

**Product Insert (1)**

**Procedure Card (1)**

### Materials Required but not Provided

Clock, timer or stopwatch

### Materials Available as an Optional Accessory

Swab Transport Tube Accessory Pack

## PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement

Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate, high or waived complexity tests and at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens
5. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
6. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
7. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
8. Proper sample collection, storage and transport are essential for correct results.
9. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
10. Do not use kit past its expiration date.
11. Do not mix components from different kit lots.
12. Do not reuse the used test card.
13. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
14. Do not store or test specimens in viral transport media, as it may result in false positive or false negative results.
15. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
16. Solutions used to make the positive control swab are non-infectious. However, patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
17. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
18. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically, ½ inch above the swab well, and add drops slowly.
19. False Negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.
20. Swabs in the kit are approved for use with BinaxNOW™ COVID-19 Ag Card. **Do not use other swabs.**
21. The Extraction Reagent packaged in this kit contains saline, detergents and preservatives that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture.
22. Do not store the swab after specimen collection in the original paper packaging, if storage is needed use a plastic tube with cap.

## STORAGE AND STABILITY

Store kit at 2-30°C. The BinaxNOW™ COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

## QUALITY CONTROL

BinaxNOW™ COVID-19 Ag Card has built-in procedural controls. For daily quality control, Abbott suggests that you record these controls for each test run.

### Procedural Controls:

- A. The pink-to-purple line at the “Control” position is an internal procedural control. If the test flows and the reagents work, this line will always appear.
- B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.

### External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. BinaxNOW™ COVID-19 Ag Card kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab’s standard Quality Control procedures.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

## SPECIMEN COLLECTION AND HANDLING

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

### Anterior Nasal (Nares) Swab

Only the swab provided in the kit is to be used for nasal swab collection.

To collect a nasal swab sample, carefully insert the entire absorbent tip of the swab (usually ½ to ¾ of an inch (1 to 1.5 cm) into the nostril. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall 5 times or more for a total of 15 seconds, then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

## SPECIMEN TRANSPORT AND STORAGE

**Do not return the nasal swab to the original paper packaging.**

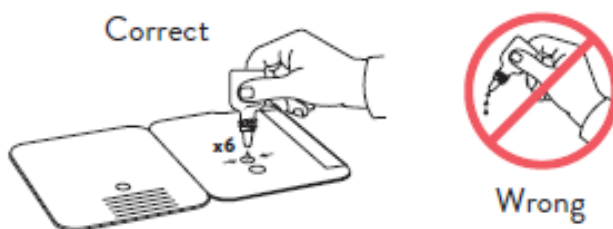
For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

## TEST PROCEDURE

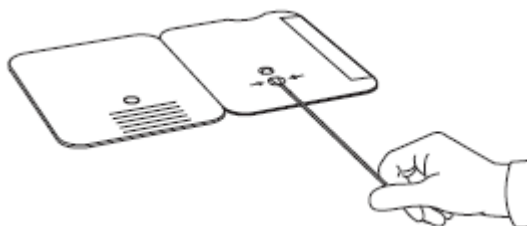
### Procedure for Patient Specimens

Open the test card just prior to use, **lay it flat**, and perform assay as follows. **The test card must be flat when performing testing, do not perform testing with the test card in any other position.**

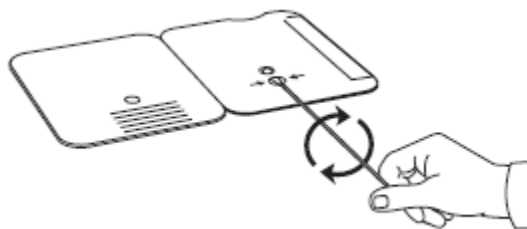
1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



2. Insert sample into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.



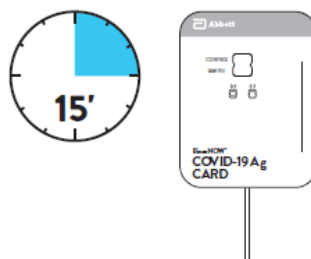
3. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.





*Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.*

4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.



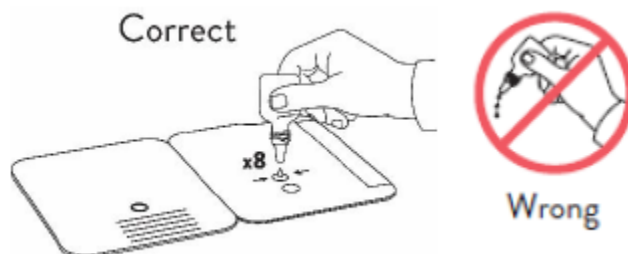
*Note: False negative results can occur if test results are read before 15 minutes.*

Note: When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.

### Procedure for BinaxNOW™ Swab Controls

Open the test card just prior to use, lay it flat, and perform assay as follows.

1. Hold Extraction Reagent bottle vertically Hovering 1/2 inch above the **TOP HOLE**, slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



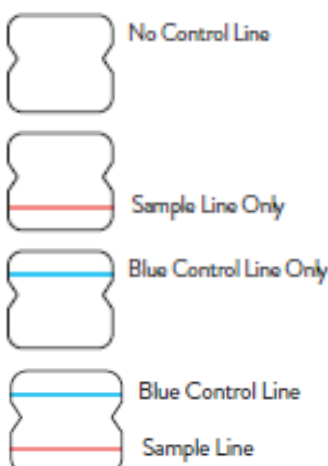


2. Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.

### RESULT INTERPRETATION

*Note: In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position. In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working. If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.*



<p><b>Negative</b> A <b>negative specimen</b> will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.</p>	 <p>Pink/Purple Control Line</p>
<p><b>Positive</b> A <b>positive specimen</b> will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive.</p>	 <p>Pink/Purple Control Line Pink/Purple Sample Line</p>
<p><b>Invalid</b> If no lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated.</p>	<p><b>Invalid Result</b></p>  <p>No Control Line Sample Line Only Blue Control Line Only Blue Control Line Sample Line</p>

## LIMITATIONS

- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- The performance of the BinaxNOW™ COVID-19 Ag Card was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- False negative results may occur if a specimen is improperly collected, transported, or handled.
- False results may occur if specimens are tested past 1 hour of collection. Specimens should be test as quickly as possible after specimen collection.
- False negative results may occur if inadequate extraction buffer is used (e.g., <6 drops).
- False negative results may occur if specimen swabs are not twirled within the test card.
- False negative results may occur if swabs are stored in their paper sheath after specimen

collection.

