

#### **SCOPE OF COVERAGE**

Directly applicable to all Ryan White Part B funded service providers.

#### **PURPOSE OF PRIMER**

In order to assist providers in understanding the variety of ways that lab results are reported.

#### BACKGROUND

Lab results are a required document for consumers who apply for benefits in the Ryan White HIV/AIDS Programs in Nevada. HIV Viral Load and CD4 T-Cell lab results are required for initial and annual enrollment for all consumers. All lab results are required to be entered into the Encounters tab and Lab Results subtab within CAREWare. Please review the 15-21 CAREWare User Guide for additional information on how to do that.



Latest Ref Rng	3/13/2017	3/13/2017	3/13/2017	3/13/2017	3/13/2017
	10:24 AM	10:24 AM	10:24 AM	10:24 AM	10:24 AN
135 - 145 mmol/L			138		
3.6 - 5.5 mmol/L			4.0		
96 - 112 mmol/L			104		
20 - 33 mmol/L			30		
0.0 - 11.9			4.0		
65 - 99 mg/dL			84		
8 - 22 mg/dL			9		
0.50 - 1.40 mg/dL			0.75		
8.5 - 10.5 mg/dL			9.4		
12 - 45 U/L			23		
2 - 50 U/L		1	16		
30 - 99 U/L			77		
0.1 - 1.5 mg/dL			0.7		
3.2 - 4.9 g/dL			4.1		
6.0 - 8.2 g/dL			10101010		
			and the second se		
			1.6		
490 - 1600 cells/uL				439 (1)	
150 - 1050 cells/uL					
660 - 2200 cells/uL				the second se	
0.80 - 6.17 ratio					
				and the second se	
100 - 199 mg/dL		196		occ note	
		30 (4)			
		the second s			
					<1.3
					<20
Not Detected					Not Detected
	>60				HOL DOLOGIOG
	3.6 - 5.5 mmol/L 96 - 112 mmol/L 20 - 33 mmol/L 0.0 - 11.9 65 - 99 mg/dL 8 - 22 mg/dL 0.50 - 1.40 mg/dL 8.5 - 10.5 mg/dL 12 - 45 U/L 2 - 50 U/L 30 - 99 U/L 0.1 - 1.5 mg/dL 3.2 - 4.9 g/dL 6.0 - 8.2 g/dL 1.9 - 3.5 g/dL 490 - 1600 cells/uL 150 - 1050 cells/uL 660 - 2200 cells/uL 0.80 - 6.17 ratio 100 - 199 mg/dL >=40 mg/dL >=40 mg/dL	135 - 145 mmol/L         3.6 - 5.5 mmol/L         96 - 112 mmol/L         20 - 33 mmol/L         0.0 - 11.9         65 - 99 mg/dL         8 - 22 mg/dL         0.50 - 1.40 mg/dL         8.5 - 10.5 mg/dL         12 - 45 U/L         2 - 50 U/L         30 - 99 U/L         0.1 - 1.5 mg/dL         3.2 - 4.9 g/dL         6.0 - 8.2 g/dL         1.9 - 3.5 g/dL         490 - 1600 cells/uL         150 - 1050 cells/uL         660 - 2200 cells/uL         0.80 - 6.17 ratio         100 - 199 mg/dL         0 - 149 mg/dL         >=40 mg/dL               Not Detected         >60 mL/min/1.73 m 2	135 - 145 mmol/L         3.6 - 5.5 mmol/L         96 - 112 mmol/L         20 - 33 mmol/L         0.0 - 11.9         65 - 99 mg/dL         8 - 22 mg/dL         0.50 - 1.40 mg/dL         8.5 - 10.5 mg/dL         12 - 45 U/L         2 - 50 U/L         30 - 99 U/L         0.1 - 1.5 mg/dL         3.2 - 4.9 g/dL         6.0 - 8.2 g/dL         1.9 - 3.5 g/dL         490 - 1600 cells/uL         150 - 1050 cells/uL         150 - 1050 cells/uL         100 - 199 mg/dL         100 - 199 mg/dL         100 - 199 mg/dL         100 - 199 mg/dL         130 - 140 mg/dL         130 - 140 mg/dL         130 - 140 mg/dL         130 - 140 mg/dL         130 - 199 mg/dL         130 - 199 mg/dL         144         >=40 mg/dL         137 (H)         137 (H)	135 - 145 mmol/L       138         3.6 - 5.5 mmol/L       4.0         96 - 112 mmol/L       104         20 - 33 mmol/L       30         0.0 - 11.9       4.0         65 - 99 mg/dL       84         8 - 22 mg/dL       9         0.50 - 1.40 mg/dL       0.75         8.5 - 10.5 mg/dL       9.4         12 - 45 U/L       23         2 - 50 U/L       16         30 - 99 U/L       77         0.1 - 1.5 mg/dL       0.7         3.2 - 4.9 g/dL       6.7         1.9 - 3.5 g/dL       2.6         1.6       20         90 - 1600 cells/uL       1.6         490 - 1600 cells/uL       1.6         90 - 1050 cells/uL       1.6         100 - 199 mg/dL       196         0.1 - 199 mg/dL       196         0.1 - 199 mg/dL       137 (H)         100 mg/dL       137 (H)	135 - 145 mmol/L       138         3.6 - 5.5 mmol/L       4.0         96 - 112 mmol/L       104         20 - 33 mmol/L       30         0.0 - 11.9       4.0         65 - 99 mg/dL       84         8 - 22 mg/dL       9         0.50 - 1.40 mg/dL       0.75         8.5 - 10.5 mg/dL       9.4         12 - 45 U/L       23         2 - 50 U/L       16         30 - 99 U/L       77         0.1 - 1.5 mg/dL       0.7         3.2 - 4.9 g/dL       6.7         1.9 - 3.5 g/dL       2.6         1.9 - 3.5 g/dL       2.6         1.6       439 (L)         150 - 1050 cells/uL       267         660 - 2200 cells/uL       649 (L)         0.80 - 6.17 ratio       1.64         90 - 1600 cells/uL       58e Note         100 - 199 mg/dL       196         0 - 149 mg/dL       30 (A)          30 (A)          30 (A)          30 (A)          30 (A)          30 (A)          30 (A)

