Attachment 6

COLLEGE of AMERICAN PATHOLOGISTS

COVAG-B 2021

Kit Instructions

SARS-CoV-2 Antigen Survey

Kit Contents

Three simulated, non-infectious specimens

- COVAG-04 — COVAG-06

For replacement materials, contact the CAP immediately.

Important: Before You Begin

New for this Mailing

None

Reporting Code Changes

The following manufacturers have deleted or updated codes for this mailing:

- DiaSorin

Storage and Stability Instructions

1. If this kit contains broken or leaking specimens, autoclave the contents of the container with minimal exposure to the atmosphere.
2. Store unopened specimens at 2 - 8°C upon receipt.
3. Once open, start testing immediately.
4. Upon arrival, if specimens are warm to the touch, call the Customer Contact Center for a replacement.

Critical Reporting Information

As directed by the Centers for Medicare and Medicaid Services (CMS), laboratories are not allowed to test and report proficiency testing specimens from multiple instruments, unless that is how they routinely test patient specimens. Report the proficiency testing results as you would for your patient samples.

Program Notes

1. Beginning in 2022, **we will no longer include a printed copy of the result form** in your kit(s) or accept emailed, faxed, or mailed results. Your laboratory can access the online result form in e-LAB Solutions Suite on cap.org. You may download or print the result form, if needed.

ANAB ACCREDITED ISO/IEC 17043 PROFICIENCY TESTING PROVIDER

Important: See the Biohazard Warning at the end of these instructions.

Customer Contact Center 800-323-4040 option 1 (domestic) or 001-847-832-7000 option 1 (international)

2. These proficiency testing specimens are contrived material to simulate nasal patient specimens.
3. The COVAG program will have two mailings offered in 2021. For a current list of program offerings, visit the cap.org Catalog and Ordering Information page.

Detailed Testing Instructions

Handling Instructions

Caution: The specimens may contain pathogen(s) or potential pathogen(s); handle with care. Do not create aerosols!

1. This material is rendered non-infectious.
2. Challenges are not specific for a particular type of clinical specimen. Laboratories may assign a specimen type acceptable for the testing performed, if needed.
3. **BD Veritor System, BinaxNOW, and Quidel Sofia users**
   - Insert the swab, provided in your manufacturer's test kit, into the proficiency testing sample for 15 seconds until thoroughly saturated. Then follow your manufacturer's instructions for patient testing.
4. **DiaSorin Liaison users**
   - Dilute the proficiency testing specimen with the Liaison SARS-CoV-2 sample inactivation buffer (REF 311502) using a 1:1 ratio, then follow your manufacturer's instructions (pre-analytical procedure workflow for swab in universal transport medium or viral transport medium).
5. **LumiraDx users**
   - Draw up the proficiency testing specimen into the Transfer pipette (20 uL) obtained in the quality control kit.
   - Apply the proficiency testing specimen to the already inserted SARS-CoV-2 Ag Test Strip. Hold the pipette over the Sample Application Area of the Test Strip and dispense the proficiency testing specimen. The LumiraDx instrument will indicate sample is detected with an audible alert (if the instrument sounds are enabled). The screen of the LumiraDx instrument will request the user to close the door. Then follow your manufacturer's instructions for patient testing.

Reporting Your Results

General Reporting Instructions

1. Verify the accuracy of all reporting codes by reviewing the online result form or the Method Summary Page.
2. **Exception Codes:** If you must report an analytical problem for a test or individual analyte, **leave the result area for that section blank** and select one of the following bubbles on the result form within that section. The exception code bubble that you select will apply **only** to the result area(s) left blank. If your laboratory does not perform testing, do not use an exception code. Documentation on the use of these codes is the responsibility of the laboratory and should be kept internally.
   - **11 Unable to analyze**
     Use code 11 to indicate **your laboratory** was unable to analyze the specimens (eg, instrument not functioning, reagents not available). You do not need to call the CAP to use this code.
   - **33 Specimen unsatisfactory**
     You **must** contact the CAP to use this code.

   For graded analytes, if you select an exception code bubble **and** enter data on the result form, the data will be graded.

Per CLIA, as published by the United States Federal Register

- A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.
- Proficiency Testing (PT) specimens must be tested with the laboratory's regular workload, using routine methods, and testing the PT specimens the same number of times it routinely tests patient specimens.
- If referral for testing is routinely performed for patient specimens, the practice cannot be followed for PT specimens. Referral is considered to be movement of the specimen from a laboratory with a CLIA identification number to another laboratory that has a different CLIA identification number.
- Laboratories must ensure that personnel do not share results or refer PT specimens for any reflex or testing outside their CLIA identification number.

Disclaimer

PT specimens, their progeny, unmodified derivatives, or modifications thereof may not be transferred or incorporated into a program intended for sale. PT specimens, their progeny, unmodified derivatives, or modifications thereof, reagents, and disposable equipment used in PT, when disposed of, should be autoclaved or incinerated and disposed of as hazardous waste. Disposal must follow local regulations, if more stringent than regulations enforced by the US Centers for Disease Control and Prevention and US Food and Drug Administration.

3. Corrections can be made to the result form at any time **prior** to the due date. For results that are approved online, corrections must also be done online. Faxed or mailed corrections will not be accepted.

