Lab Dept: Microbiology/Virology

Test Name: HERPES SIMPLEX VIRUS (HSV) PCR

General Information

Lab Order Codes:	HSVPP
Synonyms:	Herpes Simplex Virus (HSV) DNA Detection by Polymerase Chain Reaction (PCR), HSV Detection by Real-Time PCR
CPT Codes:	87529 – Infectious agent detection by nucleic acid (DNA or RNA): Herpes Simplex Virus amplified probe technique
Test Includes:	Real-Time Polymerase Chain Reaction detection of Herpes Simplex Virus reported as negative or positive for type 1 DNA or type 2 DNA.

Logistics

Test Indications:	Useful for rapid qualitative detection of HSV DNA.
Lab Testing Sections:	Molecular Diagnostics
Phone Numbers:	MIN Lab: 612-813-6280 Molecular Lab: 612-813-7103
Test Availability:	Daily, 24 hours
Turnaround Time:	1 day
Special Instructions:	Requisition must state specific collection source and date/time of collection

Specimen

Specimen Type:	●Cutaneous or Mucocutaneous ●Neonate surface swabs (≤60 days of age) ●Cerebrospinal fluid (CSF) ●EDTA Whole Blood

Container:	Swabs: Regular flocked swab in 3 mL Universal Transport Media (BD Universal Transport Systems) CSF: Sterile, plastic leak proof container Blood: Lavender top (EDTA) tube
Volume:	**CSF**: 500 mcL (Minimum: 300 mcL) **Blood**: 500 mcL (Minimum: 300 mcL)
Collection:	**CSF**: Aseptic technique or puncture **Swabs:** ● Lesions: Collected at the base of herpetic cutaneous and mucocutaneous lesions and broken into UTM ● Neonatal surface swabs: Using a single swab swab conjunctivae, mouth, nasopharynx, and rectum. Break the swab into UTM and transport to the laboratory immediately. A separate swab for the rectum can be used if necessary. **Blood:** Routine blood collection or aseptic collection. Gently invert EDTA tube to mix.
Storage/Transport:	Transport to the Laboratory immediately to maintain specimen integrity. Specimens can be stored at refrigerated temperature (2 – 8º C) for up to 7 day before processing.
Special Processing:	Lab Staff: : Specimen must be processed in a clean environment in which contamination of the specimen by HSV DNA is not likely. Specimen should be refrigerated in a screw-capped, sterile vial or original collection container based on specimen type. Do not centrifuge blood. Maintain sterility and forward promptly. Specimen stability: Refrigerated: 7 days (preferred) Frozen: 7 days
Sample Rejection:	Improperly labeled or unlabeled specimen. If an unacceptable specimen is received, the physician or nursing station will be notified and another specimen will be requested before the specimen is discarded. Calcium alginate swabs, other body fluids, any other swabs, blood collected in anything but an EDTA tube

Interpretive

Reference Range:	Negative Positive results are reported as herpes simplex type 1 (or 2) DNA detected.

Note: Detection of HSV DNA in clinical specimens supports the clinical diagnosis of infection due to the virus.		
Note: the Limit of Detection for HSV 1 and 2 varies with deviations in strain and specimen type		
	HSV1 LOD	**HSV2 LOD**
Cutaneous and Mucocutanerous Swabs	4 – 160 $TCID_{50}$/mL	2 – 10 $TCID_{50}$/mL
CSF	5 – 40 $TCID_{50}$/mL	1.25 – 20 $TCID_{50}$/mL
EDTA Blood	30 $TCID_{50}$/mL	20 $TCID_{50}$/mL

Significant Finding:

HSV 1 or 2 Positive in CSF

HSV 1 or 2 Positive in Blood

HSV 1 or 2 from NICU

HSV 1 or 2 Positive in Eye

Limitations:

● For in vitro diagnostic use.

● For Export Only.

● Results from this test must be considered in conjunction with the clinical history, epidemiological data and other laboratory information available to the clinician evaluating the patient.

● The detection of viral nucleic acid is dependent upon proper sample collection, transport, handling and storage. Failure to observe proper procedures in any one of these steps can lead to incorrect results.

● The prevalence of viral infections may affect the test's predictive value.

● Negative results do not rule out HSV infections of the CNS and should not be used as the sole basis for treatment or other patient management decisions.

● False-negative results may occur if the viruses are present at a level that is below the analytical sensitivity of the assay or if the virus has genomic mutations, insertions, deletions, or rearrangements or if performed very early in the course of illness.

●For encephalitis patients with a negative herpes simplex PCR result, consideration should be given to repeating the test 3–7 days later for patients demonstrating a compatible clinical syndrome or temporal lobe localization on neuroimaging.

●As with other tests, false-positive results may occur. Repeat testing or testing with a different device may be indicated in some settings.

● A positive result by this test cannot rule out infections caused by other viral or bacterial pathogens. Viral nucleic acids may persist in vivo independent of virus viability. Detection of target analyte(s) does not imply that the corresponding viruses are infectious or are the causative agent for clinical symptoms.

● When very high levels of HSV-1 are present with very low levels of HSV-2, the signal from the HSV-2 reaction may not be adequate to be detected, due to competitive interference.

● The prevalence of viral infections may affect the test's predictive value.

● This test is a qualitative test and does not provide the quantitative value of detected virus present.

● The performance of this test has not been established for screening of blood or blood products for the presence of HSV or for use with samples other than CSF or genital swabs.

● The performance of this test has not been established for immunocompromised individuals.

● The performance of this test has not been established for monitoring treatment of HSV infection of the CNS.

Methodology: Real-Time Polymerase Chain Reaction

References:

Simplexa HSV 1&2 Direct Package Insert. Rev. 04 ed. Cypress, CA: Diasorin Molecular 2018. p1-35

CLSI. Collection, Transport, Preparation and Storage of Specimens for Molecular Methods. 2005; CLSI document MM13-A, Wayne, PA

Andrea J. Linscott, Section editor (2010) Specimen Collection, Transport, and Acceptability, 2.1. In Lynne S. Garcia (ed) Clinical Microbiology Procedures Handbook, Third edition 2010, American Society for Microbiology, Washington, D.C.

J. Michael Miller (1999) A guide to Specimen Management in Clinical Microbiology, 1999, ASM Press, 1325 Massachusetts Ave NW, Washington, DC

Updates: 6/6/2019: Updated Significant Findings and Specimen Types for Neonates.