SPECIMEN REQUIREMENTS FOR HUMAN IMMUNODEFICIENCY VIRUS TESTING SERUM AND ORAL FLUID SPECIMENS

Revised May 16, 2011

Methodology:	
Screen:	Enzyme Linked Immunoassay
Supplemental/Confirmatory:	Western Blot
Performed:	The HIV-1/HIV-2 *Plus O* EIA is used for qualitative detection of antibodies to Human Immunodeficiency Viruses Type 1 and/or Type 2 (HIV-1/HIV-2) in human serum, plasma, cadaveric serum, and oral fluid specimens. All serum specimens found to be repeatedly reactive or equivocal using the EIA are tested by a supplemental/confirmatory western blot for HIV-1 contained in human serum, plasma, and cadaveric serum. All others are sent to CDC for confirmation. All oral fluid specimens found to be repeatedly reactive by EIA are tested by a supplemental/confirmatory western blot specifically for HIV-1 contained in oral fluid specimens.
Turn-Around-Time:	Specimens are tested in batches. Results are reported out in 7 calendar days (Oahu) to 10 calendar days (Neighbor Islands).
Specimen (type) required:	A minimum of one (1) mL of serum. A minimum of one (1) mL of plasma collected from an EDTA-anticoagulated blood. A minimum of 0.75 mL of specimen eluate from the OraSure HIV-1 Oral Specimen Collection Device.
Specimen Collection:	Serum (including serum collected in serum separator tubes); plasma containing sodium and lithium heparin,

	EDTA, sodium citrate, CPD, CPDA-1, ACD; cadaveric serum or whole blood collected in a vacutainer with no additives*. Serum collected in serum separator tubes and whole blood collected in a vacutainer with not additives (red top) should be transported to the laboratory within 72 hours after collection. ***Only the STD Control Program can submit whole blood in vacutainers with no additives to the laboratory.** Oral Fluid – the patient places the OraSure specimen collection device between the lower cheek and gum for 2-5 minutes. The pad draws oral fluid and placed in a vial that contains a preservative which stabilizes the sample for up to 21 days at 37°C.
Specimen storage, packing and Transport;	Ship serum specimens in sterile, screw-capped tubes. Oral Fluid specimens are shipped to the laboratory in the OraSure Oral Fluid Specimen Collection Device. Follow instructions for Category B – Biological Substance of the U. S. Department of Transportation (U.S. DOT) and International Air Transport Association (IATA), Packing Instructions (PI) 650 for packing and shipping.
Specimen submission:	Submitters (Authorized by the DOH STD/AIDS Branch's STD Control Program).
Requisition Form:	Provided by the STD Control Program.
Unacceptable conditions:	• Specimen that is leaking; • Improper container or handling; • Heat inactivated serum, plasma, or cadaveric specimen;

- Obvious microbial contamination;
- Specimen quantity is insufficient to perform the tests;
- Volume of centrifuged Oral Fluid specimen is less than 0.75 mL;
- Unlabeled specimens;
- Improperly filled requisition form (provided by the STD Control Program);
- Specimen label does not match the requisition;
- No informed consent for testing;
- Patient identifier is a name (testing is anonymous).

Stability:

Serum or plasma specimens may be stored at 2-8°C for 7 days. For long-term storage, specimens should be frozen (at -20°C or colder). Samples should not be used if they have incurred more than 5 freeze-thaw cycles.

OraSure HIV-1 specimens (on or off the collection pad) should be stored at 2-8°C. Specimens may be stored at 4°C to 37°C for a maximum of 21 days from the time of collection, including the time for shipping and testing. If testing or specimens cannot be completed within 21 days, OraSure HIV-1 specimens can be stored frozen at -20°C for a maximum of six (6) weeks. Specimens frozen and thawed once must be tested within the 21 days. Specimens frozen and thawed twice must be tested within 24 hours, or discarded.

Normal Value:

No antibody detected to Human Immunodeficiency Virus (HIV) Type 1/2.

Results Notification:

Laboratory results are reported to the STD Control Program.

Test performed at:	Virology Section, Medical Microbiology Branch State Laboratories Division Department of Health 2725 Waimano Home Road, 2nd Floor Pearl City, Hawaii 96782
Contact:	Robert T. Ueki, Supervisor, Virology Section (808) 453-6705 Gail Y. Kunimoto, Chief, Medical Microbiology Branch (808) 453-6700

Approved by:

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