AccuSet™ Rubella Performance Panel

0820-0347 / Batch #10373406

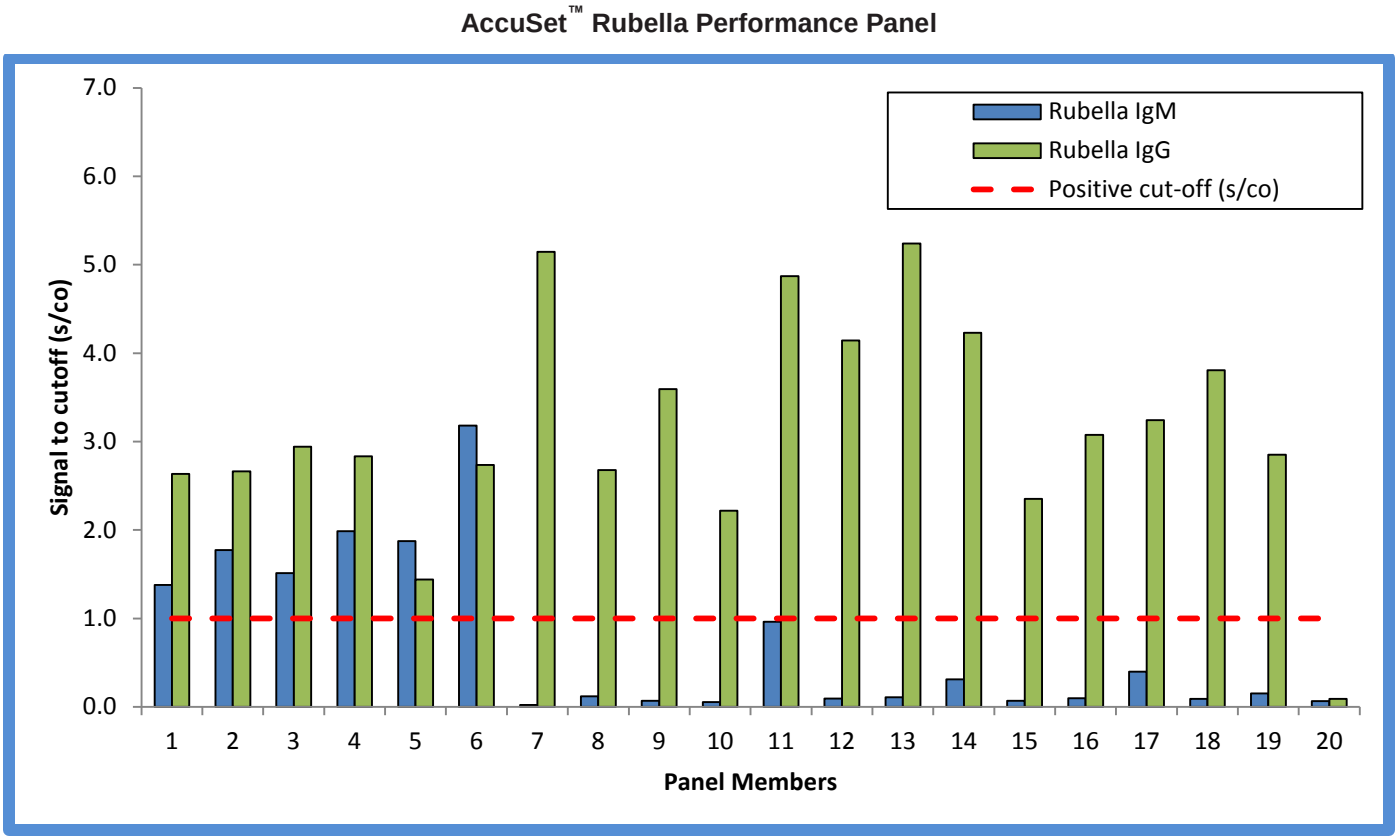
OVERVIEW

AccuSet™ Rubella Performance Panel (0820-0347) 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 rubella. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available rubella assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity on several anti-rubella test methods. One sample is included as a non-reactive sample and is negative for all rubella 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 among panel members from the Trinity Biotech Captia™ Rubella IgM and Rubella IgG assays.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	10328972	BD217646	05-May-2008
02	10328973	BD365251	16-Aug-2016
03	10328975	BD327901	04-Oct-2016
04	10355281	BD375517	24-Apr-2018
05	10363706	BD323118	27-Dec-2016
06	10363709	BD328432	11-Apr-2017
07	BM217347	NA	21-Nov-2006
08	BM216692	NA	29-Aug-2008
09	9246570	BD110198	25-Jan-2010
10	BM203089	BD101596	07-Nov-2005
11	BM204891	BD102085	04-Feb-2006
12	9254590	BD110997	01-Jun-2011
13	9254597	BD110998	13-Jul-2011
14	BM216716	NA	21-Sep-1999
15	9254585	BD110992	15-Jul-2011
16	9254582	BD110989	21-Jul-2011
17	9254581	BD110988	21-Jul-2011
18	9254578	BD110987	29-Jun-2011
19	9254574	BD110985	08-Jul-2011
20	9254572	BD110983	18-Jul-2011

