

OVERVIEW

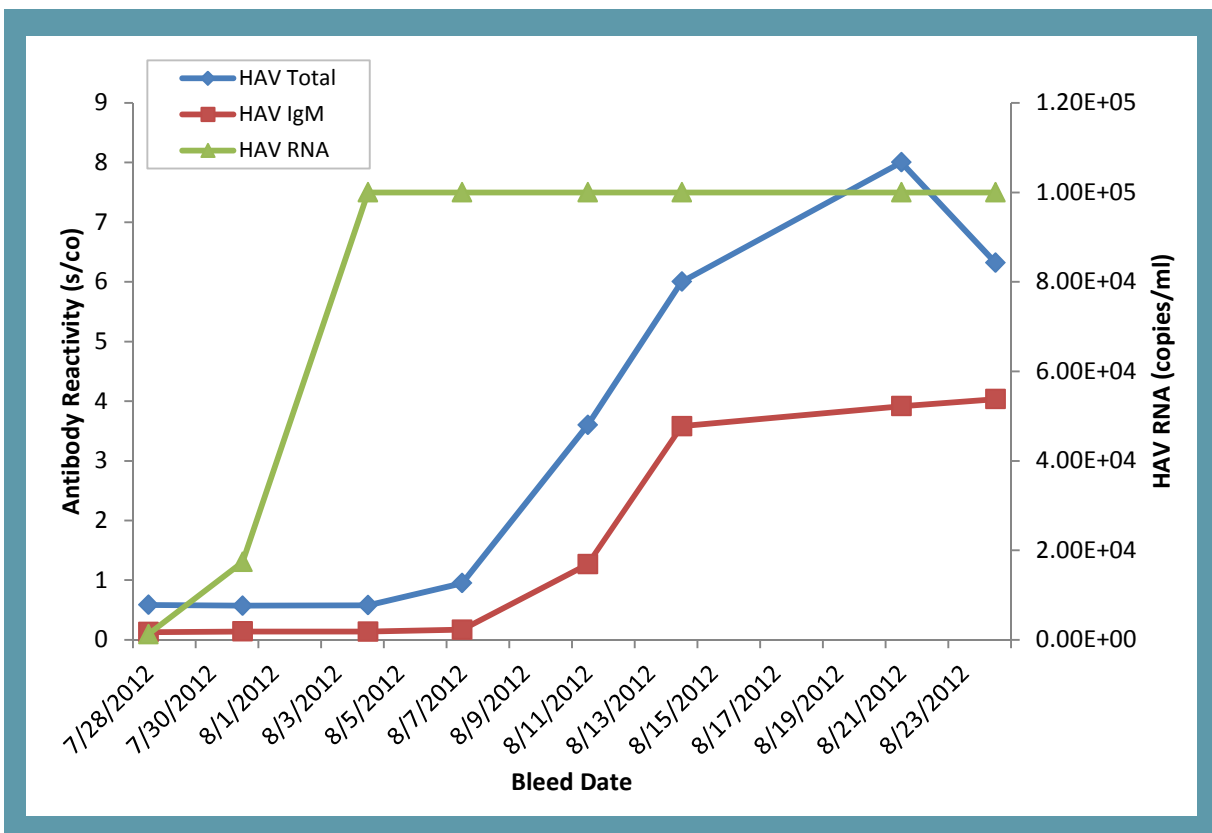
Hepatitis A (HAV) AccuVert™ Seroconversion Panel (0615-0026) is an 8-member panel of undiluted, naturally occurring plasma samples. Panel members represent serial bleeds collected from a single patient over the course of 27 days during the development of HAV infection and subsequent response. No preservatives were added.

Test results from commercially-available HAV antibody assays are included for characterization of the panel members. This panel of human plasma samples is positive for HAV RNA and demonstrates a change in expression from negative to positive for HAV antibody during the development and progression of HAV infection.

