

OVERVIEW

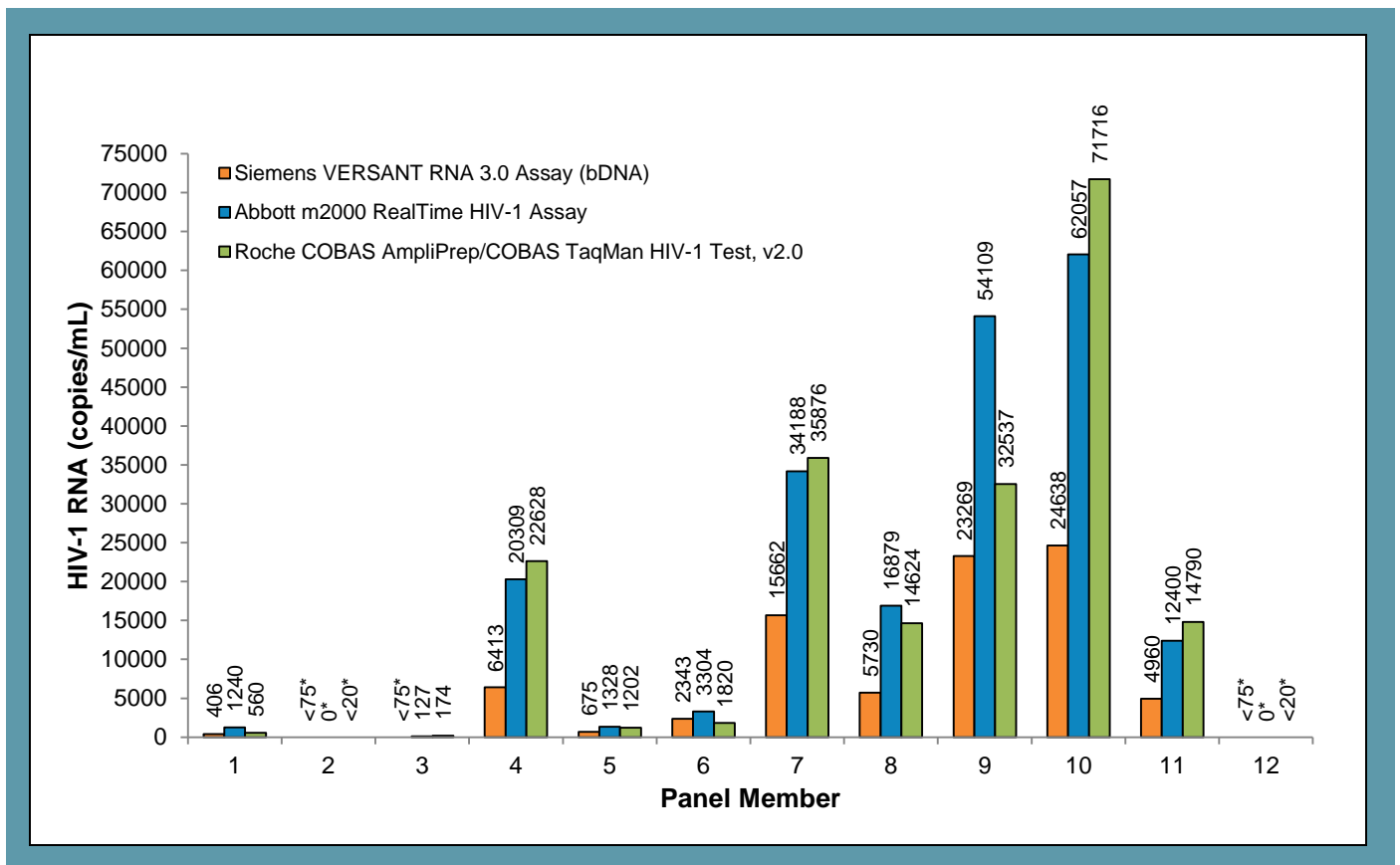
HIV-1 RNA EDTA AccuSet™ Performance Panel (0800-0315) is a 12-member validation panel of undiluted, naturally occurring plasma samples collected in K2 EDTA. Panel members represent bleeds from multiple individuals positive for HIV-1 RNA with varying viral loads. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HIV RNA, p24 antigen, antigen/antibody, and antibody assays are included for characterization of the panel members. This panel of human plasma samples demonstrates reactivity ranging from negative to high positive for HIV-1 RNA. One sample is included as a non-reactive sample and is negative for all HIV test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested for HIV-1 RNA and most panel members were found positive. This does not ensure the absence of these or other human pathogens.

HIV-1 RNA EDTA AccuSet™ Performance Panel



This graph demonstrates HIV-1 RNA viral load amongst panel members utilizing test results from the Siemens VERSANT® RNA 3.0 Assay (bDNA), Abbott m2000 RealTime HIV-1 Assay, and Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 v2.0 Test.

