ACL Laboratories
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Test Bulletin

October 2024

ACL Laboratories Test Order Code Update

ACL test order codes originally scheduled to change on **Tuesday, October 15, 2024,** will ***not*** change. You will ***not*** need to update your EMR test compendium for the tests identified below.

Test Name	Test Order Code
Potassium	K
Sodium	NA
Uric Acid	URIC
Vitamin B12	VB12
Prothrombin Time (INR/PT)	PTINR
Urinalysis with Microscopy without Culture	UCOM
Microalbumin Urine Random	MAR
PSA	PSA
Surgical Pathology	BIOPSY
Chlamydia/Gonorrhea by Nucleic Acid Amplification	CGRNA

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at https://www.acllaboratories.com/providers/test-directory/.

ACL Laboratories Performs Allergy Testing In-House

Effective Monday, November 11, 2024, ACL laboratories will perform allergy testing in-house at our Illinois Central Laboratory. Previously, allergy testing was conducted at reference labs. Performing these tests in-house will provide an improved 72-hour turnaround time, plus an expanded menu of orderable allergy panels. The testing methodology, Phadia ImmunoCAP Specific IgE, will remain unchanged.

A detailed list of orderable allergens and panels will be shared in an Important Announcement closer to ACL's November go-live.

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Specimen Collection Device Update for SARS-CoV-2 Testing

On Monday, May 6, 2024, the United States Food and Drug Administration (FDA) published a final rule, giving the FDA additional oversight over laboratory developed tests (LDTs). This rule adds significant additional regulation and cost for each test performed using testing platforms, collection devices, or specimen types that have not been formally approved for use by the FDA; even if the laboratory has done an extensive internal validation to demonstrate the accuracy of these methods or specimen types. This increased regulation and cost will require labs to scale back the number of LDTs they are able to perform to ***only*** those tests that are critical for patient care or that are performed in such high volume that the time commitment and cost associated with getting them formally approved for use by the FDA can be justified.

During the SARS-CoV-2 pandemic, due to supply shortages, ACL Laboratories performed an independent validation demonstrating that specimens collected in ESwab™ specimen collection devices were acceptable for use in the detection of SARS-CoV-2. Since these devices are not approved by the FDA for detection of SARS-CoV-2, their continued use will now be subject to additional regulation and cost. Because there are FDA approved devices readily accessible for this testing, ACL Laboratories will not pursue approval from the FDA to continue using ESwab™ collection devices for detection of SARS-CoV-2.

This testing change pertains to the following tests performed at ACL Laboratories:

- **Rapid SARS-CoV-2 by PCR (Test Order Code LAB10644)**
- **COVID/Flu by PCR (Test Order Code LAB10889)**
- **COVID/FLU/RSV Panel (Test Order Code LAB10789)**
- **2019 Novel Coronavirus (SARS-CoV-2) by PCR (Test Order Code LAB10635)**

Beginning Monday, November 4, 2024, the following collection devices **will no longer be acceptable** for the tests listed above:

Workday # 1216307

Workday # 1216308

The following collection devices will continue to be acceptable for use with all four of the SARS-CoV-2 tests listed above.

Universal Viral Transport Medium w/ mini-tip nasopharyngeal swab (Workday# 1056987):

M4RT or Universal Viral Transport medium w/ standard tipped swab (Workday# 1215785):

Over the course of the next few months, ACL Laboratories will be updating ACL policies and procedures, ACL's Directory of Services, and the Advocate Health EPIC Procedure Catalog to reflect these changes. Please ensure that your units, hospitals, and clinics have the appropriate collection devices in stock as specimens collected in ESwab™ collection devices and submitted for SARS-CoV-2 detection **will no longer be accepted beginning Monday, November 4, 2024**.

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL's website at https://www.acllaboratories.com/providers/test-directory/.

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Specimen Collection Devices for Rapid Respiratory Pathogen Panel

(Test Order Code LAB9039)

On Monday, May 6, 2024, the United States Food and Drug Administration (FDA) published a final rule, giving the FDA additional oversight over laboratory developed tests (LDTs). This rule adds significant additional oversight and cost for each test performed using testing platforms, collection devices, or specimen types that have not been formally approved for use by the FDA; even if the laboratory has done an extensive internal validation to demonstrate the accuracy of these methods or specimen types. This increased regulation and cost will require labs to scale back the number of LDTs they are able to perform to ***only*** those tests that are critical for patient care or that are performed in such high volume that the time commitment and cost associated with getting them formally approved for use by the FDA can be justified.

During the SARS-CoV-2 pandemic, due to supply shortages, ACL Laboratories performed an independent validation demonstrating that specimens collected in ESwab™ specimen collection devices were acceptable for use with the Rapid Respiratory Pathogen Panel. However, since these devices are not approved by the FDA for this test, their continued use will now be subject to additional regulation and cost. Because there are FDA approved devices readily accessible for this testing, ACL Laboratories will not pursue approval from the FDA to continue using ESwab™ collection devices with the Rapid Respiratory Pathogen Panel.

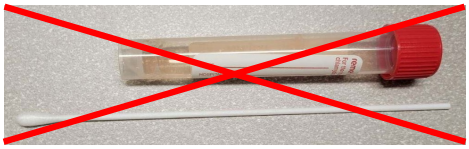
In addition, ACL Laboratories is seeing a significant number of swab specimens submitted with the standard sized tip, which cannot be used to appropriately collect a nasopharyngeal swab. The only swab specimens approved for use with this test by the FDA are mini-tipped (nasopharyngeal) swabs submitted in viral transport medium.

Beginning Monday, November 4, 2024, the following collection devices **will no longer be acceptable** for the Rapid Respiratory Pathogen Panel (Test Order Code LAB9039):

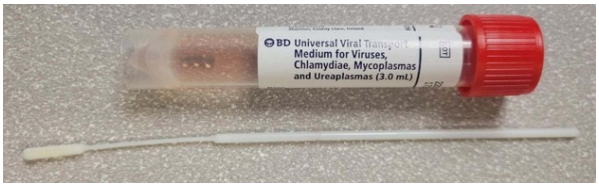
Workday # 1216307

Workday # 1216308

Workday # 1215785



The Universal Viral Transport Medium w/ mini-tip nasopharyngeal swab device (Workday # 1056987) **will be acceptable** for use with the Rapid Respiratory Pathogen Panel (Test Order Code LAB9039):



Over the course of the next few months, ACL Laboratories will be updating ACL policies and procedures, ACL's Directory of Services, and the Advocate Health EPIC Procedure Catalog to reflect these changes. Please ensure that your units, hospitals, and clinics have the appropriate collection devices in stock as swab specimens collected in ESwab™ collection devices and specimens submitted in viral transport medium with standard tipped swabs for the Rapid Respiratory Pathogen Panel **will no longer be accepted beginning Monday, November 4, 2024.**

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL's website at https://www.acllaboratories.com/providers/test-directory/**.**

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