Human Immunodeficiency Virus (HIV) Viral Load Quantitation Using the Abbott m2000 Real Time Polymerase Chain Reaction (PCR) Assay

Summary & Explanation of the Test:

The Molecular Diagnostics laboratory at UTMC has implemented a new FDAapproved assay (Abbott RealTime HIV-1 PCR assay) for measurement of Human Immunodeficiency Virus 1 (HIV-1) viral load in plasma. It has been designed to provide information for monitoring disease progression and is not intended for use in the diagnosis of HIV-1 infection or Acquired Immune Deficiency Syndrome (AIDS).

Human Immunodeficiency Virus (HIV) is the etiologic agent of Acquired Immunodeficiency Syndrome and it can be transmitted by sexual contact, exposure to infected blood or blood products, or by an infected mother to the fetus.

Quantitative measurements of HIV viremia in the peripheral blood have shown that higher virus levels are correlated with increased risk of clinical progression of HIV disease, and that reduction in plasma virus levels is associated with decreased risk of clinical progression. Quantitative measurement of HIV viral RNA in plasma using nucleic acid amplification technologies such as the Quantitative HIV Viral Load Real Time Polymerase Chain Reaction (PCR) assay using the Abbott m2000 system is particularly useful to monitor disease progression in response to therapy.

The Abbott m2000 HIV viral load assay has a dynamic range of 40-10,000,000 copies/mL (1.60-7.00 Logs), and is standardized against a viral standard from the Virology Quality Assurance (VQA) Laboratory of the AIDS Clinical Trial Group and against the World Health Organization (WHO) 1st International Standard for HIV-1 RNA. It is more sensitive and detects more viral groups/subtypes than the Cobas Amplicor HIV assay (40 versus 400 copies/mL).

Turn-Around-Time: 7-10 days

Sample requirements:

Four mL of blood collected in a lavender top tube (EDTA tube); <u>NO</u> ACD yellow top tubes are acceptable for HIV viral load testing.

Results reporting:

- 1) Not Detected (0 copies/mL plasma)
- 2) Detected but less than 40 copies/mL plasma
- 3) A numerical value is reported for a result of 40 to 10,000,000 copies/mL plasma
- 4) Detected but greater than 10,000,000 copies/mL plasma

For any questions regarding HIV viral load testing, or other types of molecular diagnostics questions please contact the UTMC Molecular Diagnostics Laboratory at (419) 383-5636.