*Results with an asterisk indicate "Not Detected".

HIV-1 RNA EDTA AccuSet™ Performance Panel

0800-0315

DATA SHEET

Panel Member Information

Panel Member	SeraCare Batch #
01	10047508
02	10056461
03	10047514
04	10047519
05	10044233
06	10056463
07	10047518
08	10047515
09	10047517
10	10047520
11	10057462
12	10057427

HIV-1 RNA

Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 (c/mL) ^{1,2}	Siemens VERSANT® HIV-1 RNA 3.0 Assay (bDNA) (c/mL) ¹	Abbott m2000 RealTime HIV-1 Assay (c/mL) ¹	GEN-PROBE® APTIMA® HIV-1 RNA Qualitative Assay
01	560	406	1240	Reactive
02	Not Detected	Not Detected	Not Detected	Reactive
03	174	Not Detected	127	Reactive
04	22628	6413	20309	Reactive
05	1202	675	1328	Reactive
06	1820	2343	3304	Reactive
07	35876	15662	34188	Reactive
08	14624	5730	16879	Reactive
09	32537	23269	54109	Reactive
10	71716	24638	62057	Reactive
11	14790	4960	12400	Reactive
12	Not Detected	Not Detected	Not Detected	Non-Reactive
Test Date	04-Nov-14/19-Dec-14	17-Dec-14	19-Dec-14	23-Dec-14
Test Site	RL	RL	RL	RL
Kit Part Code	NA	NA	NA	NA
Kit Lot No.	NA	NA	NA	NA
Kit Exp. Date	NA	NA	NA	NA
Kit Regulatory Status	IVD/CE	IVD/CE	IVD	IVD

¹Results are reported as copies per mL (c/mL); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking



DATA SHEET

HIV p24 Antigen and Antigen/Antibody

Panel Member	Perkin Elmer HIV-1 p24 Antigen ELISA (s/co) ^{1,2}	Abbott ARCHITECT HIV Ag/Ab Combo (s/co) ^{1,2}
01	0.47	879.98*
02	0.09	526.00*
03	0.14	748.91*
04	0.14	487.25*
05	0.02	725.51*
06	0.14	9.65
07	0.07	853.79*
08	0.13	591.78*
09	0.06	862.28*
10	0.04	750.84*
11	6.86	923.39*
12	0.16	0.30
Test Date	30-Dec-14	17-Dec-14
Test Site	SC	SC
Kit Part Code	NEK050A	2P36
Kit Lot No.	990-14361	45303LI00
Kit Exp. Date	01-May-15	19-Jul-15
Kit Regulatory Status	RUO	IVD/CE

¹Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

*Above the limit of reactivity (ALR)

SC = SeraCare; RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

DATA SHEET

HIV Antibody

Panel Member	Abbott PRISM HIV O Plus (s/co) ^{1,2}	Bio-Rad Genetic Systems™ HIV-1/HIV-2 Plus O EIA ²	Bio-Rad Genetic Systems™ HIV-1 Western Blot	Cambridge Biotech HIV-1 Western Blot	Bio-Rad Multispot HIV-1/HIV-2 Rapid Test ² HIV-1	HIV-2
01	102.92	Reactive	Positive	Positive	Positive	Negative
02	139.46	Reactive	Positive	Positive	Positive	Negative
03	108.06	Reactive	Positive	Positive	Positive	Negative
04	119.36	Reactive	Positive	Positive	Positive	Negative
05	121.22	Reactive	Positive	Positive	Positive	Negative
06	36.41	Indeterminate ³	Indeterminate	Indeterminate	Positive	Negative
07	130.02	Indeterminate ³	Positive	Positive	Positive	Negative
08	110.09	Reactive	Positive	Positive	Positive	Negative
09	122.98	Reactive	Positive	Positive	Positive	Negative
10	114.58	Reactive	Positive	Positive	Positive	Negative
11	118.38	Reactive	Positive	Positive	Positive	Negative
12	0.30	Non-Reactive	Negative	Negative	Negative	Negative
Test Date	18-Dec-14	18-Dec-14	29-Dec-14	22-Dec-14	23-Dec-14	
Test Site	RL	RL	SC	SC	SC	
Kit Part Code	NA	NA	32508	98002	25228	
Kit Lot No.	NA	NA	64002767	A5336-024	11131771	
Kit Exp. Date	NA	NA	11-June-15	02-Dec-15	01-Aug-15	
Kit Regulatory Status	IVD	IVD/CE	IVD	IVD	IVD/CE	

¹Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

³First result = reactive; second result = non-reactive

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The Package Insert for this panel in PDF form can be found at www.seracare.com

A printed copy of the Package Insert or Data Sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400

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- AccuVert™ Seroconversion Panels
- Disease State Biological Materials
- ACCURUN® independent quality controls
- SeraCon™ and Basematrix Processed Plasma