In CAREWare for this individual – the HIV Viral Load number was put in as **<1.3** which is connected to the HIV logarithmic scale number. Using the logarithmic scale number is incorrect. The purpose of the logarithmic scale is to turn large numbers into more manageable numbers for data presentation. For example, 10,000,000 (ten million) can also be written as 7.0 log<sub>10</sub>. Remember to use to actual Copy number, the assay would be listed as PCR.



Deput Date 01/25/2017 08/18/2016 04/10/2016	COLLECTION DATE	01/25/2017	08/15/2016	04/05/2016
	Order Date Result Date	01/25/2017	08/18/2016	
<20 -20	HIV-1 RNA by PCR		<20	
	og 10 HIV-1 RNA	1.2	(log10copy/mL)	(log10copy/mL)

This lab result is more unusual because the sensitivity of the test was able to capture 19 viral load copies. CAREWare had the correct entry at =19. The client's medical provider might explain that the individual can consider themselves viral

RNA, Real Time PCR (Non-Graph	)	· ·	1
HIV-1 RNA by PCR The reportable range for copies HIV-1 RNA/mL.	20 this assay is	copies/mL 20 to 10,000,000	03
log10 HIV-1 RNA	1.301	log10copy/mL	,

The reportable viral load for this individual would be =20 with PCR listed as the assay.