- Positive test results do not rule out co-infections with other pathogens.
- False negative results are more likely after eight days or more of symptoms.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- The presence of mupirocin may interfere with the BinaxNOW™ COVID-19 Ag test and may cause false negative results.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

### **CONDITIONS of AUTHORIZATION for LABORATORY and PATIENT CARE SETTINGS**

The BinaxNOW™ COVID-19 Ag Card Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

However, to assist clinical laboratories using the BinaxNOW™ COVID-19 Ag Card, the relevant Conditions of Authorization are listed below:

- Authorized laboratories<sup>1</sup> using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the “BinaxNOW™ COVID-19 Ag Card” Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott Diagnostics Scarborough, Inc. (via email: ts.scr@abbott.com, or via phone by contacting Abbott Diagnostics Scarborough, Inc. Technical Service at 1-800-257-9525) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Abbott Diagnostics Scarborough, Inc., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are

maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

<sup>1</sup> The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.” as “authorized laboratories.”

## **PERFORMANCE CHARACTERISTICS**

### **CLINICAL PERFORMANCE**

Clinical performance characteristics of BinaxNOW™ COVID-19 Ag Card was evaluated in a multi-site prospective study in the U.S in which patients were sequentially enrolled and tested. A total of ten (10) investigational sites throughout the U.S. participated in the study. Testing was performed by operators with no laboratory experience and who are representative of the intended users at CLIA waived testing sites. In this study testing was conducted by sixty-two (62) intended users. To be enrolled in the study, patients had to be presenting at the participating study centers with suspected COVID-19. Patients who presented within 7 days of symptom onset were included in the initial primary analysis. Two nasal swabs were collected from patients and tested using the BinaxNOW™ COVID-19 Ag Card at all study sites. An FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.

At all sites, one nasal swab was tested directly in the BinaxNOW™ COVID-19 Ag Card test according to product instructions and the other swab was eluted in viral transport media (VTM). Swabs were randomly assigned to testing with the BinaxNOW or RT-PCR testing and were tested by minimally trained operators who were blinded to the RT-PCR test result. All sites shipped the VTM sample to a central testing laboratory for RT-PCR.

External control testing, using BinaxNOW™ COVID-19 Ag Card Positive and Negative Controls, was performed prior to sample testing each day, at all study sites.

The performance of BinaxNOW™ COVID-19 Ag Card was established with 460 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

**BinaxNOW™ COVID-19 Ag Card Performance within 7 days of symptom onset against the Comparator Method**

BinaxNOW™ COVID 19 Ag Card	Comparator Method		
	Positive	Negative	Total
Positive	99	5	104
Negative	18*	338	356
Total	117	343	460
Positive Agreement: 99/117 84.6% (95% CI: 76.8% - 90.6%)			
Negative Agreement: 338/343 98.5% (95% CI: 96.6% - 99.5%)			

\*14 of the discrepant samples had high Ct values (>33) when tested by the comparator method.

The following data is provided for informational purposes:

The performance of BinaxNOW™ COVID-19 Ag Card with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. As presented in the table below, the positive agreement of the BinaxNOW™ COVID-19 Ag Card is higher with samples of a Ct count <33.

**BinaxNOW™ COVID-19 Ag Card Performance against the Comparator Method – by Cycle Threshold Counts**

BinaxNOW™ COVID 19 Ag Card	All Subjects*	
	Comparator Method (POS by Ct Category)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	116	17
Negative	12	28
Total	128	45
Positive Agreement (95% CI)	90.6 (84.2, 95.1)	37.8 (23.8, 53.5)

\*In patients presenting within seven (7) days of symptom onset, BinaxNOW COVID-19 Ag Card achieved 95.6% (86/90) positive percent agreement for samples with Ct < 33

**Patient Demographics**

Patient demographics (gender and age) are available for the 460 samples used in the analysis of patients with symptom onset within the previous seven (7) days. The table below shows the positive results broken down by age of the patient:

Age	Comparator Method		
	Total #	Positive	Prevalence
≤ 5 years	0	-	-
6 to 21 years	17	3	17.6%
22 to 59 years	312	79	25.3%
≥ 60 years	131	35	25.4%

Patient demographics, time elapsed since onset of symptoms for all patients enrolled, are presented in the table below. Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT PCR Positive (+)	Cumulative BinaxNOW COVID 19 Ag Card Positive (+)	PPA	95 % Confidence Interval	
1	12	10	83.3%	51.6%	97.9%
2	34	28	82.4%	65.5%	93.2%
3	50	41	82.0%	68.6%	91.4%
4	63	50	79.4%	67.3%	88.5%
5	78	63	80.8%	70.3%	88.8%
6	90	75	83.3%	74.0%	90.4%
7	117	99	84.6%	76.8%	90.6%
8 to 10	144	118	81.9%	74.7%	87.9%
11 to 14	161	126	78.3%	71.1%	84.4%
All specimens	167	129	77.2%	70.1%	83.4%

A cohort of patients who presented with symptom onset greater than seven days were enrolled in the clinical study (n = 161). The positive agreement in patients with symptoms greater than seven days was 60% (30/50) and negative agreement was 98% (109/111). Therefore, negative results in patients with symptom onset greater than seven days should be interpreted with caution, as the sensitivity of the assay decreases over time.

## ANALYTICAL PERFORMANCE

### Limit of Detection (Analytical Sensitivity)

BinaxNOW™ COVID-19 Ag Card limit of detection (LOD) was determined by evaluating different concentrations of heat inactivated SARS-CoV-2 virus. Presumed negative natural nasal swab specimens were eluted in PBS. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this natural nasal swab matrix pool to generate virus dilutions for testing.

Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure.

The LOD was determined as the lowest virus concentration that was detected  $\geq 95\%$  of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The BinaxNOW™ COVID-19 Ag Card LOD in natural nasal swab matrix was confirmed as 140.6 TCID<sub>50</sub>/mL.

## Limit of Detection (LoD) Study Results

Concentration TCID <sub>50</sub> /mL	Number Positive/Total	% Detected
140.6	20/20	100%

## Cross Reactivity (Analytical Specificity) and Microbial Interference

Cross reactivity and potential interference of BinaxNOW™ COVID-19 Ag Card was evaluated by testing 37 commensal and pathogenic microorganisms (8 bacteria, 14 viruses, 1 yeast and pooled human nasal wash) that may be present in the nasal cavity. Each of the organism, viruses, and yeast were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (45 TCID<sub>50</sub>/swab). No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

Potential Cross Reactant		Test Concentration
Virus	Adenovirus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human metapneumovirus (hMPV)	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Rhinovirus	1.0 x 10 <sup>5</sup> PFU/mL
	Enterovirus/Coxsackievirus B4	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human coronavirus OC43	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human coronavirus 229E	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human coronavirus NL63	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human parainfluenza virus 1	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human parainfluenza virus 2	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human parainfluenza virus 3	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human parainfluenza virus 4	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Influenza A	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Influenza B	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Respiratory Syncytial Virus A	1.0 x 10 <sup>5</sup> PFU/mL
Bacteria	<i>Bordetella pertussis</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Chlamydia pneumoniae</i>	1.0 x 10 <sup>6</sup> IFU/mL
	<i>Haemophilus influenzae</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Legionella pneumophila</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Mycoplasma pneumoniae</i>	1.0 x 10 <sup>6</sup> U/mL
	<i>Streptococcus pneumoniae</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Streptococcus pyogenes (group A)</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Mycobacterium tuberculosis</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Staphylococcus aureus</i>	1.0 x 10 <sup>6</sup> org/mL
	<i>Staphylococcus epidermidis</i>	1.0 x 10 <sup>6</sup> org/mL
	Pooled human nasal wash	N/A
Yeast	<i>Candida albicans</i>	1.0 x 10 <sup>6</sup> cells/mL

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing, *In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For *P. jirovecii* one area of sequence similarity shows 45% homology across 18% of the sequence, making cross-reactivity in the BinaxNOW™ COVID-19 Ag Card highly unlikely.
- No protein sequence homology was found between *M. tuberculosis*, and thus homology-based cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein, MERS-CoV and human coronavirus HKU1 revealed that cross-reactivity cannot be ruled out. Homology for KHU1 and MERS-CoV is relatively low, at 37.8% across 95% of the sequence and 57.14% across 87% of the sequence, respectively.

