Test Bulletin

January 2023

Important Announcement Regarding Rubella Antibody IgM (LAB8551)

Effective Thursday, January 12, 2023, Rubella Antibody IgM (Test Order Code LAB8551) will be temporarily referred to ACL's primary reference lab partner, ARUP. As a result of manufacturing issues, ACL is unable to obtain quality control (QC) materials needed to verify the performance of Rubella Antibody IgM testing reagents and will not be able to perform testing in-house.

There is no change in specimen collection or handling for this test. Please note that the turn around time (TAT) will increase from 24 hours to 3 days. Also note the difference in reference range in the chart below. ACL is working with manuafacture to secure QC material as soon as possible and resume testing in-house. Updated communication will be provided once internal testing will resume.

Test Comparison		
	In-House Test	**Referral Laboratory Test**
Methodology	Chemiluminescence	Semi-Quantitative Chemiluminescent Immunoassay
Reference Range	< or = 0.80 Negative 0.81-0.99 Equivocal > or = 1.00 Positive	19.9 AU/mL or less: Not Detected. 20.0 - 24.9 AU/mL: Indeterminate - Repeat testing in 10-14 days may be helpful. 25.0 AU/mL or greater: Detected - IgM antibody to rubella detected, which may indicate a current or recent infection or immunization
Specimen Collection Details (specimen type, amount)	One 1.0 mL (Min: 0.5 mL) serum refrigerated	Serum
Transport Temperature	One 1.0 mL (Min: 0.5 mL) serum refrigerated	Temperature Refrigerated.
CPT Codes	86762	86762
Turnaround Time	24hrs	3days

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016

ACL Implements New Methodology for Cytomegalovirus Quantitation by PCR

Effective Wednesday, January 18, 2023, ACL Laboratories will implement a new methodology for CMV viral load testing (Test Order Code CMVQN / LAB8789) and CMV Qualitative detection (Test Order Code CMVQL / LAB9915). The Aptima CMV Quant assay is an in vitro nucleic acid amplification test that uses real-time transcription-mediated amplification (TMA) technology on the Hologic® Panther system. This assay has a reportable range of 53-10,000,000 IU/mL. The new assay and the Hologic® Panther instrument are FDA approved for plasma samples.

Based on an ACL Laboratories internal evaluation, we have demonstrated that viral loads measured on the current CMV viral load assay and the new assay are highly correlated. This change will have minimal clinical impact for transplant patients being monitored with this test and re-baselining patients is not necessary.

CMVQN (LAB8789): Transport One 3.0 mL (Min: 2.0 mL) plasma refrigerated. Separate Plasma from cells within 8 hours of collection.

CMVQL (LAB9915): Transport following acceptable sources refrigerated. Refer to ACL Laboratories Directory of Service (https://acllaboratories.com/providers/test-directory/) for additional specimen collection details.

- Neonatal urine, bronchoalveolar lavage (BAL), bronchial wash (BRWA), bronchial brushes
- Body fluids 2.0 mL in sterile tube
- Vitreous fluid 0.2 mL (min 0.1 mL) in sterile tube
- Amniotic fluid 0.2 mL (min 0.1 mL) in sterile tube

Note: Tissue specimen type will require miscellaneous order and testing will be performed by ARUP Laboratories.

Transport: Refrigerated

Reporting Time: 3 days

Performing Site: Illinois Central Laboratory – Molecular Pathology

For additional information, please contact:
ACL Laboratories Molecular Pathology Department at 847-349-7182,
Michael Mihalov, MD - Medical Director at 847-349-7401, or
Lech Mazur, MS - Technical Director at 847-349-7185

ACL Laboratories Discontinues Routine Silver Staining Component for Pneumocystis Exam (Test Order Code LAB9015)

Wisconsin Patients Only

Effective Wednesday, February 1, 2023, ACL Laboratories will no longer routinely perform a silver stain when the "*Pneumocystis* Exam (PCP/P. *jiroveci (carinii*))" (Test Order Code LAB9015) is ordered.

Currently, when Test Order Code LAB9015 is ordered, specimens from Wisconsin patients are stained with both a direct fluorescent antibody (DFA) stain and a silver stain. Specimens from Illinois patients are already only stained using the DFA stain. In an effort to standardize testing across all ACL sites and to reduce redundant testing, ACL Laboratories will discontinue routine silver stain testing when Test Order Code LAB9015 is ordered for Wisconsin patients. The silver stain may still occasionally be performed and reported for specimens in which the DFA result is difficult to interpret, but these cases are expected to be rare.

A review of data from 2021 showed that of the 654 patient specimens submitted for *Pneumocystis* exam testing in Wisconsin, the results of the DFA and the silver stain were in agreement in 99.5% of the cases. For those cases in which there was disagreement, the DFA stain demonstrated greater sensitivity, which is also commonly reported in published studies.

Please contact ACL Laboratories Client Services Department at 800-877-7016 with any questions regarding this change.

ACL Laboratories Offers Tick-Borne Disease Panel by PCR, Blood and Babesia Species by PCR

Effective Wednesday, January 18, 2023, ACL Laboratories will offer the Tick-Borne Disease Panel by PCR, Blood (Test Order Code LAB11411) and Babesia Species by PCR (Test Order Code LAB11412) in order to provide comprehensive tick-borne disease testing. Providers will no longer need to utilize a Miscellaneous test ordering process. Details for the new orderable test codes are below.

Specimen Requirements	Tick-Borne Disease Panel by PCR, Blood Test Order Code LAB11411	Babesia Species by PCR Test Order Code LAB11412
Collection Tube	Lavender (EDTA) or Pink (K2EDTA)	Lavender (EDTA) or Pink (K2EDTA)
Specimen Type	Whole Blood	Whole Blood
Volume	1.0 mL	1.0 mL
Temperature	Refrigerated	Refrigerated
Stability	1 week	1 week
TAT	5 days	5 days
Performing Lab	ARUP	ARUP
Additional Information	Panel for diagnosing possible tick-borne disease (Anaplasmosis, Ehrlichiosis, or Babesiosis) during the acute phase of the disease	This test detects and speciates *B. microti*. The nucleic acid from *B. duncani, B. divergens,* strain MO-1, and strain EU-1 will be detected by this test but cannot be differentiated.

Please contact ACL Laboratories Referral testing for additional information at 847-349-7382.