AccuSet™ CMV Performance Panel

0820-0389 / Batch #10401686

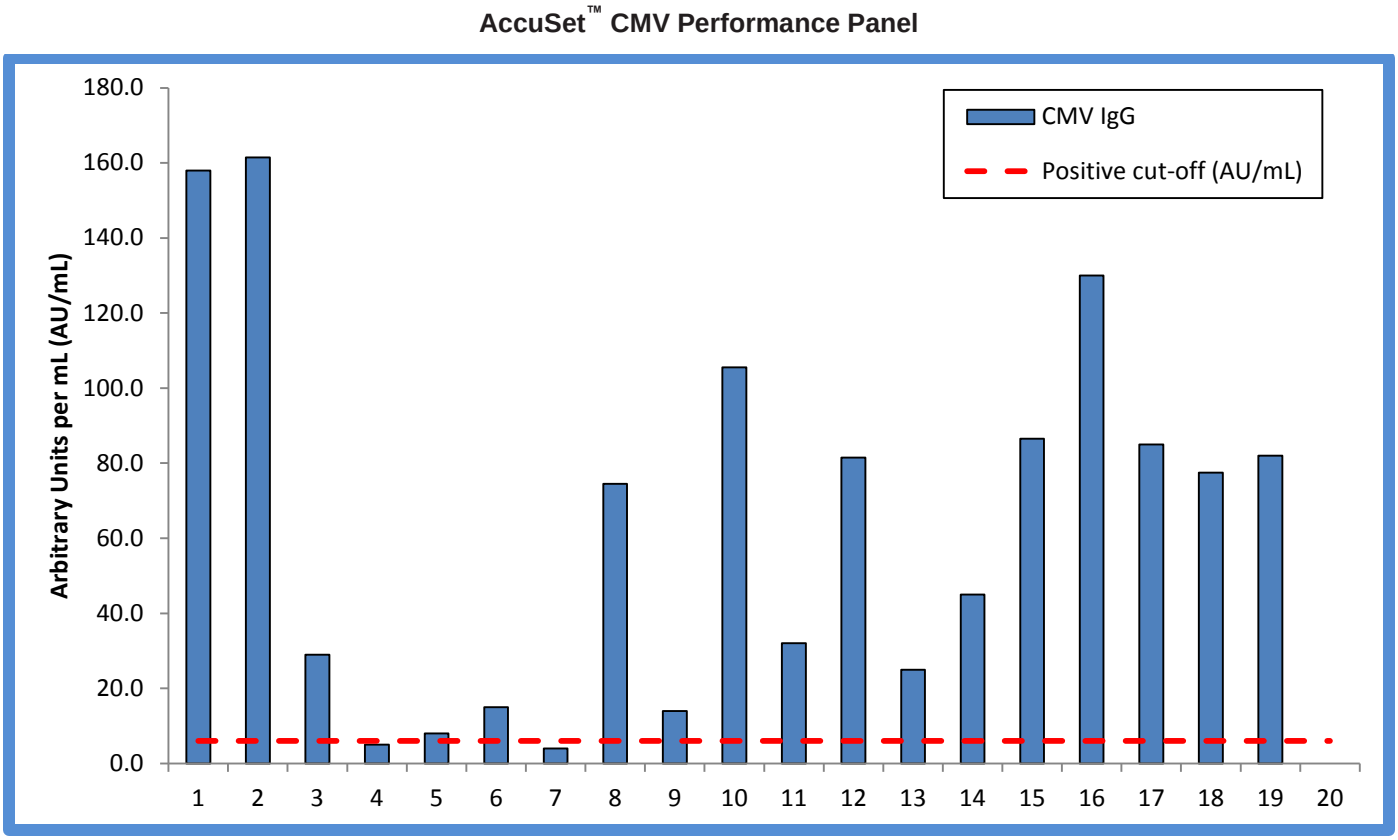
OVERVIEW

AccuSet™ CMV Performance Panel 0820-0389 / Batch #10401686 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to CMV. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available CMV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivities for several CMV test methods. One sample is included as a non-reactive sample and is negative for all CMV test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are offered 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 and found negative for anti-HIV-1/2, HBsAg, and anti-HCV. This does not ensure the absence of these or other human pathogens.