### High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of  $1.6 \times 10^5$  TCID<sub>50</sub>/mL of heat inactivated SARS-CoV-2 virus with the BinaxNOW™ COVID-19 Ag Card.


### Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the BinaxNOW™ COVID-19 Ag Card at the concentrations listed below and were found not to affect test performance.

Substance	Active Ingredient	Concentration
Endogenous	Mucin	2% w/v
	Whole Blood	1% v/v
OTC Nasal Drops	Phenylephrine	15% v/v
OTC Nasal Gel	Sodium Chloride (i.e. NeilMed)	5% v/v
OTC Nasal Spray 1	Cromolyn	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC Homeopathic Nasal Spray 2	Zincum gluconium (i.e., Zicam)	5% w/v
OTC Homeopathic Nasal Spray 3	Alkalol	10% v/v
OTC Homeopathic Nasal Spray 4	Fluticasone Propionate	5% v/v
Sore Throat Phenol Spray	Phenol	15% v/v
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	0.5% w/v
Antibiotic, Nasal Ointment	Mupirocin <sup>1</sup>	0.25% w/v
Antibacterial, Systemic	Tobramycin	0.0004% w/v

<sup>1</sup> Testing demonstrated false negative results at concentrations of 5 mg/mL (0.5% w/v). Standard dose of nasal ointment: 20 mg (2% w/w) of mupirocin in single-use 1-gram tubes.

## SYMBOLS

 Only	Prescription Only
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## ORDERING AND CONTACT INFORMATION

### Reorder Numbers:

195-000: BinaxNOW™ COVID-19 Ag Card (40 Tests)

195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit

**US +1 877 441 7440**

### Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:

US

+ 1 800 257 9525

[ts.scr@abbott.com](mailto:ts.scr@abbott.com)



**Abbott Diagnostics Scarborough, Inc.**

10 Southgate Road  
Scarborough, Maine 04074 USA

[www.abbott.com/poct](http://www.abbott.com/poct)

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IN195000 Rev. 2 2020/12



### **Antigen testing step by step instructions -**

- 1. Have them write their name on the front of the card,**
- 2. then use hand sanitizer,**
- 3. open the card and lay flat,**
- 4. open the swab, pull it out, don't touch the swab end,**
- 5. count with them 15 seconds while they insert into nose on one side, put it in the other side and count with them again,**
- 6. 6 drops of reagent are dropped in the top hole,**
- 7. put the swab in the bottom hole of the card and push up,**
- 8. twist swab handle 3 times clockwise,**
- 9. pull the tape off and close the card,**

**Set it on (wherever you want them set while you set the timer) face up and have them use hand sanitizer again on the way out. Set your timer and read the cards at 15 minutes and record it in the computer database, submit it to the state. Done.**

**IF SOMEONE'S RESULT IS POSITIVE, THE STUDENT MUST LEAVE IMMEDIATELY AND GET A PCR TEST. NOTIFY THE SCHOOL NURSE RIGHT AWAY SO CONTACT TRACING CAN BEGIN.**

**Antigen test cards with negative results can be disposed of in the normal trash. Control cards can also be disposed of in the regular trash. Cards with a positive test should be treated as biohazardous waste.**

<https://www.fda.gov/media/141570/download#:~:text=Procedure%20for%20BinaxNOW%E2%84%A2%20Swab%20Controls&text=Hold%20Extraction%20Reagent%20bottle%20vertically%20Hovering%201%2F2%20inch%20above,the%20dropper%20tip%20while%20dispensing.>

## Antigen Testing Preparation at School Clinics

### Pre-Clinic

1. Send consent forms home, email works well.
2. Check for positive cases, date of positive

### Date of Clinic

1. Table set up (three works well)
  - a. Sign in table
  - b. Names on Binex cards table
  - c. Swab and lay out table
  - d. Read in 15 minutes
  - e. Biohazard box present to discard read cards

### Operations of Clinic

1. Call students to destination
2. Students wait in line in hall or specific area of room
3. Take permission forms
4. Verbal check if registered with Covid Secure
5. Line up for card, staff write name on card
6. Send to swab line
7. Return to class

### Positive antigen test

1. If positive, call student back for PCR testing
2. If no PCR testing on site:
  - a. Place in isolation room
  - b. Parent pick up
  - c. Refer to PCR testing
3. If PCR testing available, swab and send home for isolation until results.

## Using antigen tests for COVID-19 screening in K-12 schools

**Remember: A permanent record must be kept of every test performed, including the test result, the time the sample was taken, the date, the full name of person being tested, their date of birth, their contact information, and the name of the person performing the test. Every test result must be reported to the State of Alaska. Any positive test must be reported to the State of Alaska immediately by either leaving a message on the COVID Reporting Hotline (1-877-469-8067) or electronically. In addition, all positive or negative test results must be reported electronically to the State of Alaska as soon as possible, ideally the day the test is performed. Please email Megan Tompkins ([megan.tompkins@alaska.gov](mailto:megan.tompkins@alaska.gov)) to set up electronic reporting before performing any testing.**

Regular screening of school staff is recommended by the CDC. Screening means testing staff who have no symptoms and no known exposure to COVID-19 (i.e. do not meet criteria to quarantine currently because of close contact with a person with COVID-19).

The CDC recommends regular screening tests for school staff based on the level of viral transmission in the community. DHSS recommends the following:

<b>High community transmission</b>	<b>Moderate community transmission</b>	<b>Low community transmission</b>
>10 cases/100,000 people averaged over 14 days	5-10 cases/100,000 people averaged over 14 days	<5 cases/100,000 people averaged over 14 days
<b>Test staff twice per week</b>	<b>Test staff once per week</b>	<b>Test staff once every two weeks</b>

Schools may wish to decrease the frequency of testing starting two weeks after a staff member receives the second dose of a COVID-19 vaccine.

Schools may also choose to regularly screen high-risk groups within their schools, such as student athletes and coaches who regularly travel for sports competitions. Antigen tests may be used for this purpose. The frequency of antigen tests can be discussed with DHSS, but in general testing more often will give more useful results than testing less often.

