

## HIV, HBV and HCV Viral Load Testing SERVICE SPECIFICATION SHEET

**Intended Use:** The Viral Load Test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1, HBV, and HCV-infected patients. The Test can be used to assess patient prognosis by measuring the baseline viral RNA level or to monitor the effects of antiretroviral therapy by measuring changes in plasma viral RNA levels during the course of anti-retroviral treatment.

**Technical Information:** Lab21 uses the Abbott m2000 RealTime system to quantify viral RNA in plasma by Polymerase Chain Reaction (PCR), a nucleic acid amplification technology allowing maximum sensitivity and dynamic range for the quantitative detection of HIV-1, HBV, and HCV RNA. Depending on the input volume used, 0.5ml or 0.2ml, the lower limit of quantification for HIV-1 is 75 or 150 copies/ml, for HBV 10 or 15 copies/ml, and for HCV 12 or 30 IU/ml, respectively. The upper limit of quantification is  $10^7$  copies/ml for HIV,  $10^9$  copies/ml for HBV and  $10^8$  IU/ml for HCV.

The Viral Load tests have all received CE mark status and can be used for diagnostic purposes in Europe and other countries where the CE mark is recognised.

**Assay Time:** Turnaround: 4 working days after receipt of sample.

**Specimen Requirements:** Contact your GP or Clinic to arrange for a blood sample to be drawn. Lab21 will provide suitable blood tubes and packaging in the Lab21 Ltd Patient Sample Pack which will be returned for analysis to Lab21 Ltd.

**Specimen Handling:** See 'Advice for Healthcare Providers and Individuals – HIV, HBV and HCV Viral Load Testing'.

**Reporting of Results:** The results of the test will be sent to your GP or Clinic for them to discuss with you. Lab21 will assign a Lab21 unique patient ID so that names will not be included in this report. Patient results will be identified through their Clinic number provided on the Patient Sample Information form.

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