ACL Laboratories
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Test Bulletin

October 2023

ACL Implements New Version of In-House Test for BCR/ABL (Test Order Code LAB9906)

Effective Tuesday, October 17, 2023, ACL Laboratories will implement new version of reagents for existing BCR/ABL Analysis, Quantitative, International Scale test (Test Order Codes LAB9906).

Clinical indication:

BCR/ABL assay is designed to detect target sequences of b2/e13-a2 or b3/e14-a2 BCR/ABL fusion transcripts of the p210 fusion gene (aka Philadelphia chromosome)

ACL's new version of in-house assay is based on reagents Xpert® BCR-ABL Ultra from Cepheid validated and approved by FDA. Internal verification and data comparison had shown equivalent performance between both ACL LDT and FDA assays. No re-baselining of current patients is required.

Test Method: This test is performed by RT-PCR

Specimen requirement:
- Blood: One pink EDTA 6.0 mL or two lavender EDTA 3.0 mL
- Bone marrow: not validated – will be sent out

Transport: Refrigerated

Performed: Weekdays

Performing Sites: Illinois Central Laboratory – Molecular Pathology

Reporting Time: Final within 5 days

Please note that this new methodology is only FDA approved on whole blood samples. Bone marrow specimens cannot be evaluated using this new method and will be referred to an external reference laboratory. Providers and clients who desire quantitative BCR/ABL analysis will need to order a Miscellaneous test with the following information:
- Test Name: Quantitative Detection of BCR-ABL1, Major Form
- Performing Lab: ARUP

ARUP requests 3.0 mL (min: 1.0 mL) bone marrow in EDTA. Specimen should be transported refrigerated. Due to the liability of RNA, specimen should be received by the performing lab within 48 hours. Results are expected within 10 days.

ACL is working to create an orderable test code for this sendout assay, which will negate the need for a Miscellaneous test process. Follow up communication will be provided when that is available to providers and clients.

If you have any questions, please contact:
ACL Molecular Pathology Department at ACL's Illinois Central Laboratory (ph. 847.349.7182), or
Michael Mihalov, MD - Medical Director (ph. 847.349.7401), or
Lech Mazur, MS – Technical Director (ph. 847.349.7185)

New Orderable Code for *Candida auris* Screen by PCR

Effective Tuesday, October 17, 2023, ACL Laboratories will offer *Candida auris* Screen by PCR (Test Order Code LAB11822) as an orderable test code. Testing will be performed at ACL's Illinois Central Laboratory.

Candida auris is an emerging drug resistant yeast that is rapidly spreading in many areas of the world, including the United States. *C. auris* has caused significant outbreaks in hospitals and nursing homes if patients with *C. auris* colonization or infection are not identified promptly and control measures put into place. Unlike other *Candida* species, *C. auris* can colonize skin and other environmental surfaces for a prolonged period of time (weeks to months).

The targeted population for this new assay is hospital inpatients and nursing home patients.

Refer to the table below for detailed assay information.

Test Information	*Candida auris* Screen by PCR (Test Order Code LAB11822)
Specimen Type	Axilla/groin
Collection Tube	White-capped eSwab.
Transport	Ambient
Stability	5 days
Methodology	Qualitative Real-time PCR
Reporting Time	Final within 3 days
Performing Lab	ACL Illinois Central Laboratory

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

ACL Implements New Version of In-House Test for FV Gene Mutation (Test Order Code LAB9925) and FII Genotype (Test Order Code LAB9953)

Effective Tuesday, October 17, 2023, ACL Laboratories will implement new version of reagents for existing Factor V Leiden Gene Mutation and Prothrombin Genotype. Test Order Codes LAB9925 and LAB9953. New method is using Cepheid FDA approved reagents and instrumentation.

Test Method: Real-time Polymerase Chain Reaction (PCR)

Preferred Specimen:
- One pink (K2EDTA) 6 mL **OR** One lavender (K2EDTA) 3 mL
- **For extenuating circumstances only:** One blue (sodium citrate) 2.7 mL

Transport: Refrigerated

Performed: Weekdays

Performing Sites: Illinois Central Laboratory – Molecular Pathology

Reporting Time: Final within 7 days

If you have any questions, please contact:
ACL Molecular Pathology Department at ACL's Illinois Central Laboratory (ph. 847.349.7182), or
Michael Mihalov, MD - Medical Director (ph. 847.349.7401), or
Lech Mazur, MS – Technical Director (ph. 847.349.7185)

New Panel Option for Chlamydia/Gonorrhea/*Trichomonas* by NAA

Effective Tuesday, October 17, 2023, Chlamydia/Gonorrhea and *Trichomonas vaginalis* by Nucleic Acid Amplification (NAA) can be ordered together as a panel (Test Order Code LAB11872). The new panel includes both Chlamydia/Gonorrhea by Nucleic Acid Amplification (Test Order Code LAB9913) and *Trichomonas vaginalis* by Nucleic Acid Amplification (Test Order Code LAB9964). Chlamydia/Gonorrhea and *Trichomonas vaginalis* will all be resulted on the same report. Test order codes are denoted below.

