

MOLECULAR - HERPES SIMPLEX VIRUS (HSV) TYPE 1&2 TESTING **NEW SPECIMEN REQUIREMENTS

Effective November 1, 2017, Herpes Simplex Virus (HSV) Type 1&2 testing will be performed on the Luminex ARIES[®] System. The ARIES[®] System is capable of automated nucleic acid extraction and purification, real-time PCR detection of nucleic acid sequences, and data analysis. The ARIES[®] HSV 1&2 Assay detects and differentiates HSV 1 and HSV 2 DNA sequences using thermal melt (T_m) analysis.

The ARIES[®] HSV 1&2 Assay (#2040) will replace Herpes Simplex Virus (HSV) Culture with Typing 1 and 2 (Test #1040), currently being performed in Microbiology.

****PLEASE NOTE THE SPECIMEN REQUIREMENT CHANGE LISTED BELOW: UNIVERSAL TRANSPORT MEDIA IS NOW REQUIRED****

HSV 1 and 2 are common human pathogens that cause infections in neonates, children, and adults worldwide. Combined, HSV infections affect 40 million people in the United States and cause 600,000 new infections every year (Nadelman and Newcomer 2000). Following primary infection, these viruses can establish latency in the dorsal root ganglia of the infected host, and can cause re-occurring lesions when the virus travels through nerve cells to either oral or genital sites. HSV 1 is generally associated with infection in the tongue, mouth, lips, pharynx, and eyes, whereas HSV 2 is primarily associated with genital and neonate infection.

Viral isolation, direct or indirect fluorescent antibody testing, in situ hybridization, and serology can be used to diagnose HSV infections. However, due to length of culture time, sample transport difficulties, procedural complexity, and lack of desirable sensitivity, nucleic acid amplification methods such as PCR are often preferred as the diagnostic test method (Filén, Strand et al. 2004 and Slomka 2000).

Unique features of the Luminex ARIES[®] HSV assay include:

- **High Sensitivity** - Diagnose more patients, reduce time to treatment.
- **High Accuracy** - Confidence in results gives patients and clinicians peace of mind, and helps ensure correct treatment.
- **FDA-approved**
- **Aligned with Screening Guidelines**
- **Integrated Sample Processing Control** - Ensures the assay run is successful from extraction through amplification.
- **Full Integration** - Automates all aspects of testing, from sample preparation through analysis.

Test # Test Name

2040 HSV (Herpes Simplex Virus) 1&2 Assay by PCR – Performed In-House CPT 87529 X2

Acceptable Sources:

Cutaneous and Mucocutaneous Lesions

Acceptable Specimen Types:

Universal Viral Transport Media with Sterile Swab Applicators

Specimen Stability:

Refrigerated 7 days.



Reference: Luminex ARIES[®] HSV Assay Package Insert - www.luminex.com

Test #7692 – Herpes Simplex Virus (HSV) Qualitative by PCR (Discontinued effective 10/31/2017)

Please order the following HSV test for fluid samples ~

Test # Test Name

7525 HSV (Herpes Simplex Virus) 1&2 by RT-PCR (Fluid Samples)
Performed by ARUP Laboratories – CPT Code 87529

Acceptable Sources:

CSF, bronchoalveolar lavage (BAL), amniotic fluid, vesicle fluid, ocular fluid, Lavender (EDTA), pink (K₂EDTA), or serum separator tube, tissue **OR** Endocervical specimen in ThinPrep Pap Test media.

Testing of serum or plasma samples is only recommended for newborns (<30days), immunocompromised patients, or when viremia is suspected.

Acceptable Specimen Types:

Separate Serum or Plasma from cells. Transfer 1 mL Serum, Plasma, CSF, BAL, Amniotic Fluid, Ocular Fluid or ThinPrep specimen to a sterile container and freeze.

Tissue: Transfer to a sterile container and freeze immediately. Specimen stability: Frozen 3 months.

Vesicle fluid: Transfer to universal viral transport media and freeze. Specimen stability: Frozen 3 months.

MOLECULAR – GROUP B STREPTOCOCCUS (GBS) TESTING

Effective November 1, 2017 Group B Streptococcus (GBS) testing will be performed on the Luminex Aries System. The ARIES[®] GBS Assay is a real-time polymerase chain reaction (RT-PCR) based qualitative in vitro diagnostic test. It is designed to detect Group B Streptococcus (GBS) nucleic acid from 18-24 hour Lim broth enrichments of vaginal-rectal swab specimens obtained from pregnant women.

The ARIES[®] GBS Assay does NOT provide susceptibility results. Culture isolates will still be needed for performing susceptibility testing as recommended for penicillin-allergic women.

