

Test comments:

The assay uses FDA approved VERSANT® HIV-1 RNA 3.0 branch DNA signal amplification method for direct quantitation of Human Immunodeficiency Virus type 1 (HIV-1). The dynamic range of this assay is from 75 (1.9 log₁₀ copies /ml) to 500,000 (5.7 log₁₀ copies/ml). This test is intended for use in conjunction with the clinical evaluation and other laboratory markers as an indicator of disease prognosis and as a monitor of the efficacy of antiretroviral therapy. The clinical significance of changes in HIV-1 RNA measurements has not been fully established; however, a threefold (0.5 log) change in copies/mL may be significant. The test results are not intended for use as a screening test for HIV and has the potential for false positive results in seronegative individuals.

The performance characteristics of this test were validated by the University of Florida Department of Pathology Diagnostic Reference Lab. The U.S. Food and Drug Administration (FDA) has approved this test. The UF Diagnostic Reference Lab is authorized under CLIA and by all states to perform high- complexity testing.