HIV-1 RNA OUANT REAL-TIME PCR 40085		Stage:	Final		
This test was performed using the COBAS(R) A COBAS(R) TaqMan(R) HIV-1 test kit version 2.0 Molecular Systems, Inc.) PATIENT COMMENTS:	mpliPrep/ D. (Roche				
<u>Test</u> HIV-1 RNA ULTRAQUANT LOG	<u>Result</u> 1.68	<u>Units</u> Copies/mL		<u>Fla</u> A	n <mark>g Reference Range</mark> <1.30 NEG
This test was performed using the COBAS(R). COBAS(R) TaqMan(R) HIV-1 test kit version 2 Molecular Systems, Inc.)	AmpliPrep/ 2.0. (Roche				
PATIENT COMMENTS:	****				
HIV-I RNA Quant	48	Copies/mL	,	A	<20 NEG

*The HIV Viral Load would be entered in CAREWare for this client as =48 with Other listed as the assay.* 



		MOLECU	ILAR IN	IMUNOLOGY	
Date Day of Stay Time	02/10/2017 Fri 08:49:00				
Procedure HIV-1 RNA Quant Copies i HIV-1 RNA Quant Logs	97 1.99	Units COPIES/ML Log copies/mL,	Ref Range		5 X
02/10/2017 08:49:00 HIV-1 RNA HIV VL Method: Reverse	Quant Copies:				

*The HIV Viral Load would be =97 in CAREWare with PCR selected as the assay.* 

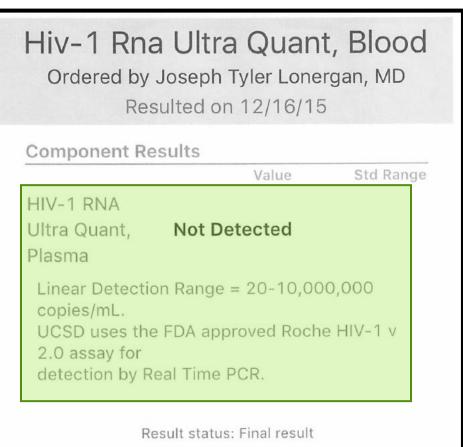
Tests: (5) RNA, Real Time PCR (Non-Graph) (550430)	
HIV-1 RNA by FCR 1140 copies/mL The reportable range for this assay is 20 to 10,000,000 copies HIV-1 RNA/mL.	
log10 HIV-1 RNA 3.057 log10copy/mL	-

*The HIV Viral Load would be =1140 in CAREWare with PCR selected as the assay* 

HIV-1 RNA, QUANTITATIVE REA HIV-1 RNA Quant	L-TIME PCR	<20 NEG copies/mL
HIV-1 RNA Log HIV-1 RNA not detected.	<1.30 NEG	<1.30 NEG copies/mL
This test was performed COBAS(R) TaqMan(R) HIV-1 Molecular Systems, Inc.)	using the COBAS(R) AmpliPrep, test kit version 2.0. (Roch	/ e

Another way you might see the HIV Viral Load is looking at the RNA Quant number. This means the quantity of HIV RNA per milliliter of blood specimen collected.





This lab result is different in that the value is Not Detected – so the indication on what would be entered into CAREWare will come from looking at the detection range of 20 to ten million. Since the lower end of the range is 20, undetectable will be <20.

# RNA HIV-1 RNA, QN, RT PCR VL BOTH

NAME

F HIV-1 RNA by PCR

<20 (coplex/mL) HIV-1 RNA not detected

VALUE

LAB

BN

The reportable range for this assay is 20 to 10,000,000 copies HIV-1 RNA/mL.

*This lab result shows the HIV viral load as <20.* 



Component	Your Value	Star	ndard Range	Flag
HIV Ag/Ab Combo Assay	Reactive	Noi	Reactive	А
Screen is POSITIVE for p24 antigen and The specimen will be sent for HIV-1/H confirmation by immunoassay.				

This lab result is a qualitative immunoassay that detects the presence of a specific HIV antigen (Ag) and HIV antibodies (Ab). This is not a test that indicated quantitative viral load. This can be used for Proof of Diagnosis along with a document of detectable HIV RNA or a different assay that is not the HIV Ag/Ab Combo Assay.

