ClearPoint DIAGNOSTIC LABORATORIES

At the ConVergence Center | 2501 South State Highway 121 Business | Suite 1200
Lewisville, TX 75067-8188 |Phone: 972.966.7700 | Fax: 972.966.7799
www.clearpointlabs.com

LAB ALERT – NEW TEST

NOTIFICATION DATE: 1/8/2014
EFFECTIVE DATE: 1/21/2014

Varicella-Zoster Virus (VZV) Viral load by PCR, Blood

NEW TEST CODE: VZVQT

INTERFACE CODE: 1004389

OLD TEST / INTERFACE CODES TO BE DEACTIVATED: VZVPCR/1001006
VZVMOL/1002634

METHODOLOGY: Qiagen ASR Quantitative Real-Time PCR

CLINICAL UTILITY: Varicella-Zoster Virus (VZV) is a member of the Herpesviridae family that causes varicella (chickenpox) as primary infection and herpes zoster (shingles) upon reactivation. Chickenpox is a childhood infection presented as generalized vesicular rash on the dermis in normal children, usually before 10 years of age. After primary infection, the virus persists in latent form in the dorsal ganglion and may retrograde in elderly or immunocompromised host to cause shingles that presents as a unilateral vesicular eruption, generally in a dermatomal distribution. VZV infection in immunocompromised individuals often leads to a progressive disease state involving multiple organs. In allogeneic bone-marrow transplant recipients, VZV reactivation occurs in 20–50% of the cases within the first year after transplantation and prompt therapy with antiviral agents can reduce the risk of dissemination or postherpetic neuralgia. Of these, 15% may develop cutaneous dissemination and 5% may develop visceral dissemination. Detection of VZV DNA in plasma can facilitate the early recognition of complicated VZV-infection and therapeutic management of VZV-infections following transplant.

Please note that there are no changes in the collection, transport and storage conditions of the specimens. This change DOES NOT affect the sharing of specimens for other tests.

PERFORMED:	Monday-Wednesday-Friday
COLLECTION:	5 ml (Min. 1 mL) of Peripheral Blood in Lavender top EDTA tube
SPECIMEN PREPARATION:	Do not centrifuge.
STABILITY (FROM COLLECTION TO INITIATION OF TESTING):	Ambient: 8 hours; Refrigerated: 5 days, Frozen: Unacceptable
TRANSPORT:	Refrigerated
REFERENCE RANGE:	Target Not Detected (TND)
RESULTS REPORTED:	100 to 1,000,000 copies/mL ($\log_{10}$ 2.00 to $\log_{10}$ 6.00 copies/mL)
GENERAL INFORMATION:	The analytical measurement range of the new test is 100 to 1,000,000 copies/mL ($\log_{10}$ 2.00 to $\log_{10}$ 6.00 copies/mL). The range of the current VZV quantitative assay is 250 to 1,000,000 copies/mL. Our data on extensive analytical verification shows a good linear correlation between the current assay and the new assay. However, please note that: • The results of the new and old test may NOT be directly comparable. This is especially true at a very low and very high viral load which is expected to have maximum variance. • The results will be reported in copies/mL and $\log_{10}$ copies/mL on the new assay. The log values more closely represent the biological and laboratory processes since each iteration of a RT-PCR process has a multiplicative effect. *In order to provide the best quality care to our patients who are being monitored using the current VZV viral load assay, we will offer testing by both the new and the old assay for a period of 6 weeks after implementation. A positive VZV viral load result (Plasma only) on the new assay will be reflexed to be tested by the old laboratory developed assay at no charge (positives will be batched and tested once a week). This will allow physicians to re-baseline the viral load if necessary. The parallel testing will only be*

performed the first time the patient is tested on the new assay. No additional specimen collection required for the reflex testing. If you require the results of parallel testing, please call the lab at 972-966-7167.

CPT CODE(S): 87799

PERFORMING LAB: med fusion

ORDER / CONTACT INFORMATION: ClearPoint Client Services: 972-966-7700 | Fax: 972-966-7799
Thomas P. Lohmann, MD: 972-966-7135

Thomas P. Lohmann, MD
Chief Medical Officer