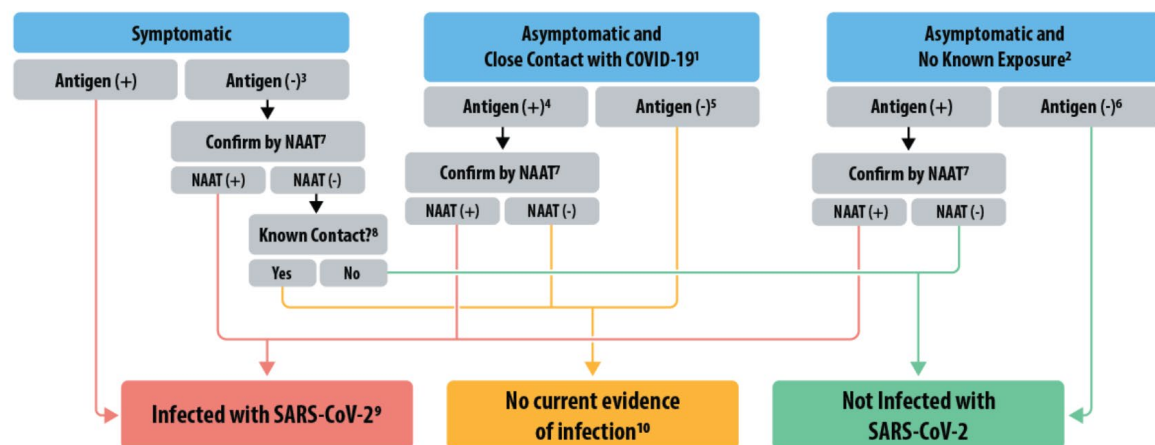
**Antigen tests do not replace the requirement for a molecular test to satisfy the AK Travel Health Orders, but a molecular test can replace an antigen test for screening.**

Staff and students who have recovered from COVID-19 and have a documented positive PCR test within the last 90 days should NOT be tested as part of a screening program. Instead, they should be considered negative unless they develop new symptoms. If they develop symptoms, they need to isolate themselves and contact their doctor to determine whether they need a test.

### To conduct a screening antigen test:

1. Confirm that the person has **no symptoms** and is **not on quarantine**
2. Confirm that the person has **not tested positive for COVID-19 (SARS-CoV-2) in the last 90 days**
3. If the person is under age 18, obtain verbal or written parent or guardian consent and verbal assent from the person; if an adult, obtain verbal or written consent from the person.
4. Perform an antigen test
5. If the test is **positive**, the person needs to get a molecular test and **must isolate** until they have the results from the molecular test. The molecular test will be the final answer for whether they have COVID-19 or not.
6. If the test is **negative**, the person is considered negative.

Figure 1. Antigen Test Algorithm

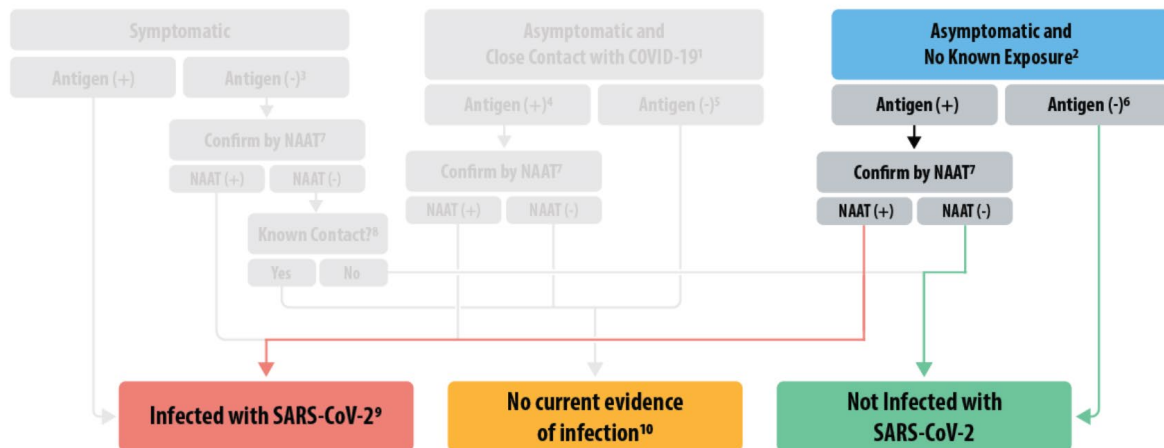


From <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Note: NAAT means a molecular test. For antigen screening tests, CDC recommends confirming **positive** tests only with a molecular test. Negative results are treated as negatives.

The part of the antigen test algorithm that is relevant to **screening testing** is as follows:

Figure 4. Antigen Testing Algorithm – Low Pretest Probability



### More information on the BinaxNOW test:

The BinaxNOW test is an antigen test. To do a BinaxNOW antigen test, a chemical is placed onto the card, a nose swab is taken (not a deep nose swab) and then the swab is placed in a small card, twirled and left in place for 15 minutes. The card performs the test and displays the result in 15 minutes. The result is displayed as either one line or two, similar to a pregnancy test. This means that the test can be easily used in schools or other places that do not have specialized lab equipment.

This antigen test has the same limitations as the other antigen tests described in these guidelines. It is not as accurate as a PCR test. If someone has one or more symptom of COVID-19, a negative BinaxNOW test, like other antigen tests, is **not enough to be able to tell that they do not have COVID-19 and they will need a PCR/molecular test before they can return to school** without completing a 10 day isolation period. If someone has symptoms of COVID-19, we can consider a positive result from an antigen test positive and start contact tracing and quarantining close contacts.

The US Department of Health and Human Services has provided a number of tests to the State of Alaska for use in many settings including schools, and can be requested through your local Emergency Operations Committee. Although the State of Alaska has a finite number of tests available, schools are encouraged to request as many as they think they will need. Federal COVID-19 relief funding allocated to schools may also be used to purchase testing supplies.

The test also integrates with a phone app called NAVICA, which can securely store and display a test result. For more information, see the company webpages at : <https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html> and <https://www.globalpointofcare.abbott/en/product-details/navica-binaxnow-covid-19-us.html> as well as the EUA at: <https://www.fda.gov/media/141570/download>

**If you receive these tests, make sure to read all directions and perform the necessary control tests. If you have questions about how to perform tests, how to use or interpret these tests, or whether you have the right certification to do these tests, contact [aksmartstart2020@alaska.gov](mailto:aksmartstart2020@alaska.gov).**

### Definitions:

**Diagnostic test:** A test performed in a person who has one or more symptoms of COVID-19 or has been exposed to COVID-19 in the last 14 days

**Screening test:** A test performed in someone who has no symptoms whatsoever and has not been in close contact with anyone with COVID-19 in the last 14 days

**Isolation:** Staying home, away from other people, after developing symptoms and/or being diagnosed with COVID-19. A typical isolation period is ten days from the first symptom. A person can come off isolation once it has been ten days since their first symptom, their fever has been gone for 24 hours and their other symptoms are resolving. If they never have any symptoms, it is ten days from their positive test. If they test positive and later develop symptoms, it is ten days from their first symptom, regardless of how far into their isolation period they developed the first symptom.

