

TEST DIRECTORY UPDATE

JULY 2020 IMMEDIATE ACTION

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Update Summary			

Update Summary	pate Summary						
Inactivate Test With Replacement	7/8/2020	HGRIT - "HIV-1 Genotype (RTI, PI, Integrase Inhibitors)" replaced by					
		HIVTO - "HIV-1 Genotype (RTI, PI, Integrase Inhibitors)"					



TEST DIRECTORY UPDATE

JULY 2020 IMMEDIATE ACTION

Inactivate Test With Replacement					
Effective Date	7/8/2020				
	Inactivated Test				
Name	HIV-1 Genotype (RTI, PI, Integrase Inhibitors)				
Code		HGRIT			
Legacy Code ¹		HGRIT			
Interface Order Code		3431201			
Notes					
	Replacement Test				
Name	HIV-1 Genotype (R	-	hibitors)		
Code	07000 07001 07005	HIVTO			
CPT Code(s)	87900, 87901, 87906				
Notes					
Specimen Requirements					
Specimen Required	Draw blood in a lavender EDTA. Centrifuge and separate plasma from cells within 24 hours. Send 5.0 mL plasma (1.6 mL minimum) frozen in a screw-capped plastic vial.				
Alternate Specimen					
Rejection Criteria	Gross hemolysis, lipemia, serum, whole blood, heparinized plasma				
Stability	Room temperature: 24 hours; Refrigerated: 5	days; Frozen: 35	days		
Performing Information					
Methodology	Reverse Transcriptase Polymera	se Chain Reaction	(TR-PCR), Sequencing		
Reference Range	E	By report			
Performed Days	Monday - Saturday				
Turnaround Time	6 - 11 days				
Performing Laboratory	Quest SJC				
Interface Information					
Legacy Code ¹	HIVTO				
Interface Order Code		3400342			
Result Code	Name	LOINC Code	AOE/Prompt ²		
3400343	HIV-1 Genotype	48558-1	No		
3400344	Value of Last Viral Load	19146-0	Yes		
3400345	Date Viral Load Collected	33882-2	Yes		
3400346	Raltegravir Resistance	72525-9	No		
3400347	Elvitegravir Resistance	72536-7	No		
3400348	Dolutegravir Resistance	72857-6	No		
3400349	Bictegravir Resistance	90080-3	No		



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

EXAMPLE, REPORT WX0000003039 M 12/05/1988 31 Y

	Referral	Testing cted: 07/02/2020 1	0.44	Dessived	07/00/2022	10.14
Test Name	Result		2.44 Ref-Ranges	Received: Un	07/08/2020	Site
	<u>rtesuit</u>		<u>ei-ranges</u>	<u>01</u>	1115	Sile
HIV-1 Genotype (RTI, PI, Integ	- ,					
HIV-1 Genotype	NOT DETECTE	D				QCRL
The method used in th: Of the HIV-1 polymeras		sequencing				
The phrases 'resistance Or emerging resistance The interpretive rules all of the interpretiv to predict drug resist recognize some of the predictive of drug res considers these mutat resistance to anti-vin clinical or scientific validated pursuant to considered investigat Treatment decisions sh All relevant clinical prescribing informatic	e' refer to the applic s. The FDA has not rev ve rules used by the f cance. FDA may not cur HIV gene mutations re- sistance, but the labor ions to be associated ral drugs based on cur c studies. The test has CLIA regulations and ional or for research hould be made in const and laboratory findir	cation of viewed laboratory rrently eported as oratory with rrent as been is not use only. ideration of				
This test was develops Performance character: Quest Diagnostics Infe cleared or approved & validated pursuant to used for clinical purg	istics have been deten ectious Disease. It ha by FDA. This assay has the CLIA regulations	as not been s been				
Test Performed at: Quest Diagnostics Infe 33608 Ortega Highway	ectious Disease, Inc.					
San Juan Capistrano, (J Batterman MD				QCRI
Value of Last Viral Load Date Viral Load Collected	456 6/30/2020					QCRI
Raltegravir Resistance	NOT PREDICT	ED				QCRI
Elvitegravir Resistance	NOT PREDICT					QCR
Dolutegravir Resistance	NOT PREDICT					QCRI
Bictegravir Resistance	NOT PREDICT	ED				QCRI
The method used in the the HIV-1 integrase ge predicted" and "probat the application of the reviewed all of the in	ene. The phrases "rest ole or emerging resist e interpretive rules.	istance tance" refer to The FDA has no				

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

B508000001	Ordered By:	CLIENT CLIENT
WX000003039	WX00000000	01595
Printed D&T: 07/08/20 12:49		



Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT** WX0000003039 M 12/05/1988 31 Y

	Referral Testing					
	Collected: 07/02/2020	0 12:44	Received:	07/08/2020	12:44	
<u>Test Name</u>	Result Flag laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations rep- as predictive of drug resistance, but the laboratory considers these mutations to be associated with resist to anti-viral drugs based on current clinical or scient studies.	ance	<u>s U</u>	<u>nits</u>	<u>Site</u>	
	This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Infectious Disease. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.					
	For more information on this test, go to: http://education.questdiagnostics.com/faq/FAQ135 (This link is being provided for informational/educational purposes only.)					
	Test Performed at: Quest Diagnostics Infectious Disease, Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 H J Batterman P	MD				
	QCRL: QUEST DIAGNOSTICS REFERENCE LAB CA	PISTRANO 33608	Ortega Highway Sa		ning Site: A 92675	

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED