



REPLY TO  
ATTENTION OF

DEPARTMENT OF THE ARMY  
WALTER REED ARMY INSTITUTE OF RESEARCH  
HIV DIAGNOSTICS AND REFERENCE LABORATORY  
9100 Brookville Rd, BLDG 508  
Silver Spring, MD 20910

MCMR-UWA-A

07 July 2015


MEMORANDUM FOR HIV Diagnostics and Reference Laboratory (HDRL) Customers

SUBJECT: Availability of ViroSeq HIV-1 Integrase Genotype Assay, Effective 07 July 2015

1. The purpose of this memo is to notify customers of the upcoming availability of the HIV-1 Integrase Genotype assay at HDRL. HIV-1 Integrase Genotype is not approved by FDA, it was developed and its performance characteristics determined by HDRL.
2. HIV-1 viral loads **must be  $\geq 2000$  copies/ml** and have been performed within 30 days for the assay to be performed. Note: if viral load is  $>1000 - <2000$  copies/ml, testing may be performed, but a resistance profile may not be generated. (See HIV-1 Integrase Genotype Test Specification)
3. HIV-1 Integrase Genotype testing must be ordered concurrently with the HIV-1 Genotype assay on the Molecular Test Request Form.
4. The three drugs tested for resistance in the HIV-1 Integrase Genotype assay are as follows:
  - a. **Raltegravir**
  - b. **Elvitegravir**
  - c. **Dolutegravir**
5. An example of HIV-1 Integrase Genotype report is attached. Treatment Decision should be made in consideration of all relevant clinical and laboratory findings and the prescribing information of the drug in question.
6. Please retain a copy of this memorandum for your records.
7. Point of contact is the undersigned at (301) 319-3173 or [jstewart@hivresearch.org](mailto:jstewart@hivresearch.org).

Encls

1. Molecular Test Request Form
2. Test Specification Form
2. Sample Report (3 pages)

  
JULIAN M. STEWART  
CPT, USA  
Laboratory Manager

HIV Diagnostics and Reference Laboratory

HIV DIAGNOSTICS AND REFERENCE LABORATORY  
9100 Brookville Road, BLDG. 508, Silver Spring, MD 20910  
**Molecular Clinical Test Request Form**

TEST REQUESTED	SPECIMEN REQUIREMENT	DRAW TUBE
<input type="checkbox"/> HIV-1 Viral Load	3 mls plasma (frozen)	EDTA
<input type="checkbox"/> APTIMA HIV-1 RNA Qualitative	3 mls plasma (frozen)	EDTA/SER/PPT
<input type="checkbox"/> APTIMA HCV RNA Qualitative	3 mls plasma (frozen)	EDTA/SER/PPT
<input type="checkbox"/> HIV-1 Resistance Genotyping	2 mls plasma (frozen)	EDTA/PPT
Viral Load Date: _____ (dd/mmm/yyyy)	Result: _____ Copies/ml (within previous 30 days)	
<input type="checkbox"/> HIV-1 Integrase Genotyping	2 mls plasma (frozen)	EDTA/PPT
Viral Load Date: _____ (dd/mmm/yyyy)	Result: _____ Copies/ml (within previous 30 days)	
<input type="checkbox"/> HIV-1 Phenotype <input type="checkbox"/> HIV-1 Trofile	4 mls plasma each (frozen)	EDTA/PPT
Viral Load Date: _____ (dd/mmm/yyyy)	Result: _____ Copies/ml (within previous 30 days)	
Genotype Date: _____ (dd/mmm/yyyy)	Current Therapeutic Regimen: _____	
<input type="checkbox"/> HIV-1 DNA PCR <input type="checkbox"/> HIV-2 DNA PCR	3 mls whole blood (ambient)	EDTA
	Ship Mon-Wed, within 24 hours of collection	

PATIENT IDENTIFICATION	CONTACT INFORMATION
<b>Patient identifiers <u>must include</u>: Full Name*, DoD#*, FMP*/SSN*, DOB*</b>  Ship Date: _____ Sample Storage (circle): <b>Frozen</b> / <b>Refrig</b> Sample Shipping (circle): <b>Dry Ice</b> / <b>Cold Pack</b> / <b>Ambient</b> Specimen Draw Date / Time*: _____	<b>POC*</b> _____ <b>Physician Name*</b> _____ <b>Clinic / Center*</b> _____ <b>Center Address*</b> _____ _____ Telephone Number _____ Fax Number _____ (Commercial # only; please include area/country code) Alternate POC Name _____ Alternate POC Phone _____

**\*Required**

PROCESSING LAB (For internal use only)		
BARCODE	DATE RECEIVED	QUANTITY & TYPE RECEIVED / INITIALS

**SPECIMEN SUBMISSION GUIDELINES**  
 Department Of Laboratory Diagnostics And Monitoring  
 Walter Reed Army Institute Of Research  
 HIV Diagnostics and Reference Laboratory

**Test Specification**

Test Name: HIV-1 Integrase Genotype	Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time
<p>Intended for use in detecting genomic mutations in Integrase region of HIV-1 conferring resistance to specific types of antiretroviral drugs.</p> <p>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</p> <p>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.</p> <p>FDA-not approved, Laboratory Developed Test using commercially available test kit from Abbott Viroseq HIV-1 Integrase Genotype.</p>	<p>Two (2) vials of non-heparinized plasma at 1 ml per tube</p> <p>Centrifuge at room temperature at 800-1600 x g for 20 minutes within separation times below:</p> <p>PPT Tubes: Centrifuge immediately or within 2 hours of collection. Store at ambient temperature for overnight delivery, or transfer to sterile 2.0 ml polypropylene screw-cap tubes at 1 ml per tube and store at -60 to -80°C.</p> <p>EDTA Plasma: Store blood at 25°C until centrifuged. Centrifuge within 4 hours of collection. Aliquot EDTA plasma to sterile 2.0 ml polypropylene screw cap tubes at 1 ml per tube. Store at -70°C.</p> <p><u>Please note:</u> Patients presently on antiretroviral drug therapy should still be on their drug regimen when specimen collected.</p>	<p>PPT Tubes: Store spun tubes refrigerated (2-8°C) for overnight or same day delivery. If transport longer than overnight or same day, aliquot plasma, freeze at -70°C, then ship frozen. Store plasma frozen (-70°C or colder).</p> <p>EDTA Plasma: Store refrigerated (2-8°C) for overnight or same day delivery. If transport longer than overnight or same day, aliquot plasma, freeze at -70°C, then ship frozen. Store plasma frozen (-70°C or colder).</p> <p>Use 2 lbs. dry ice per day of transport.</p> <p>Recommended: Ship on 6 lbs dry ice in case of shipment delay.</p>	<p>This test was developed and its performance characteristics determined by HDRL. It has not been cleared or approved by the US Food and Drug Administration.</p>	<p>15 business days after receipt at HDRL.</p> <p>Due to low volume of tests requested, samples are batched for testing.</p>	
<p><u>Please note:</u></p> <ol style="list-style-type: none"> <li>Viral load MUST BE ≥ 2000 copies/ml and result must have been obtained within the past 30 days. Viroseq HIV-1 Integrase Genotype testing can be performed if viral load is between 1000 to 2000 copies/ml, but a resistance profile may not be generated.</li> <li>When requesting HIV-1 Integrase Genotype, requesting lab must provide most recent Viral Load result on request form at time of submission.</li> <li>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 Integrase Genotype request.</li> <li>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.</li> <li>Duplicate specimens will be discarded.</li> <li>Treatment Decision should be made in consideration of all relevant clinical and laboratory findings and the prescribing information of the drug in question.</li> </ol>					



# ViroSeq™ Integrase Drug Resistance Report

Subject ID :  
Accession Number :  
Sample Name : POS

Laboratory : Military HIV Research Program  
Report Generated by : Administrator  
Report Date & Time : Jun 29, 2015 10:53:54 AM

## Drug Resistance :

<i>Drug</i>	<i>Trade Name</i>	<i>Evidence of Resistance</i>
(raltegravir, RAL)	ISENTRESS®	None
(elvitegravir, EVG)		None
(dolutegravir, DTG)		None

*EVG and DTG are in advanced clinical development.  
There are limited or no clinical data to support genotypic susceptibility scores for these compounds.*

## Drug Resistance Mutations :

None

## Additional Mutations :

G123S, A124T, R127K, N232D, A265V

## Reference Co-existing with Mutations :

None

## Nucleotide Variants :

297 T>C, 303 T>C, 345 T>A, 367 G>A, 370 G>A, 380 G>A, 694 A>G, 794 C>T



# ViroSeq™ Integrase Drug Resistance Report

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## Comments

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## Review & Release of Results

Signature / Date: \_\_\_\_\_

Name(Print) / Title: \_\_\_\_\_

Notes: \_\_\_\_\_



# ViroSeq™ Integrase Drug Resistance Report

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## Subject Information :

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Subject ID  
Subject Last Name  
Subject First Name  
Accession Number  
Subject Gender  
Subject Birthdate  
Requestor  
Institution  
Date Drawn  
Assay Operator

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## Site Information :

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Testing Laboratory	Military HIV Research Program
Lab Director	Dr. Sheila Peel
Department	HDRL
Street Address1	9100 Brookville Road
Street Address2	
City	Silver Spring
State/Province	MD
Country	
Postal Code	20910
Telephone	301-319-3123
Fax	
E-mail	
Web Site	

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## Run Information :

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Run ID	Run 2015-02-06-08-16-39-917
Instrument Model	3500
Instrument Serial Number	3500 Instrument

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