HIV-1 Group O AccuSet™ Performance Panel

DATA SHEET

0800-0262

OVERVIEW

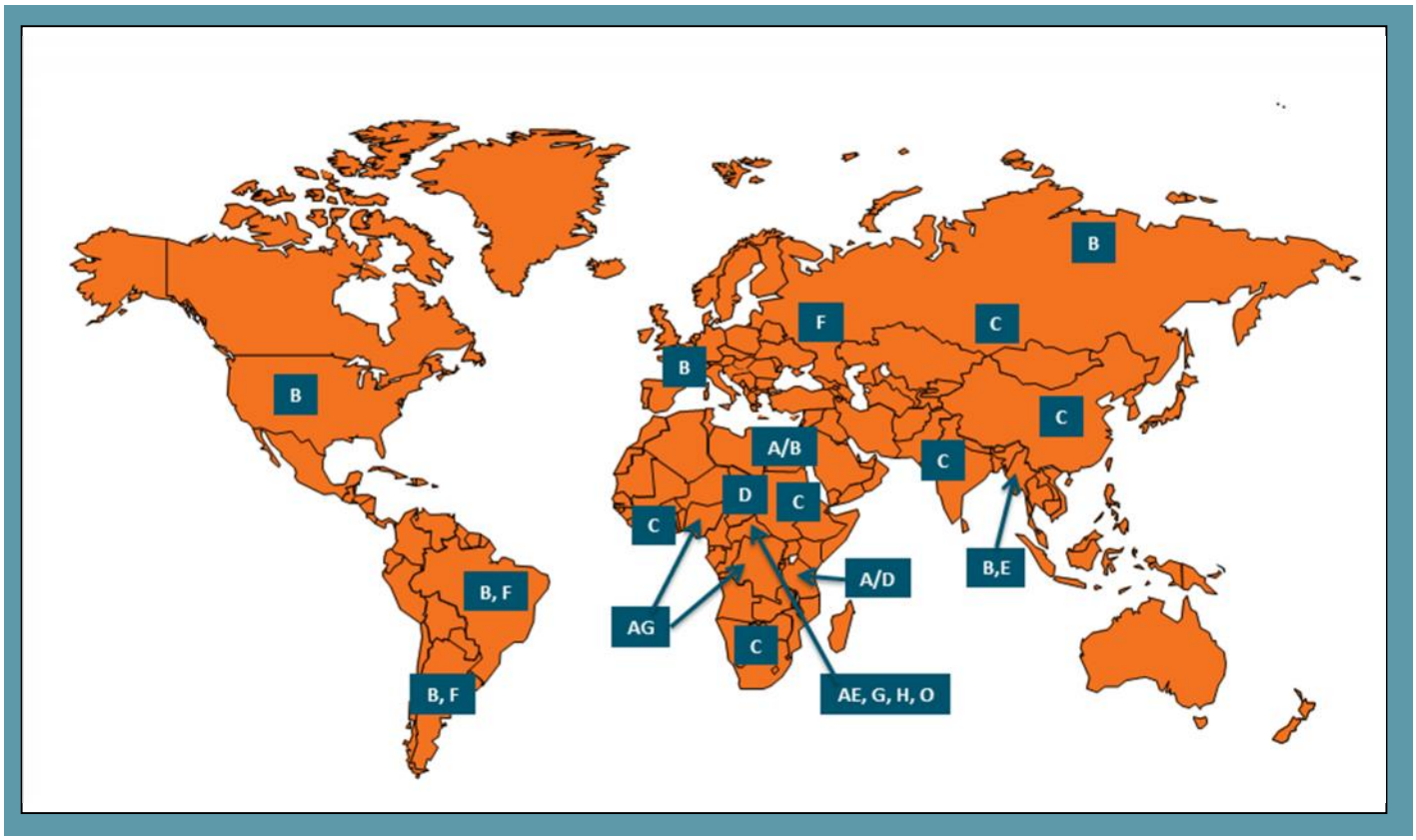
HIV-1 Group O AccuSet™ Performance Panel (0800-0262) is a 5-member panel of formulated human plasma samples representing unique HIV-1 group O isolates from Cameroon, USA, and Spain.

Four panel members were prepared using HIV-1 group O AccuType™ viral isolates diluted in defibrinated plasma negative for anti-HIV-1/2, anti-HCV, HBsAg, and HIV-1 RNA. One non-reactive panel member (diluent only) is also included. Sodium azide (0.09%) was added as a preservative. Test results from commercially-available HIV-1 RNA assays are included for characterization of the panel members.

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. Positive HIV-1 group O panel members are reactive for HIV-1 RNA and HIV-1 p24 antigen. All panel members are manufactured using plasma negative for anti-HIV-1/2, anti-HCV, HBsAg, and HIV-1 RNA. This does not ensure the absence of these or other human pathogens.

Worldwide Distribution of HIV-1 Genotypes



Reference: Spira S, et al. Impact of clade diversity on HIV-1 virulence, antiretroviral drug sensitivity and drug resistance. Journal of Antimicrobial Chemotherapy; 2003:51:229-240. Illustration adapted from Figure 1 – Subtype diversity of HIV-1 infections prevalent worldwide.

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HIV-1 Genotype

Panel Member	Country of Origin	Isolate ID	Genotype[1]
01	Cameroon	BCF06	O
02	Cameroon	BCF11	O
03	USA	I-2478B	O
04	Spain	I-2481	O
05	N/A	N/A	N/A
Test Date			NA
Test Site			RL
Kit Part Code			NA
Kit Lot No.			NA
Kit Exp Date			NA
Kit Regulatory Status			NA

HIV-1 RNA

Panel Member	Genotype[1]	Roche COBAS® Ampliprep/COBAS® Taqman® HIV-1 Test, v2.0 (c/mL)[2]	Abbott M2000 RealTi*me* HIV-1 Assay (c/mL)[2]	Siemens VERSANT® HIV-1 RNA 3.0 Assay (bDNA) (c/mL)[2]
01	O	**65008**	**25125**	**963**
02	O	**100740**	**55976**	**1321**
03	O	**63927**	**62398**	**522**
04	O	**36454**	**167728**	**2844**
05	N/A	<20	BLD	<75
Test Date		13-Sep-11	15-Sep-14	11-Sep-14
Test Site		RL	RL	RL
Kit Part Code		NA	NA	NA
Kit Lot No.		NA	NA	NA
Kit Exp Date		NA	NA	NA
Kit Regulatory Status		IVD/CE	IVD/CE	IVD/CE

[1]Members 1 and 2 (viral isolates) originate from the NED Panel (NIH-ENVA-DOD), an international HIV-1 subtype reference panel. Reference: Huang D, et al. Sequence Characterization of the Protease and Partial Reverse Transcriptase Proteins of the NED Panel, an International HIV Type 1 Subtype Reference and Standards Panel. AIDS Research and Human Retroviruses 2003;19:321-328. Members 3 and 4 (viral isolates) were genotyped using PCR/sequencing methods at external reference laboratories. Member 5 is comprised of diluent only. [2]Results are reported as copies per mL (c/mL); positive/reactive results are noted in bold red; results are reported as the mean result of duplicate testing. RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic, N/A = Not Applicable

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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