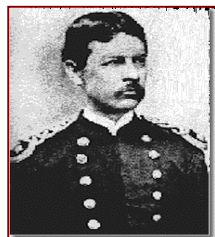


HIV Diagnostics and Reference Laboratory
Department of Laboratory Diagnostics and Monitoring
US Military HIV Research Program, Walter Reed Army Institute of Research
9100 Brookville Road, BLDG 508, Silver Spring, MD 20910



Walter Reed Army Institute of Research



DEPARTMENT OF LABORATORY DIAGNOSTICS AND
MONITORING



SPECIMEN SUBMISSION GUIDELINES

Version: July 2015

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SUMMARY OF CHANGES

July 2015

- Effective 01 July 2015, Viroseq HIV-1 Integrase Genotype Assay is added to HDRL testing menu.
 - Test Specimen Form for HIV-1 Integrase Genotype Assay has been added.
 - Molecular Test Request Form has been updated.

March 2015

- Effective 01 April 2015, HIV Genotype Assay will be performed on Viroseq HIV-1 Genotype Assay instead of Trugene Assay.
 - Test Specimen Form for HIV-1 revised for Viroseq HIV-1 Trugene Assay. Minimum Viral load requirement changed from ≥ 1000 copies to ≥ 2000 copies/ml.
 - Viroseq HIV-1 Genotype Assay may be performed if viral load is between 1000-2000 copies/ml, but a resistance profile may not be generated.
- Multispot result interpretation changed on US Army Surveillance HIV Algorithm.
- Point of Contact information changed on the Notification and Follow-Up Point of Contact Form and Verification Kit Instructions.

Please see the Summary of Changes (on the HDRL web page for a complete list of revisions to these Specimen Submission Guidelines and a chart of current test methods and specimen requirements.

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HDRL Mission: The HIV Diagnostics and Reference Laboratory (HDRL), as part of the Department of Laboratory Diagnostics and Monitoring (DLDM), is dedicated to defining and executing state-of-art infectious disease diagnostics and monitoring in support of the Department of Defense and Department of Army personnel and their beneficiaries. HDRL assures the highest quality test results within a short turnaround time.

1.0 GENERAL INFORMATION

1.1 LABORATORY SERVICES

The HIV Diagnostics and Reference Laboratory (HDRL), Department of Laboratory Diagnostics and Monitoring (DLDM), US Military HIV Research Program (USMHRP), at the Walter Reed Army Institute of Research (WRAIR), is DoD-CLIP and College of American Pathologists (CAP) accredited Reference Laboratory that offers testing to Department of Defense (DoD) Laboratories.

HDRL began in 1986 as the HIV Diagnostics Laboratory, when Congress authorized creation of the U.S. Military HIV Research Program (MHRP) to protect U.S. troops and serve the global community by reducing the risk of HIV-1 infection.

HDRL conducts standard retroviral serology and HIV clinical (viral load) monitoring testing for both clinical care and in support of the MHRP research protocols. The Laboratory also provides HIV-1 resistance genotyping services to all DoD HIV infected force members. HDRL is responsible for technical oversight for all Army retroviral diagnostics performed by independent government contractors.

NOTE: Only the U.S. Army European Command (USAREUR) and U.S. Army Central Command (CENTCOM) are authorized to use WRAIR/HDRL to meet HIV Surveillance (Force Screen) requirements. Non-USAREUR facilities must use Service-directed test facilities (contract laboratory); special requests for assistance must be coordinated with HDRL.

1.2 TEST MENU

Type	Tests Available	Test Specs Link
Serology	<ul style="list-style-type: none">○ HIV Combo Ag/AB○ HIV-1 Western Blot (WB) Supplemental○ HIV 1/2 Multispot Rapid Test	[HIV Combo] [HIV1WB] (Multispot)
Molecular	<ul style="list-style-type: none">○ HIV-1 Viral Load (COBAS AmpliPrep/ COBAS TaqMan)○ HCV Viral Load (COBAS AmpliPrep/ COBAS TaqMan)○ HIV-1 RNA Qualitative Assay (APTIMA)○ HCV RNA Qualitative Assay (APTIMA)○ HIV-1 Resistance Genotype○ HIV-1 Integrase Genotype○ HIV-1 Phenotype (sent out to Monogram Biosciences)○ HIV-1 Trofile (sent out to Monogram Biosciences)○ HIV-1 DNA PCR, HIV-2 DNA PCR	[HIV1VL] [HCV VL] [HIV1Aptima] [HCV Aptima] [HIV1Geno] [HIV1 Int] [HIV1Pheno] [HIV1Trofile] [HIVDNA]

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1.3 LABORATORY HOURS AND ADDRESS

Open Monday through Friday from 0745 to 1630 hours; closed Saturdays, Sundays and holidays.

SPECIMEN SUBMISSION SHIPPING ADDRESS

LABORATORY MAILING ADDRESS:

HIV Diagnostics and Reference Laboratory

Department of Laboratory Diagnostics and Monitoring

US HIV Military Research Program, Walter Reed Army Institute of Research
9100 Brookville Road, BLDG 508, Silver Spring, MD 20910

Phone: (301) 319-3123

Fax: (301) 319-3502

Web Site

US Military HIV Research Program – <http://www.hivresearch.org>

HIV Diagnostics and Reference Laboratory – <http://www.hivresearch.org/hivdiagnostics>

Please see the HDRL web page for the latest Specimen Submission Guidelines, test descriptions, Testing algorithms, Test Request and Point of Contact (POC) forms, and Accreditation Certificates (CAP and Clinical Laboratory Improvement Program [CLIP]).

1.4 POINTS OF CONTACT

Director, US Military HIV Research Program

COL Nelson Michael, MD, PhD

Chief, Department of Laboratory Diagnostics and Monitoring

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CDR Jennifer Malia, MS, DrPH, Commercial (301) 319-3510

Laboratory Director, HIV Diagnostics and Reference Laboratory

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Manager, HIV Diagnostics and Reference Laboratory

CPT Julian Stewart, Commercial (301) 319-3173

HIV Clinical Monitoring (Viral Load and Genotype), HDRL

Jason Ouellette, Technical Supervisor, Commercial (301) 319-3076

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Lt. Annette Mott, Assistant Laboratory Manager, Commercial (301) 319-3177

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2.0 SPECIMEN COLLECTION, PROCESSING AND HANDLING

2.1 PATIENT PREPARATION

Verify patient identification and tests requested before blood draw and follow local approved standard operating procedures.

2.2 ORDER OF DRAW

When multiple specimens are required, follow the proper order of draw (CLSI H3-A6 section 8.10).

Order	Tube Type	Tube Stopper Color
1	Blood Culture – SPS	Yellow
2	ACD *	Yellow
3	Citrate	Light Blue
4	BD Vacutainer® SST™ Gel Separator *	Orange or Red/Black
5	Serum (plastic only) *	Red
6	Heparin	Green
7	BD Vacutainer® PST Gel Separator with Heparin	Light Green or Light Green/Black
8	EDTA* and PPT *	Lavender, White
9	Flouride (Glucose)	Grey

* Signifies collection tubes used for tests identified in this manual

2.3 REQUIREMENTS (IF NOT SPECIFIED IN INDIVIDUAL TEST)

FOR SPECIFIC TEST REQUIREMENTS, SEE INDIVIDUAL TEST DESCRIPTIONS. SEND THE REQUIRED VOLUME OR TEST MAY BE REJECTED DUE TO INSUFFICIENT VOLUME.

WHOLE BLOOD

Collect whole blood according to instructions provided for the individual test. Thoroughly mix blood tubes containing additives by gently inverting the tube: plastic lavender 6-8 times; light blue top, no more than 4 times (mixing more than 4 times will activate clotting).

Maintain the specimen at room temperature before shipping to our laboratory unless instructed otherwise by the specimen requirements. Never freeze whole blood unless specifically instructed in the specimen requirements. Do not place whole blood specimens in direct contact with ice/cool packs.

PLASMA

Plasma contains fibrinogen and other clotting factors when separated from the red blood cells. Evacuated tubes used to collect plasma specimens contain anticoagulants and, frequently, a preservative. The additive in each tube is specified on the label and tube stoppers are color-coded according to the additive present.

Consult the individual test specimen requirements to determine the correct additive/tube to use. If sample is transferred to a secondary tube, indicate the specimen type (plasma) on the plastic screw-cap vial for transport and on the test request form.

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SERUM

We recommend the use of serum separator collection tubes (SSTs) for most serological analyses. When using a serum separator tube, invert the tube gently no more than five times. Further inversion may cause alterations in sample integrity. Do not centrifuge immediately after drawing blood. Allow the blood to clot in an upright position for at least 30 minutes, but not longer than 1 hour before centrifugation. If sample is transferred to a secondary tube, indicate that the specimen is serum on the plastic screw-cap vial for transport and on the test request form.

CENTRIFUGE

Instructions for centrifugation of specimen collection tubes:

- 1) Draw 5 mL of whole blood for each 2 mL of serum or plasma required. Collect in an appropriate collection tube.
- 2) If serum is required, allow the sample to clot for at least 30 minutes in an upright position, but no longer than 1 hour, before centrifugation.
- 3) For serum, centrifuge within 1 hour of collection per manufacturer guidance, *if not specified otherwise for the individual test*.
- 4) For plasma, centrifuge within 4 hours of collection per manufacturer guidance, *if not specified otherwise for the individual test*.
- 5) Pipette the serum or plasma into a clean plastic screw-cap vial and attach the label. Do not transfer red cells to the vial.

2.4 LABELING OF SPECIMENS

Verify identification once again post draw and before labeling the tubes.

Each submitted specimen must be labeled with the following information:

- Name of patient
- Unique DOD number
- Social Security number (SSN) and family member prefix (FMP) is still required to look up patients in legacy data until both identifiers are completely phased out.
- Date of birth and/or barcode written exactly as it appears on the test request form
- Date of collection (ensure that draw date is legible)
- Specimen type – indicate on label when submitting specimen in transfer tube (e.g., serum, plasma)

Failure to include required information on the specimen label will result in rejection of the sample (see section 2.6, Sample Rejections).

2.5 SPECIMEN TEST REQUEST FORMS

Complete the appropriate HDRL test request form for each specimen:

Serology Clinical Test Form, HIV Verification Algorithm Test Form, Molecular Clinical Test Form or Vaccine Induced Sero-Reactivity Test Form.

If you suspect an acute HIV infection, please order the Acute HIV Algorithm on the Serology Clinical Test Request Form. A 4th generation HIV Ag/Ab Combo test (with a shorter diagnostic window period) will be performed along with HIV RNA Qualitative Test to assist with diagnosis of acute or primary HIV infection.

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Aptima HCV RNA Qualitative Assay has been placed on the Molecular Test menu as a confirmatory test for the repeat reactive HCV EIA result. A quantitative HCV RNA test is available, if required to assist with diagnosis and management of HCV infection.

For Vaccine Induced Sero-Reactivity (VISR) individuals in whom Sero-Reactivity is suspected due to participation in a HIV vaccine trial, a complete HIV algorithm will be performed inclusive of DNA PCR (Additional testing may be performed if needed).

Enclose the appropriate Test Request Form with each patient sample in the shipment. Multiple tests may be requested on the same request form for one patient.

Please ensure that the specimens are shipped using federal, state, and international regulations as appropriate.

VERBAL TEST REQUESTS WILL ONLY BE ACCEPTED WHEN AN ADDITIONAL REQUEST IS ADDED AND ONLY IF FOLLOWED BY THE APPROPRIATE TEST REQUEST FORM WITHIN FIVE (5) BUSINESS DAYS.

PLEASE NOTE: WRAIR follows test algorithms (See Section 5.0). We may modify your request in order to run an initial screening test and then reflex, if needed, for the test you requested.

2.6 SAMPLE REJECTIONS

The HIV Diagnostics and Reference Laboratory reserves the right to reject and discard specimens that (1) do not meet the specimen collection and storage requirements (see individual test guidelines) or (2) contain the following errors:

A. Errors on test request form, including:

- Illegible information
- Missing draw date
- Missing family member prefix (FMP)
- Missing/incomplete Social Security Number (SSN)
- Missing/incomplete date of birth
- Missing name of requesting physician or site

B. Sample errors, including:

- Quantity Not Sufficient (QNS)
- Duplicate sample (same assay requested for same person within one 7-day period), unless authorized by the Laboratory Director
- Illegible label
- Incomplete information on label (at least two identifiers required per regulation).
- Leaking/Cracked specimen tube
- Hemolyzed, contaminated, lipemic, or coagulated specimen
- Package not in compliance with applicable federal and state shipping standards (such shipments will be rejected)
- Specimens not shipped at identified shipping temperature

C. Mismatch errors between test request form and sample, including:

- Discrepancy between sample label and test request form
- Incorrect type of specimen for test requested
- Missing sample or test request form

The submitting laboratory will be notified of any rejected specimen either by email or telephone call.

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2.7 PACKAGING AND SHIPMENT OF SPECIMEN

DO NOT SEND SPECIMENS TO ARRIVE ON WEEKENDS OR FEDERAL HOLIDAYS.

Sites submitting specimens must comply with all applicable federal and state regulations concerning shipment for diagnostic substances. Minimum requirements for packaging and shipping follow:

- A. Package sample in a watertight primary container and secondary container. (See HDRL web page or section 5.0 for packaging illustration.)
- B. Surround individually wrapped specimens with enough absorbent material to contain spillage.
- C. Wrap all vials individually to avoid contact.
- D. Place request forms within the container but separate from the tubes.
- E. Label container and ship specimens according to applicable guidelines for diagnostic samples.
- F. Mail to shipping address listed in section 1.3, Laboratory Hours and Address.
- G. **Fax a FedEx tracking and/or invoice number to ensure all shipments sent to the HIV Diagnostics and Reference Laboratory are received, IAW CAP GEN.40530 (REQUIRED).**

All personnel handling specimens for transport should be trained in safe handling practices and in decontamination procedures in case of spillage.

NOTE: If you would like your shipping boxes returned to your site, please enclose a prefilled FedEx or address slip with FedEx billing information and material to cover hazardous warnings.

2.8 SAMPLE STORAGE

Immediate Shipping: To avoid hemolysis, separate serum from cells within 1 hour of draw and separate plasma within 4 hours of draw for EDTA or 2 hours of draw for PPT. Ship specimen to HDRL in an approved container and per specimen requirements listed on the Test Request Forms.

Delayed Shipping: Separate serum or plasma from cells within specified time (1 hour for serum, 4 hours for EDTA plasma, 2 hours for PPT plasma), then freeze. Ship specimen frozen on dry ice in an approved container to HDRL. Use 2+ lbs. of dry ice per day of transport. **Specimens must arrive frozen.** Add additional dry ice for any delays that may occur during shipment. HDRL recommends using an additional 6 lbs. of dry ice.

3.0 REPORTING OF RESULTS

The HIV Diagnostics and Reference Laboratory will test all specimens submitted as expeditiously as possible, within the timelines specified for each test.

For all sites, HDRL generates hardcopy reports and returns them by next-day courier or secured fax line to a designated Point of Contact (POC) for each submitting facility, or sends electronic results via CHCS for specimens received through LIO. Result reports are also sent via secure file transfer to the Navy as well as MEPCOM. Due to the sensitive nature of our reports, only the designated POC (or alternate) can receive our reports. The facility POC then forwards the reports accordingly within that institution.

To designate a POC for results reporting, please complete a Point of Contact Form. To designate a healthcare provider POC for notification and follow-up of positive patient test results, complete a Notification/ Follow-up POC form. Fax these forms to HDRL at 301-319-3502. **New sites must submit these forms before shipping specimens to HDRL for the first time. Use the same forms for updates/changes. We cannot change or create POCs without these forms.**

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4.0 FOLLOW-UP PROCEDURES FOR POSITIVE RESULTS

Complete follow-up procedures are outlined in HDRL Standard Operating Procedure GEN 002. HDRL/WRAIR complies with AR 600-110 Army HIV Surveillance Program; key points follow:

- For any initial (first-time) HIV positive result for Active Duty Service members, a second independent verification specimen is required as soon as possible.
- For CONUS Active Duty Service members:
 - A HIV Verification Request Kit will be shipped to your site.
 - Please mark the test required and ship it back to HDRL according to instructions provided.
- For all other Active Duty Service members and other Service Components:
 - Please mark the test required on the HIV Verification Request form, which can be downloaded from the HDRL web site.
 - Ship the sample to address provided on the form.
- If the original sample and verification sample are discordant, a third independent verification sample will be required.
- Per AR 600-110, each site is required to have an HIV Program Manager. This individual will serve as the POC for follow-up contacts completed by the HIV Diagnostics and Reference Laboratory.
- The identified Primary or Secondary POC will be notified by the HDRL or Army Public Health Command in accordance with HDRL SOP GEN 002.

5.0 SUPPORTING DOCUMENTS

Test Descriptions (see Test Menu in section 1.2 for links)

Test Request Forms: Serology (TR SER or TR HIVVER), Molecular (TR MOL), Vaccine Induced Sero-Reactivity Form (TRVISR)

POC Forms: Results Reporting (Form POC RR), Notification/Follow-up (Form POC NF)

HIV Testing Algorithm (HIV TA)

HIV Acute Infection Algorithm (HIV AIA)

Summary of Changes, Packaging Illustration, and Certificates: CAP, DoD-CLIP

NOTE: All documents are available online at <http://www.hivresearch.org/hivdiagnostics>.