

Patient Information	Specimen Information	Client Information
TESTCASE, TWENTYSIX DOB: 05/10/1984 AGE: 30 Gender: M Fasting: Y Phone: 610.650.2000 Patient ID: 0418581	Specimen: BH045148A Requisition: 0418581 Collected: 10/03/2014 / 08:00 EDT Received: 10/03/2014 / 14:19 EDT Reported: 10/07/2014 / 09:37 EDT (* A Copy Sent To)	Client #: 205 AARRSSS COLMENAR, ANTONIO QLS FAX Attn: KATHY 400 EGYPT RD NORRISTOWN, PA 19403-3406

COMMENTS: TEST CASE 26

HIV 1 RNA, QN PCR W/RFL GENO (RTI,PI,INTEGRASE)

HIV 1 RNA, QN PCR

Lab: TXC

Test Name	Result	Reference Range/Comments
HIV 1 RNA, QN PCR	401 H	copies/mL
HIV 1 RNA, QN PCR	2.61 H	Log copies/mL

REFERENCE RANGE:

Copies/mL: <20 copies/mL
Log copies/mL: <1.30 Log copies/mL

This test was performed using the COBAS(R) AmpliPrep/
COBAS(R) TaqMan(R) HIV-1 test kit version 2.0 (Roche
Molecular Systems, Inc.).

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HIV 1 GENOTYPE

Lab: TXC

Test Name	Result	Reference Range/Comments
HIV 1 GENOTYPE	DETECTED	

HIV Subtype: B

Antiretroviral Drugs	Resistance Predicted	Mutations/Results
NRTIs		
RT codons 1-335		
ZDV (zidovudine or Retrovir®)	<input type="radio"/> NO	
ABC (abacavir or Ziagen®)	<input type="radio"/> NO	
ddI (didanosine or Videx®)	<input type="radio"/> NO	
3TC (lamivudine or Epivir®)	<input checked="" type="radio"/> YES	M184I/M
FTC (emtricitabine or Emtriva®)	<input checked="" type="radio"/> YES	M184I/M
d4T (stavudine or Zerit®)	<input type="radio"/> NO	
TDF (tenofovir or Viread®)	<input type="radio"/> NO	

NNRTIs		
ETR (etravirine or Intelence®)	<input type="radio"/> NO	
EFV (efavirenz or Sustiva®)	<input checked="" type="radio"/> YES	K103N,M230M/L
NVP (nevirapine or Viramune®)	<input checked="" type="radio"/> YES	K103N,M230M/L
RPV (rilpivirine or Edurant®)	<input type="radio"/> NO	

PIs		
PR codons 1-99		
FPV (fos-amprenavir or Lexiva®)	<input type="radio"/> NO	
IDV (indinavir or Crixivan®)	<input type="radio"/> NO	
NFV (nelfinavir or Viracept®)	<input type="radio"/> NO	
SQV (saquinavir or Invirase®)	<input type="radio"/> NO	
LPV (lopinavir or Kaletra®)	<input type="radio"/> NO	
ATV (atazanavir or Reyataz™)	<input type="radio"/> NO	
TPV (tipranavir or Aptivus™)	<input type="radio"/> NO	
DRV (darunavir or Prezista™)	<input type="radio"/> NO	

= Resistance Predicted
 = No Predicted Resistance
 = Probable or Emerging Resistance

Other Mutations Detected

Gene Name	Mutations
RT	K65K/N,Y188Y/C,F214L/F
PR	L10I,I13V,L33V/L,M36I,I62V,L63I,I64V

All Trademarks are the properties of their respective owners.

Subtype determined by sequence analysis of the viral cDNA generated for this assay.

The Quest Diagnostics June 2014 Interpretation Algorithm

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The method used in this test is RT-PCR and sequencing of the HIV-1 polymerase gene. The phrases "resistance predicted" and "probable or emerging resistance" refer to the application of the interpretive rules. The FDA has not reviewed all of the interpretive rules used by the laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations reported as predictive of drug resistance, but the laboratory considers these mutations to be associated with resistance to anti-viral drugs based on current clinical or scientific studies. The test has been validated pursuant to CLIA regulations and is not considered investigational or for research use only. Treatment decisions should be made in consideration of all relevant clinical and laboratory findings and the prescribing information for the drugs. This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.

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HIV 1 INTEGRASE GENOTYPE

Lab: TXC

Antiretroviral Drugs	Resistance Predicted
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INIs	
RAL (raltegravir or Isentress®)	● PREDICTED
EVG (elvitegravir)	● PREDICTED
DTG (dolutegravir or Tivicay®)	● PREDICTED

● = Resistance Predicted
 ○ = No Predicted Resistance
 ◐ = Probable or Emerging Resistance

Mutations Detected

E138EK,G140S,Q148H

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Resistance predictions for current specimen interpreted according to The Quest Diagnostics December 2013 Interpretation Algorithm.

Elvitegravir is an ingredient of the antiretroviral drug STRIBILD™.

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PERFORMING SITE:

TXC FOCUS DIAGNOSTICS, 33608 ORTEGA HIGHWAY, SAN JUAN CAPISTRANO, CA 92690 Laboratory Director: JAY LIEBERMAN,MD, CLIA: 05D0644251

* Copy To Client: TEST CLIENT (HQ); QDRS - AUTODIAL

LIST OF RESULTS PRINTED IN THE OUT OF RANGE COLUMN:

HIV 1 GENOTYPE **DETECTED** TXC
 HIV Subtype: B

Antiretroviral drugs	Resistance Predicted	Mutations Detected
NRTIs		
ZDV (zidovudine or Retrovir)	NO	
ABC (abacavir or Ziagen)	NO	
ddI (didanosine or Videx)	NO	
3TC (lamivudine or Epivir)	YES	M184I/M
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NNRTIs	
ETR (etravirine or Intelence)	NO
EFV (efavirenz or Sustiva)	YES K103N,M230M/L
NVP (nevirapine or Viramune)	YES K103N,M230M/L
RPV (rilpivirine or Edurant)	NO

PIs	
FPV (fos-amprenavir or Lexiva)	NO
IDV (indinavir or Crixivan)	NO
NFV (nelfinavir or Viracept)	NO
SQV (saquinavir or Invirase)	NO
LPV (lopinavir or Kaletra)	NO
ATV (atazanavir or Reyataz)	NO
TPV (tipranavir or Aptivus)	NO
DRV (darunavir or Prezista)	NO

PRB = PROBABLE OR EMERGING RESISTANCE
 OTHER MUTATIONS DETECTED:
 RT GENE MUTATIONS: K65K/N,Y188Y/C,F214L/F
 PR GENE MUTATIONS: L10I,I13V,L33V/L,M36I,I62V,L63I,I64V

The Quest Diagnostics June 2014 Interpretation Algorithm
 The method used in this test is RT-PCR and sequencing of
 the HIV-1 polymerase gene.

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