This graph demonstrates reactivity amongst panel members from the BioMerieux VIDAS® CMV IgG Assay.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9250933	BD110740	16-Mar-2011
02	9250934	BD110740	18-Mar-2011
03	BM217339	BD103226	24-Feb-2007
04	10349331	BD375507	16-Feb-2017
05	10349334	BD375508	02-Feb-2017
06	10350909	BD375503	26-Nov-2017
07	10350921	BD375500	17-Apr-2018
08	10371963	BD386382	20-Oct-2017
09	10371968	BD340647	09-Feb-2017
10	BM217749	BD105345	24-Jul-2007
11	BM204423	BD101653	17-Nov-2005
12	9160450	NA	NA
13	BM216648	NA	NA
14	BM204440	BD101592	14-Nov-2005
15	BM204768	BD101886	13-Jan-2006
16	9265286	BD111441	26-Dec-2012
17	BM204896	BD102086	05-Feb-2006
18	BM204208	BD101589	09-Nov-2005
19	BM216710	NA	NA
20	9245209	NA	26-Sep-2009

NA = Not Available

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CMV DNA, CMV Total

Panel Member	Roche COBAS® AmpliPrep/COBAS® TaqMan® CMV Test (IU/mL)[1]	Beckman Coulter PK® CMV-PA System[2]
01	TND	**POS**
02	TND	**POS**
03	TND	**POS**
04	TND	NEG
05	TND	**POS**
06	TND	**POS**
07	TND	**POS**
08	TND	**POS**
09	<137.0	**POS**
10	TND	**POS**
11	TND	**POS**
12	TND	**POS**
13	TND	**POS**
14	TND	**POS**
15	TND	**POS**
16	TND	**POS**
17	TND	**POS**
18	TND	**POS**
19	TND	**POS**
20	TND	NEG
Test Date	03-Apr-2019	02-Apr-2019
Test Site	RL	RL
Kit Part Code	NA	NA
Kit Lot No.	E18158	NA
Kit Exp. Date	31-Jul-2020	NA
Kit Regulatory Status	IVD	BDS

[1]Results are reported as international units per mL (IU/mL).
[2]Positive/reactive results are noted in bold red.
TND = Target Not Detected; POS = Positive; NEG = Negative
RL = Reference Lab; NA = Not Available
IVD = In Vitro Diagnostic; BDS = Approved for blood donor screening

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CMV IgM

Panel Member	Abbott ARCHITECT CMV IgM (Index)[1,6]	BioMerieux VIDAS® CMV IgM Assay (TV)[2,6]	DiaSorin LIAISON® CMV IgM Assay (AU/mL)[3,6]	Roche Elecsys CMV IgM (COI)[4,6]	Trinity Biotech Captia™ CMV IgM ELISA (ISR)[5,6]
01	**1.9**	**1.2**	**94.5**	0.6	**3.1**
02	**1.7**	**1.1**	**86.9**	0.6	**2.8**
03	**5.3**	**1.4**	**84.7**	0.4	**1.5**
04	**1.1**	0.2	34.6[7]	0.3	**2.8**
05	**11.6**	**2.1**	**229.0, >240.0**	**1.1**	**7.4**
06	**4.2**	**2.0**	**226.0**	**6.7**	**7.3**
07	**8.4**	**1.9**	**178.0**	0.8[7]	**6.0**
08	**4.2**	**1.9**	**126.5**	**4.7**	**6.0**
09	**9.4**	**2.4**	**>240.0**	**12.6**	**6.8**
10	0.2	0.1	<8.0	0.2	0.2
11	0.1	0.0	<8.0	0.2	0.1
12	0.3	0.1	<8.0	0.3	0.6
13	0.2	0.0	<8.0	0.2	0.1
14	0.2	0.1	<8.0	0.2	0.2
15	0.1	0.0	<8.0	0.2	0.2
16	0.1	0.0	<8.0	0.2	0.0
17	0.9[7]	0.5	12.3	1.0[7]	**2.1**
18	0.6	0.4	14.6	0.4	0.8
19	0.6	0.1	19.9	0.2	**1.6**
20	0.1	0.0	<8.0	0.2	0.2
Test Date	08-Apr-2019	02-Apr-2019	03-Apr-2019	12-Apr-2019	29-Mar-2019
Test Site	RL	RL	RL	RL	SC
Kit Part Code	NA	NA	NA	NA	2325260
Kit Lot No.	95075FN00	1006841910	012042	NA	2325260-075
Kit Exp. Date	28-Nov-2019	24-Aug-2019	03-Nov-2019	NA	28-Feb-2020
Kit Regulatory Status	IVD/CE	IVD	IVD	CE	IVD/CE