Test Order Code	Test Name	Test Components	Number of Test Results
LAB9913	Chlamydia/Gonorrhea by NAA	Chlamydia, Gonorrhea	2
LAB9964	*Trichomonas vaginalis* by NAA	*Trichomonas*	1
LAB11872	Chlamydia/Gonorrhea/*Trichomonas* by NAA	Chlamydia/Gonorrhea/*Trichomonas vaginalis*	3

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

Mycoplasma genitalium removed from SwabOne Vaginitis Panel by NAA

Since *Mycoplasma genitalium* was removed from the SwabOne Vaginitis Panel by NAA (Test Order Code LAB9961) on August 15, 2023, *Mycoplasma genitalium* orders have greatly decreased. SwabOne *Mycoplasma genitalium* by NAA (Test Order Code LAB9960) may still be ordered as a single test. SwabOne *Mycoplasma genitalium* by NAA can be run on specimen sources of endocervical and male urethral collected with an APTIMA Unisex Swab, Vaginal collected with an APTIMA Multi-Test Swab, or Urine collected in APTIMA Urine Specimen Collection Kit.

Note: Due to automation, testing sample volume is a limiting factor for multiple orders. If also ordering Chlamydia/Gonorrhea by NAA and *Trichomonas vaginalis* by NAA, it is highly recommended that two Aptima Swabs or Urine Collection Tubes are collected and submitted. Any Chlamydia and/or Gonorrhea test orders (Test Order Code LAB9913 Chlamydia/Gonorrhea, Test Order Code LAB9912 Chlamydia only, Test Order Code LAB9928 Gonorrhea only), *Trichomonas vaginalis* (Test Order Code LAB9964) or Chlamydia/Gonorrhea/Trichomonas by NAA (Test Order Code LAB11872), will take priority over any SwabOne testing.

Test Order Code	Test Name	Test Components	Number of Test Results
LAB9961	SwabOne Vaginitis Panel by NAA	Bacterial Vaginosis, *Candida* species, *Candida glabrata,* and *Trichomonas vaginalis*	4 Test Results
LAB9957	SwabOne Bacterial Vaginosis by NAA	Bacterial Vaginosis Panel *(Lactobacillus* species, *Gardnerella vaginalis, Atopobium vaginae)*	1 Test Result
LAB9958	SwabOne Candida/Trichomonas Panel by NAA	*Candida* Species (C. Spp), *Candida glabrata,* and *Trichomonas vaginalis*	3 Test Results
LAB9960	SwabOne *Mycoplasma genitalium* by NAA	*Mycoplasma Genitalium*	1 Test Result

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 acllaboratories.com/providers/test-directory.

ACL Laboratories Updates Respiratory Pathogen Panel Testing

Test intended for Inpatient Testing Only

Effective Thursday, October 19, 2023, ACL Laboratories will change the testing platforms for the Respiratory Pathogen Panel (Test Order Code LAB9955). The current Respiratory Pathogen Panel detects 19 different respiratory viruses (including subtypes) and three different bacterial pathogens. The new panel utilizes similar technology, detects similar pathogens, and has similar sensitivity and specificity as the current panel. As a result, updating this panel, testing is simpler to perform enabling a quicker turn-around on test results.

As with the previous version of the respiratory pathogen panel assay, the new version of the panel is only intended for use in the inpatient setting on patients who are negative for the presence of influenza, respiratory syncytial virus, and SARS-CoV-2.

For ambulatory and emergency room patients who have signs and symptoms of upper respiratory infection, ACL recommends testing only for the presence of influenza, respiratory syncytial virus, and SARS-CoV-2. Larger respiratory panels have limited clinical utility in the outpatient setting and are often not covered by insurance companies, leading to significant patient out of pocket expenses.

The changes between the current Respiratory Pathogen Panel and the new Panel are outlined below:

1) Test name and test order code change.
   a. **Current and will be discontinued effective Thursday, October 19, 2023:** — Respiratory Pathogen Panel (Test Order Code LAB9955)
   b. **Effective Thursday, October 19, 2023:** Rapid Respiratory Pathogen by PCR (Test Order Code LAB9039)
2) The test will no longer be performed by the Illinois Central Molecular Pathology Laboratory.
   a. **Effective Thursday, October 19, 2023:** Testing will take place within all Advocate Health Midwest Region Hospitals and within ACL's Illinois and Wisconsin Central Laboratories.
   b. The turnaround time of the test should decrease significantly with efforts being made to complete testing within 8 hours of receipt within the laboratory.
3) The composition of the panel will have the following changes:

Effective Thursday, October 19, 2023: The following results will be **eliminated** from the panel	**Effective Thursday, October 19, 2023:** The following results will be **included** in the panel
Human Bocavirus	SARS-CoV-2
Legionella pneumophila	*Bordetella pertussis*
Respiratory Syncytial Virus A and B will no longer be differentiated (both will still be detected)	*Bordetella parapertussis*

4) **Effective Thursday, October 19, 2023:** Testing for Legionella pneumophila will be referred to ACL's primary reference laboratory, ARUP Laboratories, using orderable test, "Legionella species by Qualitative PCR" (Test Order Code LAB11883).

The Respiratory Pathogen Panel (Test Order Code LAB9955) will be discontinued **effective Thursday, October 19, 2023,** and all orders for this test should be placed using Rapid Respiratory Pathogen by PCR (Test Order Code LAB9039).

Outpatient Providers should test for influenza, respiratory syncytial virus, and SARS-CoV-2 as appropriate based on clinical needs.

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

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