Component	Your Value	Standard Range	Flag
HIV 1/2 Ab Diff	See Below		
associated re-entry p	t be used for blood donor screer protocols, or for screening Huma	ning, n Celí.	
associated re-entry p Tissues, and Celiular	rotocols, or for screening Huma and Tissue-Based Products (HCT	n Celí.	
associated re-entry p	rotocols, or for screening Huma	n Celí.	A
associated re-entry p Tissues, and Celiular	rotocols, or for screening Huma and Tissue-Based Products (HCT	n Celí, /P).	A

1 This lab result is a qualitative immunoassay that detectes the presence of a specific HIV antibody (Abs). This is a lab test that tests for the presence of HIV-1 and HIV-2 antibodies. This can be used for Proof of Diagnosis along with a document of detectable HIV RNA or a different assay that is not the "HIV 1/2 Ab Diff."

Observations	Result	Reference / UoM	Date/Status
HIV-1 RNA Quant <sup>1</sup>	<b>@</b> 41	<20 NEG copies/mL Abnormal (applies to non-numeric results)	02/20/2017 04:37 am
HIV-1 RNA Log <sup>1</sup>	● 1.61	<1.30 NEG copies/mL Abnormal (applies to non-numeric results)	02/20/2017 04:37 am
Vendornote: This test was p COBAS(R) TaqMan Molecular Syste	(R) HIV-1 test ki	e COBAS(R) AmpliPrep/ t version 2.0. (Roche	

*The quantitative HIV Viral Load for this lab is =41.* 



		2		3	Ţ	4	H	5	111 0 11
	2/22/2017 1735	2/22/2017 0214	Π	2/21/2017 0740	1	2/20/2017 1938		2/20/2017 1649	6 2/20/2017
INMUNOCHEMISTRY		·	-i			1.000	Ш	1043	1303
Vitamin 812 -True		1106	1						
Femilin		1093.1	A			••••••••••••••••••••••••••••••••••••••			
Folate -Folic Acid		127		·					
THYROID TESTING		F day F				ļ		+ m L	
TSH	]	0.910							
<b>HEPATITIS TESTING</b>		We for a se							
Hepatitis A Virus				Nogative "					
Hepatitis B Surfac				Negative "					
Hepatitic B Cors A				Negative *					
Hepatitis C Antibody				Negative *					
INFECTIOUS DISEASE			-	Negaure	-		-		
HIV 1/2 Ab Diff						Carl Rate -			
HIV 2 Abs, EIA						See Below *			
HIV Ag/Ab Combo Assay			_			Negative			
HIV Antibody						83 47		$\rightarrow$	Reactive 1
HIV Interp						Negative			
HIV PRNA PCR Copy/MI						HIV Abs Neg "			
HIV RNA PRC Interp	(100 mm m m m m m m m m m m m m m m m m m					→ 2,400,000		No	
HIV-1 RNA PCR log						Detected *			
Influenza A 2009,	Not Detected *					6.1			
Influenza virus A RNA	Negative "								
Influenza virus B RNA	Negative "								
SEROLOGY					4				
Syphilis, Treponem		Non Reactive *							
Stat C-Reactive Pr					••• •				
			_		-			261 4	b.

This combination document can be used as Proof of Diagnosis and current viral load. The Proof of Diagnosis is determined from a detectable viral load of 2,400,000 (two-million, four-hundred-thousand) and an immunoassay of the HIV Ag/Ab Combo Assay. You might notice that the individual is negative for the HIV Antibody test – this means that this sample was collected soon after infection and the body has not yet produced antibodies specific to HIV.

LYMPHOCYTE SUBSET PANEL 1 %CD3(Mature T Cells) Absolute CD3+ Cells %CD4 (Helper Cells)	67	116 L 1 L	57-85 % 840-3060 Cells/uL 30-61 %
Absolute CD4+ Cells		3 L	490-1740 Cells/uL
<pre>%CD8(Suppressor T-Cells) Absolute CD8+ Cells Helper/Suppressor Ratio %CD16+CD56(NK Cells) Absolute NK Cells %CD19 (B Cells)</pre>	21 12	62 H 112 L 0.02 L 35 L	12-42 % 180-1170 Cells/uL 0.86-5.00 Cells/uL 4-25 % 70-760 Cells/uL 6-29 %
Absolute CD19+ Cells Absolute Lymphocytes		20 L 174 L	110-660 Cells/uL 850-3900 Cells/uL

The result to be entered into CAREWare is the Absolute CD4+ Cells value of =3.



