SPECIMEN SUBMISSION GUIDELINES

HIV Diagnostics and Reference Laboratory, Diagnostics and Countermeasures Branch
Center for Infectious Disease Research Walter Reed Army Institute of Research
508 Research Dr., Silver Spring, MD, 20910

Sentosa® SQ HIV-1 Genotyping Assay *Test Specification*

Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time
Sentosa® SQ HIV-1 Genotyping is a Next Generation Sequencing (NGS) Assay based on *in vitro* diagnostic (IVD) test intended for use in detecting HIV-1 genomic mutations in protease, reverse transcriptase and integrase regions of the pol gene as an aid in monitoring and treating HIV-1 infection. Sentosa® SQ HIV-1 Genotyping Assay is intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease progression and as an assay to monitor or assess viral response to antiretroviral treatment. The test is available for all patients who are: (1) initiating drug therapy; (2) not responding to antiretroviral drug therapy (low viral RNA level at 1,000 to 3,000 copies/ml); or (3) failing their antiretroviral regimen. Sentosa® SQ HIV-1 Genotyping is an FDA-approved test that uses commercially available test kit from VELA Sentosa SQ HIV-1 Genotyping Assay. **Reference Range:** Sensitive	Three (3) vials of EDTA plasma (1 ml per tube). Centrifuge at room temperature at 1900 x g for 10 minutes at 2 to 8℃ following the steps below: EDTA: Invert 8-10 times. Store the tubes upright at room temperature, spin tubes within 2 hours of collection. Centrifuge at 1900 x g for 10 minutes at 2 to 8℃ to remove plasma. Using a pipette, immediately transfer the resulting supernatant (Plasma) to clean polypropylene tubes while ensuring 2-8℃ when handling the samples. **Please note:** Patients presently on antiretroviral drug therapy should be on their drug regimen when specimen is collected.	EDTA Plasma: Store refrigerated (2-8°C) for overnight or same day delivery. If transport will be longer than overnight or same day, aliquot plasma, freeze at -70°C, then ship frozen. Store plasma frozen (-70°C or colder). Use 2 lbs. dry ice per day of transport. Shipment with an additional 6 lbs. of dry ice is recommended in case of shipment delay.	The Sentosa® SQ HIV-1 Genotyping Assay is FDA-approved for therapeutic (HIV-1 resistance genotype) monitoring of HIV-infected individuals.	10 business days after receipt at HDRL.

Please note:

1. Viral load MUST BE ≥ 1000 copies/ml and result must have been obtained within the past 30 days.
2. When requesting Sentosa® SQ HIV-1 Genotyping Assay, the requesting laboratory must provide most recent Viral Load result on the request form at time of submission.
3. If the patient has not had a Viral Load determination within the past 30 days, request a HIV-1 Viral Load along with the HIV-1 Genotype.
4. Any specimen without a Viral Load reported (or a Viral Load requested) on the request form will need resolution and may affect Turn Around Time.
5. Duplicate specimens will be discarded.
6. Treatment Decision should be made in consideration of all relevant clinical and laboratory findings and the prescribing information of the drug in question.

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