Infection with Group B Streptococcus (GBS) is the leading infectious cause of neonatal morbidity and mortality, causing meningitis, pneumonia, and septicemia in newborns and their mothers. Women vaginally or rectal colonized with GBS during pregnancy are at increased risk of transmitting the bacteria to their newborn infant during child birth. Vaginal GBS colonization has been reported to occur in about 12% to 27% of women worldwide (WHO 2006).

In current CDC guidelines, the use of a combination of screening at 35 to 37 weeks of gestation and intrapartum antibiotic prophylaxis have yielded significant reductions in the rate of GBS disease among newborns, but the rates of maternal GBS colonization have remained constant for over four decades (Verani, et al 2010). Although laboratory testing with culture media, which typically requires up to three days with long incubations and sub-culture remains the gold standard, polymerase chain reaction (PCR) based nucleic acid amplification tests (NAAT) are being established to enable fast turn-around time and improved accuracy for detection of GBS (Goodrich and Miller 2007 and Davies, et al., 2004).

Unique features of the Luminex ARIES[®] GBS assay include:

- **High Sensitivity** - Aid in the diagnosis of more patients, using PCR to improve patient outcomes.
- **High Accuracy** - Confidence in results gives patients and clinicians peace of mind, and helps ensure correct treatment.
- **FDA-approved**
- **Integrated Sample Processing Control** - Ensures the assay run is successful from extraction through amplification.
- **Full Integration** - Automates all aspects of testing, from sample preparation through analysis.

Test # Test Name

1614 GBS (Group B Streptococcus) Assay by PCR CPT 87653

Acceptable (FDA approved) Source:

Vaginal/Rectal

Acceptable Specimen Types:

E-Swab (Amies Media)

Specimen Stability:

Room temperature 3 days.

Reference: Luminex ARIES[®] GBS Assay Package Insert - www.luminex.com



MICROBIOLOGY – GROUP B STREPTOCOCCUS (GBS) SUSCEPTIBILITY TESTING

Penicillin remains the drug of choice for prophylaxis of pregnant women colonized with GBS. Positive Group B Streptococcus (GBS) reflex susceptibility testing will occur when penicillin allergy is indicated on the GBS (Group B Streptococcus) Assay by PCR requisition. Currently, susceptibility testing for penicillin and vancomycin are not considered necessary since penicillin non-susceptible GBS isolates are extremely rare. Only 2 known vancomycin non-susceptible isolates have been reported in the literature. Per recommended guidelines, clindamycin will be the only drug reported along with the following comment:

“Current CDC and ACOG guidelines state that in the event penicillin cannot be used for treatment, patients with low-risk for anaphylaxis should be treated with cefazolin. Resistance to clindamycin (including inducible) is provided in the event that the patient is high-risk for anaphylaxis. If clindamycin cannot be used due to resistance or patient allergies, vancomycin is recommended. “

Stability and Storage:

GBS (Group B Streptococcus) PCR samples will be held for 7 days post-testing.

If penicillin allergy information was originally submitted as “unknown” and further testing is indicated, contact Client Services to request add-on susceptibility testing.

MICROBIOLOGY – OCCULT BLOOD TEST METHOD CHANGE.

Effective December 1, 2017 Fecal Occult Blood testing will be performed utilizing the Hemosure® One Step Immunological Fecal Occult Blood Test (iFOB). Hemosure® iFOB is a rapid, immunochemical test for the qualitative determination of Fecal Occult Blood.

Hemosure® iFOB detects lower levels of fecal occult blood than the standard guaiac tests by employing an immunospecific, sandwich assay that is not affected by dietary peroxidases, animal blood, or ascorbic acid.

Test # Test Name

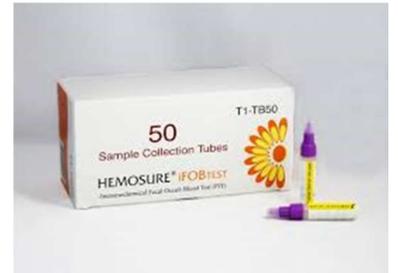
| | | |
|------|---------------------------|--------------------------------|
| 2620 | Occult blood (Diagnostic) | CPT 82274 |
| 620 | Occult blood (Screening) | CPT 82274 (Medicare CPT G0328) |

Acceptable Specimen Types:

Fecal sample in Hemosure® iFOB sample collection tube (preferred)

-or- Fecal sample in clean container within 24 hours of collection

Specimen Stability: Room temperature 6 days.



MICROBIOLOGY – ENVIRONMENTAL CULTURE #617 DISCONTINUED.