[1]Results are reported as Index value (Index); positive/reactive results are noted in bold red.
[2]Results are reported as Test Value (TV); positive/reactive results are noted in bold red.
[3]Results are reported as Arbitrary Units per milliliter (AU/mL); positive/reactive results are noted in bold red.
[4]Results are reported as Cut-Off Index (COI); positive/reactive results are noted in bold red.
[5]Results are reported as Immune Status Ratio (ISR); positive/reactive results are noted in bold red.
[6]Results are reported as the mean result of duplicate testing.
[7]Result is reported within the assay's equivocal range.
RL = Reference Lab; SC = SeraCare; NA = Not Available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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CMV IgG

Panel Member	Abbott ARCHITECT CMV IgG (AU/mL)[1,4]	BioMerieux VIDAS® CMV IgG Assay (AU/mL)[1,4]	DiaSorin LIAISON® CMV IgG Assay (U/mL)[2,4]	Roche Elecsys CMV IgG (U/mL)[2,4]	Trinity Biotech Captia™ CMV IgG ELISA (ISR)[3,4]
01	**>250.0**	**158.0**	**>10.0**	**>500.0**	**5.9**
02	**>250.0**	**161.5**	**>10.0**	**>500.0**	**5.7**
03	**57.8**	**29.0**	**2.4**	**24.3**	**2.2**
04	2.0	5.0[5]	0.3	0.2	0.2
05	**49.5**	**8.0**	**0.9**	0.7	**1.8**
06	**60.0**	**15.0**	**1.6**	**7.2**	**2.8**
07	**22.5**	4.0[5]	0.3	0.2	1.0[5]
08	**247.1, >250.0**	**74.5**	**>10.0**	**305.5**	**5.2**
09	**171.0**	**14.0**	**2.4**	**11.3**	**1.3**
10	**246.0**	**105.5**	**6.7**	**444.4**	**4.1**
11	**73.0**	**32.0**	**3.2**	**106.4**	**2.5**
12	**230.2**	**81.5**	**5.5**	**>500.0**	**4.6**
13	**60.0**	**25.0**	**1.4**	**62.1**	**2.6**
14	**123.0**	**45.0**	**4.1**	**289.4**	**3.3**
15	**187.1**	**86.5**	**5.0**	**>500.0**	**3.2**
16	**249.4, >250.0**	**130.0**	**>10.0**	**441.0**	**5.7**
17	**179.7**	**85.0**	**8.3**	**385.6**	**4.8**
18	**178.1**	**77.5**	**4.2**	**420.3**	**3.1**
19	**248.4, >250.0**	**82.0**	**5.3**	**239.8**	**3.7**
20	0.3	<4.0	<0.2	0.2	0.2
Test Date	8-Apr-2019	2-Apr-2019	3-Apr-2019	12-Apr-2019	2-Apr-2019
Test Site	RL	RL	RL	RL	SC
Kit Part Code	NA	NA	NA	NA	2325200
Kit Lot No.	94399FN00	1003842540	011046	NA	2325200-584
Kit Exp. Date	13-Dec-2019	22-Aug-2019	22-Sep-2019	NA	29-Feb-2020
Kit Regulatory Status	IVD/CE	IVD	IVD/CE	CE	IVD/CE

[1]Results are reported as Arbitrary Units per mL (AU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as Units per mL (U/mL); positive/reactive results are noted in bold red.
[3]Results are reported as Immune Status Ratio (ISR); positive/reactive results are noted in bold red.
[4]Results are reported as the mean result of duplicate testing.
[5]Result is reported within the assay's equivocal range.
RL = Reference Lab; SC = SeraCare; NA = Not available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

The package insert for this panel 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.