Helper	Helper T-Lymph-CD4 CD4					
NAME		VALUE	REFERENCE RANGE	LAB		
F Absolute C	D 4 Helper	543	359-1519 (/uL)	PDLCA		
F % CD 4 Po	s. Lymph.	36.2	30.8-58.5 (%)	SE		

*The result entered into CAREWare is the Absolute CD 4 Helper value of =543* 

Tests: (1) Helper T-Ly Order Note: Clinical	mph-C Info	D4 (505008) rmation: SRC:TH	SRC:RT
Absolute CD 4 Helper			359-1519
B CD 4 Pos. Lymph. WBC RBC Hemoglobin Hematocrit MCV MCH MCHC RDW Platelets Neutrophils Lymphs Monocytes Eos Basos		1.5 % 4.4 x10E3x1000 3.23 x10E6x1000 9.2 g/dL 27.4 % 85 fL 28.5 pg 33.6 g/dL 13.8 % 379 x10E3x1000 53 % 29 % 13 % 4 % 0 %	30.8-58.5 3.4-10.8 4.14-5.80 12.6-17.7 37.5-51.0 79-97 26.6-33.0 31.5-35.7 12.3-15.4 150-379

The result for this lab result may seem odd but the result to be entered into CAREWare for CD4 is the <u>Absolute CD 4 Helper</u> value of =20. The x1000 is not necessary. You can tell that 20 is the correct answer because it is tagged with a [L] meaning it is a low result outside of the range; if it was 20,000 then it would be tagged with a [H].



Helper T-Lymph-CD4 CD4		
COLLECTION DATE	02/03/2017	07/05/2016
Order Date Résult Date Ordering Physician	02/03/2017 02/05/2017 DANKO, REKA	07/06/2016 07/09/2016 SPADONE, IVY
Immature Grans (Abs)	0.0 (0.0-0.1 x10E3/uL)	0.0 (0.0-0.1 x10E3/uL)
Immature Granulocytes	0 (%)	0 (%)
Baso (Absolute)	0.1 (0.0-0.2 x10E3/uL)	0.0 (0.0-0.2 ×10E3/uL)
Hemoglobin	15.7 (12.6-17.7 g/dL)	15.2 (12.6-17.7 g/dL.)
MCV	102 H (79-97 fL)	101 H (79-97 fL)
Eos (Absolute)	1.0 H (0.0-0.4 x10E3/øL)	0.6 H (0.0-0 4 ×10E3(uL)
Absolute CD 4 Heiper	1642 H (359-1519 /uL)	1190 (359-1519 /ul.)
% CD 4 Pos. Lymph.	<del>33.5</del> (30.8-58.5 %)	34.0 (30.8-58.5 %)

The results entered into CAREWare can be both of the Absolute CD 4 Helper entries. The first one on 02/03/17 for =1,642 and for 07/06/16 for =1,190.

CD4/T-HELPER CELL PROFILE esuit Date: 04/13/18 09:41 AM Analyte	Result Value	Ref. Range	Units
WHITE BLOOD CELL COUNT	5.8	3.8-10.8	k/uL
LYMPHOCYTES	31.3		%
Lymphocytes	1899	850-3900	Cells/ui
CD4+,CD3+(Helpers)	675	490-1740	Celis/uL
CD4,CD3+(%Helpers)	36	30-61	%
CD8+,CD3+(Suppressors)	722	180-1170	Cells/uL
CD4/CD8 Ratio	0.94	0.86-5.00	ratio

Figure 2 – These results indicates the CD4+/CD3+ (Helpers) rather than the CD4+ alone. CD3s represent the total number of T lymphocytes. All T Cell Lympocytes (immune cells) have CD3 receptors on them but they can either have CD4 receptors or CD8 receptors. The result entered into CAREWare would be =675.