

NOTIFICATION DATE: 9/16/2013

EFFECTIVE DATE: 9/26/2013

Herpes Simplex Virus (HSV) 1 and 2 Detection and Typing by Qualitative PCR

TEST CODE: HSVQL

INTERFACE CODE: 1004215

METHODOLOGY: Qualitative Real-Time Polymerase Chain Reaction (PCR)

CLINICAL UTILITY: Herpes simplex virus (HSV) infections can cause both systemic and localized infections including skin, lips, oral cavity, eyes, genital tract, and central nervous system (CNS). HSV PCR testing aids in detection and typing of HSV 1 and 2 for rapid diagnosis. HSV PCR is analytically more sensitive than culture and is **standard of care** for diagnosis of neonatal encephalitis (primarily caused by HSV 1) or meningitis (primarily caused by HSV 2). HSV PCR testing in blood, serum, or plasma specimen has clinical utility for **only** potential cases of disseminated HSV infection, such as in neonates or immunosuppressed individuals. Testing from these sources does not support the diagnosis of mucosal or CNS infections.

PERFORMED: Monday-Saturday

COLLECTION: CSF (Cerebrospinal Fluid); Body Fluids (Amniotic Fluid, Ocular Fluid); Urine (<1 month old); Blood and Bone Marrow in a lavender top EDTA tube; Upper respiratory specimens (nasal/throat specimens using polyester-tipped, Dacron or rayon-tipped collection swabs with plastic shafts) in M4 or M5 Viral Transport Media; Lower respiratory specimens (BAL, bronchial washings, tracheal secretions) in M4 or M5 Viral Transport Media, Dry swab for dermal sore/lesion, Tissue, or gynecological specimens (See below).

Specimen preparation:

Submit 1 mL CSF (Min. 0.5 mL), Body Fluid (Min. 2 mL), Urine (Min. 2 mL) in a sterile plastic screw capped container or tube. Submit 5 mL Blood (Min. 1 mL) and 2 mL Bone Marrow (Min. 0.5 mL). Submit respiratory specimens in M4 or M5 transport. Do not centrifuge any specimen type. Submit Fresh and Frozen Tissue in sterile container. Fresh tissue must be put in RPMI media. Frozen tissue must be in OCT compound. Submit Paraffin embedded Tissue in sterile biohazard plastic bag. Submit slides in slide holder.

Gynecological Specimens: Vaginal swab should be submitted using APTIMA[®] Vaginal Swab Collection Kit. Pap specimen may also be submitted in cytology (Pap) vials: Cytc ThinPrep vial or SurePath vial.

Instructions for collection:

Vaginal Specimens (Clinician Collected): APTIMA[®] Vaginal Swab Collection Kit

1. Collect vaginal fluid sample using the Gen-Probe APTIMA[®] vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid.
2. Immediately place the swab into the transport tube and carefully break the swab shaft against the

- Tightly screw on the cap.

Cytology (Pap) vials:

- Obtain cervical scrapings using either ThinPrep or SurePath fixative according to the Pap smear collection guidelines.

Gynecological Specimen Preparation: Refer to specimen collection comment for vaginal specimen submission in Aptima transport tube. Pap (cytology) should be submitted in Cytc ThinPrep vial or SurePath vial, or pre-aliquoted 1mL of either ThinPrep or SurePath liquid cytology media in an APTIMA[®] Specimen Transfer kit tube (green tube).

STABILITY (FROM COLLECTION TO INITIATION OF TESTING)

- Specimen in viral transport media (M4 or M5), CSF, body fluids and urine: Ambient: 8 hours; Refrigerated: 5 days; Frozen: 1 month
- Blood and Bone Marrow: Ambient: 8 hours; Refrigerated: 5 days; Frozen: Unacceptable
- Paraffin embedded tissue: Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
- Dry swab or Fresh tissue: Refrigerated: 24 hours; Frozen: 3 months
- Gynecological Specimens:**
 Swab specimens: 2°C to 30°C for 7 days
 Pap (cytology): 2°C to 30°C for 7 days
 Frozen: 30 days

TRANSPORT:

Bone Marrow, CSF, Body Fluid, Urine, Specimen in M4 or M5, or Fresh Tissue: Refrigerated
 Frozen Tissue: Frozen
 Paraffin embedded Tissue: Ambient or on ice pack in summer
 Gynecological Specimens or Slides: Ambient

REFERENCE RANGE:

Target Not Detected (TND)

RESULTS REPORTED:

1-3 days

CPT CODE:

87529 (X 2)

PERFORMING LAB:

med fusion

The new HSV 1 and 2 detection and typing assay will replace our current laboratory developed HSV assay. The following codes will be deactivated effective September 26, 2013:

Test Code	Test Name	Interface Code
HSVMOL	Herpes Simplex Virus (HSV), Quantitative by PCR	1002504
HSVPCR	Herpes Simplex Virus PCR, Blood	1000504
HSVNB	Herpes Simplex Virus PCR, Non Blood	1000498

ORDER/CONTACT INFORMATION: ClearPoint Client Services: 972-966-7700 | Fax: 972-966-7799