Submitting Results

1. Results **must** be received no later than midnight, Central Time by the due date on the result form.
2. In order to enter results on cap.org, laboratory staff must first create a personal Web account, affiliate themselves with a laboratory, obtain approval from their site administrator, and then log in.
3. Your laboratory must enroll/register by using the PIN number that was originally emailed to your laboratory director. If you are not enrolled/registered and need your PIN number, contact the CAP.

Biohazard Warning

All program specimens should be treated as if potentially infectious and should be handled as if they are capable of transmitting disease.

Program specimens are prepared from blood or other source material obtained from human donors or animals.

When working with program specimens, precautions should be taken to protect yourself and others from accidental exposure to infectious agents such as HIV, HBV, and HCV.

HIV can be transmitted through accidental parenteral inoculation, mucous membranes, or non-intact skin contact with HIV infected blood or body fluids. HBV and HCV can be transmitted through accidental parenteral inoculation, mucous membranes, non-intact skin contact, aerosolization or ingestion.

Precautions described in CDC and FDA recommendations and OSHA blood borne pathogen rules should be followed at all times when handling program specimens and reagents.

Such precautions include the following:

- Gloves should be put on **before opening the container** and should be kept on throughout the period specimens are handled. Replace gloves if contaminated, or if their ability to function as a barrier is compromised.
- At high altitudes, specimens should be opened in a hood or biologic safety cabinet.
- There should be no eating, drinking, or smoking in the laboratory.
- Hands should be washed after removing gloves and before leaving the testing area.
- Program specimens and reagents should be kept in separate refrigerators from those containing blood or blood components for transfusion.
- Program specimens, reagents, and disposable equipment used in testing should be autoclaved or incinerated and disposed of as hazardous waste. Disposal must follow local regulations, if more stringent than regulations enforced by the CDC or the FDA.

If there has been an accident in which you have been exposed to the testing materials, call the CAP Hot Line at 800-443-3244 (domestic) or 001-847-470-2812 (international) at any time. You can access Safety Data Sheets (SDS) by logging on to cap.org. Under the Laboratory Improvement tab, click on Catalog and Ordering Information.

For Assistance

Provide your CAP number and contact information with all correspondence.
Participants in countries serviced by a designated CAP distributor should contact their distributor's customer service department.

Telephone: 800-323-4040 option 1
(Monday - Friday, 7:00 AM – 5:30 PM US Central Time)
International Participants: 001-847-832-7000 option 1

Email: contactcenter@cap.org
Website: cap.org

Address: CAP Surveys Program
325 Waukegan Road
Northfield, IL 60093-2750
USA

Manufacturer Master List

Deleted codes
None

New/Updated codes

2187	DiaSorin Liaison

2628	BD Veritor System
1872	BinaxNOW
2187	DiaSorin Liaison
2778	Euroimmun
3701	LUMIPULSE
1746	LumiraDx
3702	Panbio
3468	Quidel Sofia
1154	Quidel Sofia 2
3703	Vitrex PCL
1544	Vitros
0010	Other, specify on result form

Attachment G

CAP | COVAG-B 2021

Last Updated:

KIT 34912389 6 01 68

Results are due no later than midnight, Central Time:

October 26, 2021

The due date that displays online is the most current due date.

CAP # 1297601 - 01 SEQ # 01

Products:COVAG
Veterans Affairs Med Ctr - Erie
Bernadette Hall MT(ASCP)
TEL# 1-814-860-2178 FAX# 1-814-860-2082

SARS-CoV-2 Antigen Survey Result Form

Result Forms Going Paperless in 2022

Beginning in 2022, **we will no longer send your laboratory a printed copy of this result form** or accept emailed, faxed, or mailed results. You can access the online result form in e-LAB Solutions Suite on cap.org. You may download or print the result form, if needed.

Results

010 Manufacturer Code: 1872

020 ○ 11 Exception Code ○ 33

COVAG-04	COVAG-05	COVAG-06
030 ○ 110 Negative	040 ○ 110 Negative	050 ○ 110 Negative
○ 111 Positive	○ 111 Positive	○ 111 Positive
○ 145 Indeterminate	○ 145 Indeterminate	○ 145 Indeterminate

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TEL# 1-814-860-2178 FAX# 1-814-860-2082

October 26, 2021

Attestation/Use of Other Form

Attestation Statement

As stated in the February 28, 1992 United States *Federal Register* under Subpart H 493-801 (b) (1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee and the testing personnel must sign on the result form.
Retain a signed copy of this page in your laboratory for your records and inspection purposes.
If your laboratory requires additional space for signatures, copy this form as needed.

We, the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient specimens. We confirm that results were not shared or PT specimens referred or tested outside our CLIA identification number.

Director (or Designee) (signature required)

010

Survey Mailing Information (eg, CA2021)

030

Testing Personnel (signature required)

040

Testing Personnel (signature required)

070

Testing Personnel (signature required)

100

Use of Other

If applicable, use this section to list methodology information not found on the master lists or result form. For online entry, you can enter only 255 characters. CAP Accreditation Program Participants: Do not use this section to make changes to your test/activity menu. Update your test/activity menu using Organization Profile on cap.org via e-LAB Solutions Suite.

130

Signatures will not display when viewed online.