The Microbiology department will no longer be performing environmental cultures (including water cultures) as of November 1st, 2017. Spore strip (autoclave/sterilizer testing) test #616 will still be offered.

HEMATOLOGY – CLIENT PIPETTE CALIBRATIONS

Effective November 1, 2017 pipette calibrations for clients will be raised from \$12 to \$20 per pipette. Please remember when submitting pipettes for calibration to also include the appropriate pipette tips. Please contact Kay Japp (Hematology and Molecular Supervisor) with any questions.

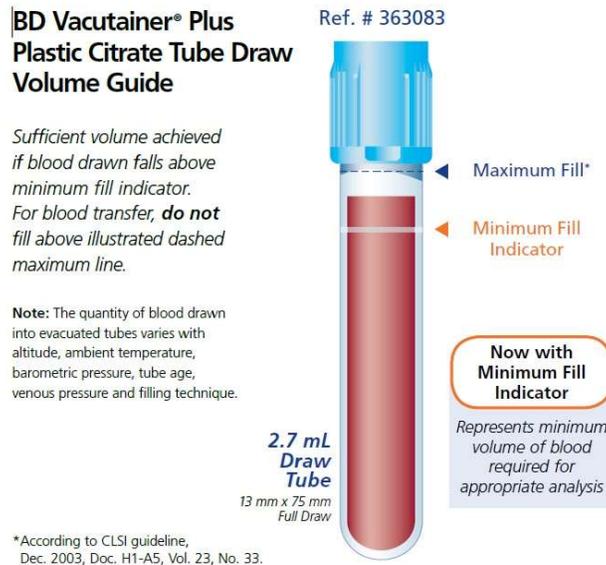
HEMATOLOGY – SEMEN ANALYSIS

Effective November 1, 2017 the reference limit for Normal Spermatozoa on the Semen Analysis report will be updated from >14% (Strict Kruger) to >3% (WHO 5th Edition). This will reflect the most current normal spermatozoa morphology reference limit utilized by the World Health Organization (WHO- 5th Edition). Reference limits and thresholds of 3-5% normal spermatozoa have been found in studies of in-vitro fertilization (Coetzee et al., 1998), intrauterine insemination (Van Waart et al., 2001) and in-vivo fertilization (Van der Merwe et al., 2005). Please note that test results below the reference limit are not an absolute indication of decreased fertility or infertility.

Reference: The World Health Organization Laboratory Manual for the Examination and Processing of Human Semen. Fifth edition. Cambridge University Press, 2010

HEMATOLOGY – PT, PTT, D-DIMER COLLECTION, STORAGE, AND STABILITY REMINDERS

Light blue top tubes must be filled completely in order to ensure accurate results. Sufficient volume is achieved if the blood drawn falls between the minimum and maximum fill line on the tube. If transferring blood from a syringe do not fill the tube above the illustrated dashed maximum line in the picture below. It is recommended a discard tube be used to establish blood flow prior to filling the light blue tube. Specimens that are not filled to the line on the tube or are overfilled will be cancelled.



After blood collection, there is progressive degradation of the labile coagulation factors V and VIII, leading to increased prolongation of the aPTT and PT. The allowable time interval between specimen collection and sample testing depends on the temperature encountered during transport and storage of the specimen. Allowable time intervals are as follows:

1. PT specimens, uncentrifuged, centrifuged with plasma remaining in the tube above the packed red cells, or as centrifuged plasma separated from the cells, should be kept at room temperature (18 to 24°C) and tested no longer than 24 hours from the time of specimen collection. **PT specimens should not be refrigerated during storage or transport.**
2. aPTT specimens that are uncentrifuged with plasma remaining in the tube with the packed red cells should be kept at room temperature (18 to 24°C) and tested no longer than 4 hours after the time of specimen collection.
3. aPTT specimens that are centrifuged and plasma separated from the cells should be kept 4 hours at room temperature (18 to 24°C) and tested no longer than 4 hours after the time of specimen collection.
4. If PT or aPTT testing cannot be performed within these times, platelet-poor plasma should be removed from the cells and frozen at -20°C for up to 2 weeks.
5. D-Dimer specimens are stable 4 hours refrigerated and stable indefinitely if frozen. If testing cannot be performed within 4 hours, platelet-poor plasma should be removed from the cells and frozen at -20°C.

Specimens that exceed the appropriate stability requirements and/or are stored incorrectly will be canceled.

Reference:

BD Vacutainer Plus Plastic Citrate Tube Draw Volume Guide. Ref #363083. <http://education.bd.com/images/view.aspx?productId=1544>
College of American Pathologists. Survey Coagulation, Limited CGL-A 2016.