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. All panel members were found negative for HBsAg, anti-HIV, and anti-HCV.

Expression of Hepatitis A (HAV) Markers during Progression of Infection



This graph demonstrates the development and progression of an early HAV infection from a single individual. HAV antibody reactivity is measured with Abbott AxSYM HAV total antibody and IgM antibody test results. HAV RNA is measured with quantitative real-time PCR analysis.

Hepatitis A (HAV) AccuVert™ Seroconversion Panel

0615-0026

DATA SHEET

HAV RNA

Panel Member	Bleed Date	Days Since 1 st Bleed	RNA Hepatitis A Virus (c/ml) ¹
01	28-Jul-12	0	1.26 x 10³
02	31-Jul-12	3	1.74 x 10⁴
03	04-Aug-12	7	>1.00 x 10⁵
04	07-Aug-12	10	>1.00 x 10⁵
05	11-Aug-12	14	>1.00 x 10⁵
06	14-Aug-12	17	>1.00 x 10⁵
07	21-Aug-12	24	>1.00 x 10⁵
08	24-Aug-12	27	>1.00 x 10⁵
Test Date	29-Jul-13		
Test Site	RL		
Kit Part Code	NA		
Kit Lot No.	NA		
Kit Exp Date	NA		
Kit Regulatory Status	RUO		

¹Results are reported as HAV genomic copies per ml. Results in bold red are considered positive/reactive. Quantitative real-time PCR test performed at Laboratori de Seguretat Transfusional (Spain).

HAV Total Antibody

Panel Member	Bleed Date	Days Since 1 st Bleed	Abbott ARCHITECT HAV Total (s/co) ^{1,2}	Abbott AxSYM HAV Total (co/s) ³
01	28-Jul-12	0	0.6	0.6
02	31-Jul-12	3	0.5	0.6
03	04-Aug-12	7	0.4	0.6
04	07-Aug-12	10	0.3	0.9
05	11-Aug-12	14	0.4	3.6
06	14-Aug-12	17	1.4	6.0
07	21-Aug-12	24	4.4	8.0
08	24-Aug-12	27	5.6	6.3
Test Date	20-Dec-13		03-Oct-12	
Test Site	SC		SC	
Kit Part Code	6L27		8D21-20	
Kit Lot No.	29281LI00		16499M500	
Kit Exp Date	26-Feb-14		08-Nov-12	
Kit Regulatory Status	IVD/CE		IVD/CE	

¹Results are reported as a signal to cut-off value (s/co). Values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red. ²Results are reported as the mean result of duplicate testing. ³Results are reported as a cut-off to signal value (co/s). Values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red.

SC = SeraCare; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking



Hepatitis A (HAV) AccuVert™ Seroconversion Panel

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DATA SHEET

HAV IgM Antibody

Panel Member	Bleed Date	Days Since 1 st Bleed	DiaSorin ETI-HA-IGMK PLUS HAV IgM (s/co) ^{2,3}	Abbott AxSYM HAV IgM (s/co) ^{1,2}
01	28-Jul-12	0	<1.1	0.1
02	31-Jul-12	3	<1.1	0.1
03	04-Aug-12	7	<1.1	0.1
04	07-Aug-12	10	<1.1	0.2
05	11-Aug-12	14	3.3	1.3
06	14-Aug-12	17	6.2	3.6
07	21-Aug-12	24	6.2	3.9
08	24-Aug-12	27	6.0	4.0
Test Date			19-Dec-13	01-Oct-12
Test Site			SC	SC
Kit Part Code			P001925	5E20-20
Kit Lot No.			9850390A	11356M500
Kit Exp Date			29-Apr-14	20-Oct-12
Kit Regulatory Status			IVD/CE	IVD/CE

¹Results are reported as a signal to cut-off value (s/co). Values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red.

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

³Results are reported as a signal to cut-off value (s/co). Values greater than 1.1 are considered positive/reactive and are noted in bold red.

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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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