**Quarantine:** Staying home, away from other people, after being exposed to (having close contact with) someone with COVID-19. A quarantine period is 14 days after the last contact with a person with COVID-19. If you live with that person, the quarantine period is their isolation period PLUS 14 days after they finish their isolation period. Currently, Alaskans may quarantine for 10 days after an exposure and then return to school on day 11 without a test as long as they continue to watch for symptoms and are very careful about masking, distancing, etc for the full 14 days. Alaskans may also return to school after 7 days (on day 8) after a negative test within 48 hours of returning to school, again as long as they continue to watch for symptoms and are very careful about masking, distancing, etc for the full 14 days.

**Symptoms:** Any one or more new symptoms from the following list, **even if it is very mild**, is considered possible COVID-19. Anyone with one or more new symptoms should isolate themselves and get tested as soon as possible. Symptom list: Fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea.

**PCR test:** A test that looks for fragments of virus genetic material from a nose swab or saliva/mouth swab. One brand name is Cepheid. Some PCR tests are rapid tests. All PCR tests are molecular tests.

**Molecular test:** A test that looks for fragments of virus genetic material from a nose swab or saliva/mouth swab. PCR tests are molecular tests. Some molecular tests are rapid tests. One rapid test brand name is Abbot ID NOW, which is now commercially available but supplies are extremely limited and may not be available in the next few months (for more information, see their website at [www.globalpointofcare.abbott/en/product-details/id-now-covid-19.html](http://www.globalpointofcare.abbott/en/product-details/id-now-covid-19.html)).

**Antigen test:** A test that looks for fragments of the outside of the virus from a nose swab or saliva/mouth swab. One brand name is Sofia. Most antigen tests are rapid tests, but some rapid tests are not antigen tests.

**Antibody tests:** A blood test that looks for a past reaction to the virus. Antibody tests cannot be used to diagnose or exclude COVID-19 so will not be used in this testing guidance.

**Close contact:** Someone who has been within 6 feet for 15 minutes of someone else with COVID-19, or has had other notable exposure such as having been coughed on. The 15 minutes is cumulative, so even short times spent near someone can count if it happens often.

**CLIA certification:** A certificate that allows someone to perform a test. The certification costs \$180 currently for a multi-site certificate that lasts for two years, which a district may use for covering up to 200 schools. The certificate can be obtained by submitting Form CMS-116. Forms and more information can be obtained here: [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How\\_to\\_Apply\\_for\\_a\\_CLIA\\_Certificate\\_International\\_Laboratories](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories)

### CUE COVID-19 Test Users Advisement

- Treat all biological specimens as if capable of transmitting infectious agents. Wear clean lab coats and gloves. Change gloves between patients.
- This assay should not be used within 30 minutes of administering nasal or throat sprays.
- Do not use a Cue COVID-19 Test Cartridge that has been stored below 59°F (15°C) or above 86°F (30°C).
- Open the Cartridge foil pouch when you are ready to test. Do not open the foil pouch more than 30 minutes before you begin a test.
- The Cartridge must be inserted into the Cue Cartridge Reader before the Cue Sample Wand. The cartridge must be inserted logo side up. When you have fully inserted the Cartridge, all five lights on top of the Reader will flash.
  - The Reader needs to be on a level surface when the Cartridge is inserted and while the test is running. Do not move the Reader while the test is running.
  - The Cartridge must heat up for the full 100% heat cycle (approximately one minute) before the Sample Wand is inserted into the cartridge. All of the LED lights on the Reader will flash 5 times when the cartridge is ready for the Sample Wand.
  - Do not wait longer than 10 minutes after the heat cycle is complete to insert the Sample Wand.
  - Do not attempt to open the cartridge.
- The Cue Sample Wand is sterile. Do not use if the packaging is damaged or accidentally opened before use. Open another cartridge foil pouch for a sterile Cue Sample Wand.
  - If the Cartridge or Sample Wand is dropped, cracked, or found to be damaged when opened, do not use and discard.
  - You must insert the Sample Wand with nasal sample into the Cartridge within 5 minutes of collecting the nasal sample.
  - After the Sample Wand is inserted do not remove the wand from the Cartridge.
- If a used Cartridge is open or broken a deep clean must be done of the device and surrounding area. Wear clean lab coat and gloves. Wipe the exterior of the Reader and surrounding area it sits on with CLOROX germicidal bleach wipe (or equivalent wipe containing 0.55% sodium hypochlorite as the active ingredient) solution and let air dry. Discard any open foil pouches that may have been exposed.

### Quality Control (QC)

Controls must be used to show that the Cue COVID-19 Test is working properly. The Cue COVID-19 Test Positive Control Swab (REF C2111) and Cue Test Negative Control Swab (REF C2112) are available separately.

- Purchase the Cue COVID-19 External Control Swabs Pack (REF 2110) that contains three Cue COVID-19 Test Positive Control Swabs (REF C2111) and three Cue Test Negative Control Swabs (REF C2112) from Cue Health Inc., by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).
- Control Swabs are stored at room temperature (15-30°C / 59-86°F). Control Swabs are tested using the same procedure as for a patient sample.
- Cue Health recommends that a Cue Test Negative Control Swab and a Cue COVID-19 Test Positive Control Swab be run:
  - Once for each new lot of cartridge packs received
  - When problems with testing are suspected or identified
  - Alternatively, as deemed necessary in order to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups
- If correct control results are not obtained, repeat the test using a new Control Swab, and a new test Cartridge. If the control testing continues to fail, do not perform additional clinical specimen tests or report results. Contact Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378) before testing additional clinical specimens.





## LabOnline Facility Request Form

Alaska State Public Health Laboratory  
Alaska State Virology Laboratory  
Email: [help.aklabonline@alaska.gov](mailto:help.aklabonline@alaska.gov)

**Email Completed Form to: [help.aklabonline@alaska.gov](mailto:help.aklabonline@alaska.gov)**

**About Lab Online** LabOnline is a secure web portal that interfaces with the Alaska State Public Health Laboratory Information System and enables authorized laboratory users to order tests and receive test results, as well as download and/or print reports.

### Prerequisites

- Make sure cookies are enabled for your browser.
- LabOnline was tested on Internet Explorer 11; Microsoft Edge, and Google Chrome browsers.
- The minimum screen resolution for LabOnline is 1024 x 768 pixels. The maximum screen resolution for LabOnline is 1920 x 1080 pixels.

### 1. Facility Information

Facility Name					
Address					
City		State		Zip	
Phone		Fax			

### 2. Medical Provider Information: Enter your Facility's Medical Director, or the person under whom the laboratory tests are ordered.

