

ACL Laboratories Introduces New Testing Menu – SwabOne™ – for Detection of Bacterial Vaginosis and Vaginitis

Effective Wednesday, November 15, 2017, ACL Laboratories will introduce a new vaginal pathogens testing menu called SwabOne™. These panels provide an opportunity to improve patient care with earlier and more accurate diagnosis of bacterial vaginosis with molecular diagnostic testing, detecting up to 11 pathogens in one sample. The following test order codes will be implemented.

ACL Test Order Code	Bacterial	Candida	Mycoplasma/ Ureaplasma	Trichomonas
SWOPNL SwabOne™ Vaginitis Panel	<i>Atopobium vaginae</i> BVAB2 <i>Megasphaera 1</i>	<i>Candida spp.</i> <i>C. glabrata</i> <i>C. krusei</i>		<i>T. vaginalis</i>
SWOEXT SwabOne™ Extended Vaginitis Panel	<i>Atopobium vaginae</i> BVAB2 <i>Megasphaera 1</i>	<i>Candida spp.</i> <i>C. glabrata</i> <i>C. krusei</i>	<i>M. hominis/</i> <i>genitalium</i> <i>U. urealyticum/</i> <i>parvum</i>	<i>T. vaginalis</i>
SWOBV SwabOne™ Bacterial Vaginosis Panel	<i>Atopobium vaginae</i> BVAB2 <i>Megasphaera 1</i>			
SWOCN SwabOne™ Candida Panel		<i>Candida spp.</i> <i>C. glabrata</i> <i>C. krusei</i>		
SWOMU SwabOne™ Mycoplasma Ureaplasma Panel			<i>M. hominis/</i> <i>genitalium</i> <i>U. urealyticum/</i> <i>parvum</i>	

ACL Laboratories SwabOne™ testing menu was validated by ACL against BD MAX™ Vaginal Panel (FDA approved panel). This assay is validated on vaginal, vaginal fluid, and cervical specimens collected in Universal Transport Medium (UTM), ThinPrep or ESwab and is designed for detection of vaginitis and bacterial vaginosis.

The new assay is designed to detect the most common vaginal pathogens, including:

- Bacteria: *Atopobium vaginae*, BV-associated bacteria 2 (BVAB2), *Megasphaera 1*
- Yeast: *Candida spp* (albicans), *Candida glabrata*, *Candida krusei*
- *Trichomonas vaginalis*
- Mycoplasma/Ureaplasma: *M. hominis*, *M. genitalium*, *U. parvum*, *U. urealytica*

SwabOne™ tests menu will replace Mycoplasma genitalium by PCR (Test Order Code MYGPCR).

For additional information regarding SwabOne™, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.

Transport Temperature Changes for Cytomegalovirus Antibody Testing

Effective Wednesday, November 15, 2017, only frozen samples will be accepted as the transport temperature for the Cytomegalovirus antibody testing (Test Order Codes CMVRAY, CMVGAB, CMVMAB). Refrigerated samples, previously acceptable for three (3) days, **will no longer be acceptable beginning November 15, 2017**. This change is being made to ensure sample optimum stability for initial and reflexive testing.

The following tests will be affected by this change:

- Cytomegalovirus Antibody IGG & IGM w/Reflex (Test Order Code CMVRAY)
- Cytomegalovirus Antibody, IGG (Test Order Code CMVGAB)
- Cytomegalovirus Antibody, IGM (Test Order Code CMVMAB)

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 www.acllaboratories.com/test-catalog/.

FibroMeter Liver Fibrosis Test Update

Effective immediately, ACL Laboratories will be unable to offer the FibroSPECT test (Test Order Code FSPECT) as the reference laboratory has discontinued this testing.

The FibroMeter Liver Fibrosis test, performed by ARUP Laboratories (ARUP Test Order 2005661), is a suitable replacement test. This test, however, is currently not available as an orderable test and will need to be ordered as a Miscellaneous Test until an orderable code is made available in the near future.

FibroMeter is a blood test used to aid in the evaluation and management of liver fibrosis. This is a non-invasive test that evaluates the level of fibrosis in the liver using algorithms based on several blood biomarkers and patient demographic information. The calculated scores include the following:

- Fibrosis score (FibroMeter)
- Cirrhosis score (CirrhoMeter)
- Necroinflammatory activity score (InflaMeter)

The corresponding Metavir Classification scores are also reported:

- FO – F4 for fibrosis/cirrhosis
- AO – A3 for activity grade

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 www.acllaboratories.com/test-catalog/.

Low Alkaline Phosphatase Results

Effective Wednesday, November 15, 2017, the following comment will be appended to all results that are below the reference interval, *"Low Alkaline Phosphatase results may indicate hypophosphatasia, malnutrition, hypothyroidism or other disease states. Please correlate with clinical symptoms"*. ACL Laboratories has already established sex and age-specific reference ranges in order to alert providers of the significance of low levels of alkaline phosphatase.

Elevated Alkaline Phosphatase levels are associated with several well defined clinical disorders; however, decreased levels are often overlooked as not being significant. The impact of low alkaline phosphatase levels can be significant, particularly in the pediatric population. A decreased alkaline phosphatase level is a biochemical hallmark of hypophosphatasia (HPP), a life-threatening, inherited, metabolic disorder caused by loss of the gene that codes for the enzyme. The rapid diagnosis based on decreased levels allows for further investigation and treatment intervention of this debilitating disease.

For additional information, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.