Provider Name		NPI	
---------------	--	-----	--

### 3. Contact Information: *If we have any questions concerning your account, this is whom we will contact.*

Primary Contact Name:			
Email		phone	

### 4. IP address: LabOnline requires an external facing static IP address or IP pool (range). *(IP addresses beginning with 10. or 192.168 are not external facing) (if unsure speak to your IT staff or go to [whatsmyIPaddress.com](http://whatsmyIPaddress.com))*

--

### 5. Testing: Please check the expected testing groups your Facility sends to ASPHL. Check all that apply.

<input type="checkbox"/> Blood Lead	<input type="checkbox"/> Reportable Organisms
<input type="checkbox"/> Corona Virus	<input type="checkbox"/> Sexually Transmitted Diseases
<input type="checkbox"/> Influenza and other respiratory viruses	<input type="checkbox"/> TB (Mycobacteriology)
<input type="checkbox"/> Rabies	<input type="checkbox"/> Other

## LabOnline Facility Request Form

### Facility Access Requirements

1. You must coordinate your user access requirements, and user access parameters, with your Alaska State Public Health Laboratory Contact or Sponsor.
2. You must immediately discontinue use of any of your Facility's computers or electronic devices that show signs of being infected by a virus or other malware and report the suspected incident.
3. You must ensure your Facility only accesses lab results for which you have been granted authorization.
4. You must ensure that your Facility uses only currently supported browsers such as Internet Explorer, Microsoft Edge, or Google Chrome.
5. Within 48 hours, communicate any employment status changes to the ASPHL that eliminate your employee's need for access to LabOnline.
6. Review your Facility's employees' access to LabOnline every 30 days, and report any access status changes to the ASPHL.
7. Recognize that ASPHL will monitor use of the web portal by individual users and that laboratory reports can be modified solely by ASPHL.
8. You must report all security incidents or suspected incidents (e.g., hacked accounts or computers with access, improper or suspicious acts) related to LabOnline to [hss-security@alaska.gov](mailto:hss-security@alaska.gov).

### ACCEPTANCE AND SIGNATURE

I have read the above LabOnline Facility Request Form. By my signature below, I acknowledge and agree that my Facility's access to LabOnline is covered by, and subject to, such Rules. Further, I acknowledge and accept that any violations of these Rules may subject my Facility to civil and/or criminal actions and that ASPHL retains the right, at its sole discretion, to terminate, cancel or suspend my access rights to the LabOnline at any time, without notice.

\_\_\_\_\_  
Facility Representative Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Email address

\_\_\_\_\_  
Your Organization

State of Alaska internal use:

\_\_\_\_\_  
State of Alaska LAB Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

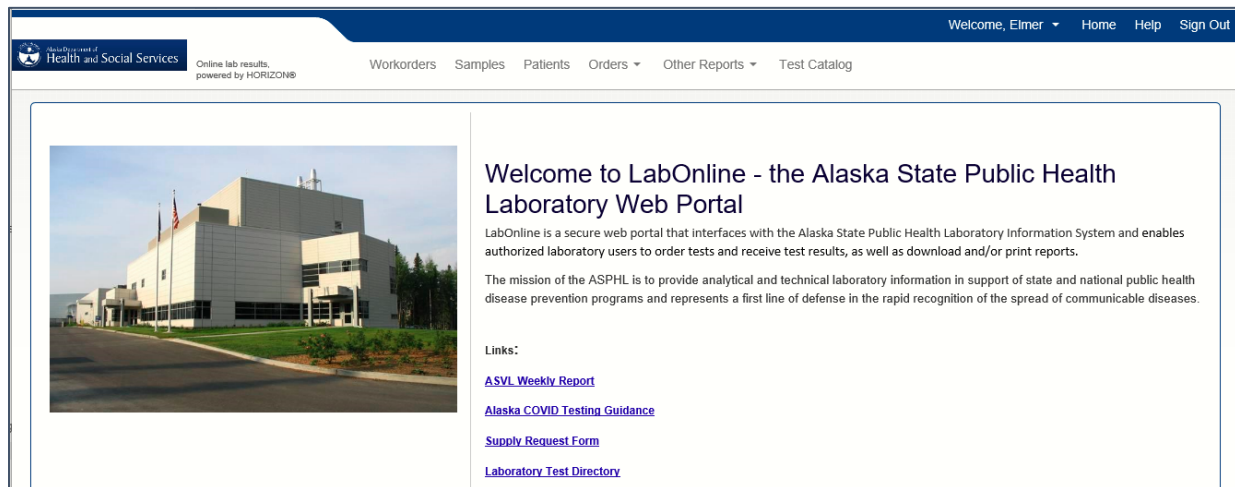
\_\_\_\_\_  
Title



## Introducing LabOnline Alaska Public Health Laboratory Web Portal

Alaska State Public Health Laboratory  
Alaska State Virology Laboratory  
Email: [help.aklabonline@alaska.gov](mailto:help.aklabonline@alaska.gov)

LabOnline is a secure web portal that interfaces with the Alaska State Public Health Laboratory Information System and enables authorized laboratory users to order tests and receive test results, as well as download and/or print reports.



- Facility IP addresses are whitelisted for secure access.
- Each user has a unique ID and password to log into the portal

### LabOnline Account Types



- **Order-only accounts** allow the user to order tests through the LabOnline portal
- **Full-access accounts** are individual accounts that give the user access to patient data, as well as sample results. This account type can also order tests and track sample progression.
- Users can be notified by an email for each report or a daily summary. Reports can then be viewed online or printed.

### Prerequisites

- LabOnline was tested on Internet Explorer 11; Microsoft Edge, and Google Chrome browsers.
- The minimum screen resolution for LabOnline is 1024 x 768 pixels.
- The maximum screen resolution for LabOnline is 1920 x 1080 pixels.
- Make sure cookies are enabled for your browser.



- ① Complete the LabOnline Facility Request Form
- ② Complete the LabOnline User Agreement
- ③ Check your email for your Login Information
- ④ Login to the LabOnline Portal

# Confidential Infectious Disease Report Form

## State of Alaska, Section of Epidemiology

Health care providers may use this form for making infectious disease reports. Please use the STD/HIV Disease Report Form for reporting of Sexually Transmitted Diseases (STD) and HIV. Forms may be found at <http://dhss.alaska.gov/dph/Epi/Pages/pubs/conditions/crforms.aspx>.

**Immediately report any suspected or confirmed public health emergency to 907-269-8000 (during business hours) or 1-800-478-0084 (afterhours). Diseases classified as public health emergencies are listed in bold on page 6 on the Disease Reporting Manual (<http://dhss.alaska.gov/dph/Epi/Documents/pubs/conditions/ConditionsReportable.pdf>).**

### Patient Information

Last Name \_\_\_\_\_ First Name \_\_\_\_\_ MI \_\_\_\_\_

Date of birth \_\_\_\_/\_\_\_\_/\_\_\_\_ Sex: Female Pregnant: No Yes EDC \_\_\_\_/\_\_\_\_/\_\_\_\_ Unknown  
(mm/dd/yyyy) Male  
Transgender

Race: ☐ White ☐ Asian Ethnicity: ☐ Hispanic  
☐ Black ☐ Unknown ☐ Non-Hispanic  
Alaska Native/American Indian Other \_\_\_\_\_ Unknown  
Native Hawaiian/Pacific Islander

Physical Address \_\_\_\_\_ PO Box \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_  
Phones (home) \_\_\_\_\_ (cell) \_\_\_\_\_ (work) \_\_\_\_\_

### Disease Information

Name of Disease \_\_\_\_\_ Specimen Collection Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Was the diagnosis laboratory confirmed? Yes No Result: Positive  
Negative  
Indeterminate

\*If so, please include a copy of the lab result

Type of Specimen: ☐ Stool Type of Test: Culture  
☐ Blood PCR  
☐ CSF Rapid test  
☐ Nasopharyngeal swab Antigen test  
☐ Other \_\_\_\_\_ Serology  
Other \_\_\_\_\_

Name of Medical Facility \_\_\_\_\_ Phone \_\_\_\_\_

Patient Status: Inpatient Outpatient Emergency Department

Attending Health Care Provider \_\_\_\_\_ Laboratory Name (if known): \_\_\_\_\_

Reported by: \_\_\_\_\_ Date Reported: \_\_\_\_/\_\_\_\_/\_\_\_\_

Fax reports to (907) 561-4239 – please verify fax has been transmitted.

This form is also available online at <http://dhss.alaska.gov/dph/Epi/Pages/pubs/conditions/crforms.aspx>.

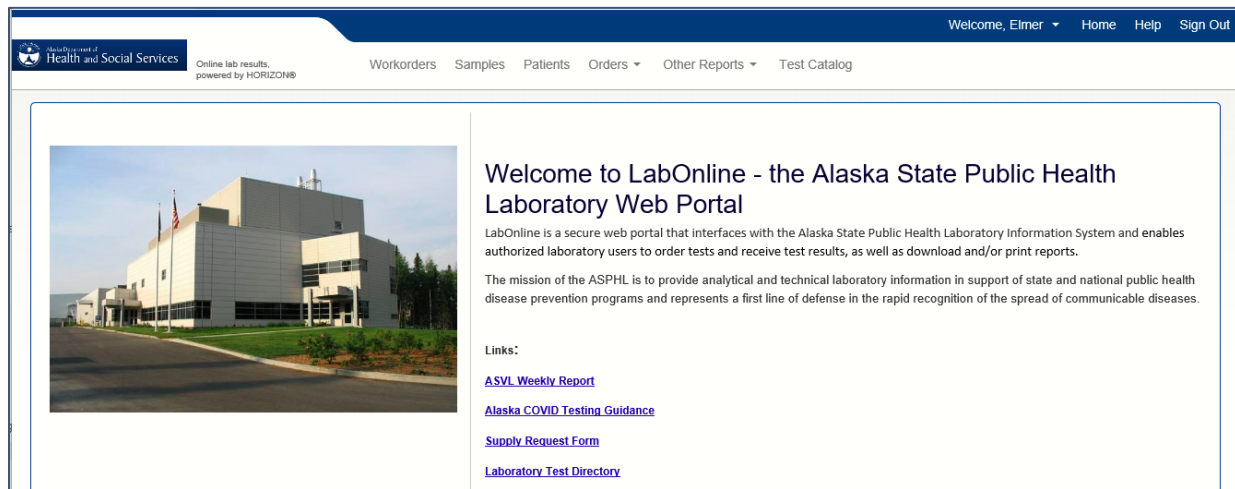




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### LabOnline Account Types



- **Order-only accounts** allow the user to order tests through the LabOnline portal
- **Full-access accounts** are individual accounts that give the user access to patient data, as well as sample results. This account type can also order tests and track sample progression.
- Users can be notified by an email for each report or a daily summary. Reports can then be viewed online or printed.

### Prerequisites

- LabOnline was tested on Internet Explorer 11; Microsoft Edge, and Google Chrome browsers.
- The minimum screen resolution for LabOnline is 1024 x 768 pixels.
- The maximum screen resolution for LabOnline is 1920 x 1080 pixels.
- Make sure cookies are enabled for your browser.



- ① Complete the LabOnline Facility Request Form
- ② Complete the LabOnline User Agreement
- ③ Check your email for your Login Information
- ④ Login to the LabOnline Portal

## Reporting COVID testing to the State of Alaska

Reporting all COVID results to the State DHSS DPH Section of Epidemiology (SOE) is required by both state and federal regulations. Reporting should be done daily and include both positive and negative results. The regulations apply to all COVID-related test types (PCR, Antigen, Antibody). All sites performing testing need to coordinate their reporting methodology with the SOE prior to beginning testing, to initiate reporting via an acceptable process.

State testing/ reporting guidance: <http://dhss.alaska.gov/dph/Epi/id/SiteAssets/Pages/HumanCoV/AKCOVIDTestingGuidance.pdf>

Federal reporting guidance:

- CDC site: <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html>
- HHS site: <https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html> , as well as <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf> which specifies the required data elements.

Acceptable reporting methodologies include:

1. Electronic Lab Reporting (ELR) via HL7 2.5.1 messages.
2. CSV line list uploaded to an SFTP folder
3. Web Portal
4. Faxing paper reports. This is to be used only as a last resort, for testing facilities with very low volume, or as an immediate stop-gap if other methods fail.

## ELR reporting instructions

Scope internally with your IT, LIMS, and EHR teams to ensure that your software can produce an HL7 2.5.1 message. Initiate an ELR onboarding request by emailing Megan Tompkins at [megan.tompkins@alaska.gov](mailto:megan.tompkins@alaska.gov). Facilities with existing ELR feeds for reportable conditions do not need to initiate new feeds, but should implement any necessary local changes to EHR and LIMS software that allow COVID tests to be included in the feed. Any time an additional COVID-related test is added to the facility's lab capacity, ensure that configurations have been put into place to report that test.

## CSV reporting instructions

Use the CSV file format included in this packet. Email Megan Tompkins at [megan.tompkins@alask.gov](mailto:megan.tompkins@alask.gov) to request initiation of an SFTP account, which will be provided via the healthconnect vendor Audacious Inquiry. Facilities will be expected to review the file format and upload a test file, respond to formatting feedback, and reach 100% compliance with formatting expectations, after which they can go live with daily CSV reporting via SFTP. Files should be saved in the SFTP location in a .csv file type, not a MS Excel file.

### File format guidance

General formatting requirements: No commas or other special characters are allowed. If information is not available, leave blank rather than enter in “Unknown” or “Refused” or other indicator, but take note of the column status below prior to leaving any columns blank. The status column indicates whether a variable is Required, Preferred, or Optional. RF variables, or “Required or will hard fail”, indicates values that absolutely must be included in the file or the results import will fail. Items indicated R are required, and should be provided, but the message will not fail on import if not provided. Every reasonable effort should be taken to collect and report all Required data elements.

Tools/ guidance for selecting the appropriate LOINC test codes: <https://loinc.org/sars-coronavirus-2/#ivd> and <https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>, especially the Mapping tool “LIVD SARS-CoV-2 Test Codes.xlsx”

COLUMN NAME	COLUMN HEADER	DESCRIPTION	STATUS (RF=REQUIRED OR WILL HARD FAIL, R=REQUIRED, P=PREFERRED, O=OPTIONAL)	FORMATTING REQUIREMENTS
A	reportingOrganizationCode	CLIA number of facility reporting results to the Section of Epidemiology	RF; If facility does not have a CLIA, coordinate with Section of Epidemiology to be assigned a local ID number	CLIA number
B	reportingOrganizationDescription	Name of facility reporting results to the Section of Epidemiology	RF	No commas
C	firstName	Patient's first name	RF	No commas
D	middleName	Patient's middle name	O	Middle initial or middle name; No commas
E	lastName	Patient's last name	RF	No commas
F	dateOfBirth	Patient's date of birth	R	MM/DD/YYYY
G	patientSex	Patient's self-reported current sex	R	A= Ambiguous F= Female M= Male N= Not applicable O= Other U= Unknown

	Can leave blank for unknown			
<b>H</b>	Race	Patient's self-reported race	R	1002-5= American Indian or Alaska Native 2028-9= Asian 2054-5= Black or African-American 2076-8= Native Hawaiian or Other Pacific Islander 2106-3= White 2131-1= Other race
<b>I</b>	Ethnicity	Patient's self-reported ethnicity	R	H= Hispanic or Latino N= Not Hispanic or Latino U= Unknown
<b>J</b>	Street	Patient's permanent residence street address	R	No commas
<b>K</b>	City	Patient's permanent residence city	R	
<b>L</b>	State	Patient's permanent residence state	R	2-letter code
<b>M</b>	Zip	Patient's permanent residence zip	R	5-digit zip
<b>N</b>	patientPhone	Current contact phone number	R	(XXX)XXX-XXXX
<b>O</b>	accessionNumber	Must be unique to patient/ test event	O; provide if generated at the facility, otherwise leave blank	
<b>P</b>	specimenCollectionDate	Date the specimen was collected	RF	MM/DD/YYYY
<b>Q</b>	specimenAnalysisDate	Date the test was performed	RF	MM/DD/YYYY
<b>R</b>	orderedTestCode	LOINC code, search for appropriate code based on performed test <a href="https://loinc.org/sars-coronavirus-2/">https://loinc.org/sars-coronavirus-2/</a>	RF	LOINC codes only
<b>S</b>	orderedTestDescription	Test name, such as "SARS-CoV2-PCR"	RF	
<b>T</b>	orderedTestCodingSystem	LN	RF	Literal value: LN
<b>U</b>	resultedTestName	Test name, such as "SARS-CoV2-PCR"	RF	
<b>V</b>	resultedTestCode	LOINC code, search for appropriate code based on performed test <a href="https://loinc.org/sars-coronavirus-2/">https://loinc.org/sars-coronavirus-2/</a>	RF	LOINC codes only
<b>W</b>	resultedTestCodingSystem	LN	RF	Literal value: LN



<b>X</b>	resultedTestResult	Test result	RF	Acceptable responses are Positive, Negative, Indeterminate, or Unsatisfactory
<b>Y</b>	resultedTestNameTwo	Test name, such as “SARS-CoV2-PCR”	O; Only required if performing an ordered test with multiple resulted tests possible, such as a multi-target flu/ SARS-CoV-2	
<b>Z</b>	resultedTestCodeTwo	LOINC code, search for appropriate code based on performed test <a href="https://loinc.org/sars-coronavirus-2/">https://loinc.org/sars-coronavirus-2/</a>	O; Only required if performing an ordered test with multiple resulted tests possible, such as a multi-target flu/ SARS-CoV-2	LOINC codes only
<b>AA</b>	resultedTestTwoCodingSystem	LN	O; Only required if performing an ordered test with multiple resulted tests possible, such as a multi-target flu/ SARS-CoV-2	Literal value: LN
<b>AB</b>	resultedTestResultTwo	Test result	O; Only required if performing an ordered test with multiple resulted tests possible, such as a multi-target flu/ SARS-CoV-2	Acceptable responses are Positive, Negative, Indeterminate, or Unsatisfactory
<b>AC</b>	orderingProvider	Name of provider ordering the test	P	No commas; LASTNAME FIRSTNAME
<b>AD</b>	orderingProviderStreet	Address of provider ordering the test	P	
<b>AE</b>	orderingProviderCity	City of provider ordering the test	P	
<b>AF</b>	orderingProviderState	State of provider ordering the test	P	2-letter state abbreviation
<b>AG</b>	orderingProviderZip	Zip of provider ordering the test	P	5-digit zip code
<b>AH</b>	orderingFacilityID	CLIA number for the facility ordering the test	R; If facility does not have a CLIA, coordinate with Section of Epidemiology to be assigned a local ID number	CLIA number (unless assigned a local ID by Epidemiology)
<b>AI</b>	orderingFacilityDescription	Name of the facility ordering the test	R	No commas
<b>AJ</b>	orderingFacilityStreet	Street address of the facility ordering the test	R	No commas
<b>AK</b>	orderingFacilityCity	City of the facility ordering the test	R	
<b>AL</b>	orderingFacilityState	State of the facility ordering the test	R	2-letter abbreviation
<b>AM</b>	orderingFacilityZip	Zip of the facility ordering the test	R	5-digit zip code
<b>AN</b>	testingFacilityID	CLIA number for facility performing the test	RF; If facility does not have a CLIA, coordinate with Section	CLIA number (unless assigned a local ID by Epidemiology)

			of Epidemiology to be assigned a local ID number	
<b>AO</b>	testingFacilityDescription	Name of the facility performing the test	RF	No commas
<b>AP</b>	testingFacilityStreet	Street address of the facility performing the test	RF	No commas
<b>AQ</b>	testingFacilityCity	City of the facility performing the test	RF	
<b>AR</b>	testingFacilityState	State of the facility performing the test	RF	2-letter abbreviation
<b>AS</b>	testingFacilityZip	Zip of the facility performing the test	RF	5-digit zip code

## Web Portal

The State of Alaska has a web portal that can be used to satisfy reporting requirements. It's a secure website where identified users can log in and submit individual patient results for their test site. The web portal is best suited to static groups of people who undergo repeat testing (schools, sports teams, etc) and is discouraged for clinics or laboratories that report on many different individuals or have high volume. If you think this method of reporting is right for your organization, please contact our office for additional information.

## Paper reporting instructions

Complete an Infectious Disease Report Form (<http://dhss.alaska.gov/dph/Epi/Documents/pubs/conditions/frmlnfect.pdf>) for each individual tested. In response to the question "Was the diagnosis laboratory confirmed?" select Yes for positives, and No for negatives. Also write the result immediately next to this question. Fax the form and a printed lab report (if available) to the SOE at 907-561-4239. This method is incredibly manual for facilities as well as the SOE. Please note that it is not an acceptable method for facilities conducting 100 or more tests per week.

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