NA = Not Available

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Rubella IgM

Panel Member	DiaSorin LIAISON Rubella IgM (AU/mL)[1,5]	Roche Elecsys Rubella IgM (COI)[2,5]	Zeus Rubella IgM ELISA (S/CO)[3,5]	Trinity Biotech Rubella IgM ELISA (S/CO)[3,5]	Bio-Rad Rubella IgM EIA (INDEX)[4,5]
01	**66.1**	**1.9**	**2.3**	**1.4**	**4.3**
02	**86.3**	**2.4**	**2.0**	**1.8**	**3.9**
03	**123.0**	**5.8**	**2.2**	**1.5**	**4.7**
04	**98.7**	**9.7**	**1.7**	**2.0**	**4.4**
05	**214.0**	**5.7**	**3.1**	**1.9**	**5.1**
06	**138.5**	**2.4**	**2.3**	**3.2**	**7.4**
07	<10.0	0.2	0.1	0.0	0.2
08	<10.0	0.2	0.4	0.1	0.4
09	<10.0	0.2	0.2	0.1	0.2
10	<10.0	0.3	0.1	0.1	0.1
11	**39.0**	**1.8**	**1.0**	**1.0**	**1.9**
12	10.7	0.4	0.1	0.1	0.1
13	<10.0	0.2	0.1	0.1	0.2
14	<10.0	0.2	0.5	0.3	0.7
15	<10.0	0.3	0.1	0.1	0.1
16	<10.0	0.3	0.3	0.1	0.2
17	<10.0	0.3	0.4	0.4	0.8
18	<10.0	0.2	0.2	0.1	0.5
19	<10.0	0.2	0.2	0.2	0.3
20	<10.0	0.2	0.1	0.1	0.1
Test Date	03-Oct-2018	12-Oct-2018	03-Oct-2018	28-Sep-2018	12-Oct-2018
Test Site	RL	RL	SC	SC	SC
Kit Part Code	NA	NA	9Z9801M	2325360	25174
Kit Lot No.	178018	NA	18050160	2325360-088	D15018
Kit Exp. Date	05-Sep-2019	NA	30-Nov-2019	31-May-2019	30-Apr-2019
Kit Regulatory Status	IVD	IVD/CE	IVD/CE	IVD/CE	IVD

[1]Results are reported as Arbitrary Units per mL (AU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as Cut Off over Index (COI); positive/reactive results are noted in bold red.
[3]Results are reported as Signal to Cut Off ratio (S/CO); positive/reactive results are noted in bold red.
[4]Results are reported as Index Value (INDEX); positive/reactive results are noted in bold red.
[5]Results are reported as the mean result of duplicate testing.
RL = Reference Lab; SC = SeraCare; NA = Not available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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Rubella IgG

Panel Member	DiaSorin LIAISON Rubella IgG (INDEX)[1,4]	Roche Elecsys Rubella IgG (IU/mL)[2,4]	Trinity Biotech Rubella IgG ELISA (S/CO)[3,4]	Zeus Rubella IgG ELISA (S/CO)[3,4]
01	**5.1**	**12.1**	**2.6**	**3.9**
02	**5.8**	**19.5**	**2.7**	**4.4**
03	**8.4**	**26.7**	**2.9**	**4.4**
04	**7.8**	**15.4**	**2.8**	**4.0**
05	**1.9**	3.9	**1.4**	**2.1**
06	**2.6**	7.4	**2.7**	**3.3**
07	**>33.0**	**500.0**	**5.1**	**6.3**
08	**3.5**	**93.8**	**2.7**	**3.3**
09	**10.8**	**90.9**	**3.6**	**4.8**
10	**2.0**	**240.0**	**2.2**	**2.1**
11	**16.0**	**500.0**	**4.9**	**6.4**
12	**>33.0**	**500.0**	**4.1**	**5.7**
13	**>33.0**	**500.0**	**5.2**	**6.7**
14	**15.6**	**191.9**	**4.2**	**5.7**
15	**2.5**	**34.8**	**2.4**	**3.0**
16	**10.0**	**386.8**	**3.1**	**4.1**
17	**10.2**	**500.0**	**3.2**	**4.1**
18	**>33.0**	**500.0**	**3.8**	**6.6**
19	**3.7**	**203.2**	**2.9**	**3.3**
20	<10.0	0.2	0.1	0.1
Test Date	04-Oct-2018	12-Oct-2018	28-Sep-2018	01-Oct-2018
Test Site	RL	RL	SC	SC
Kit Part Code	NA	NA	2325300	9Z9801G
Kit Lot No.	NA	NA	2325300-588	18060255
Kit Exp. Date	NA	NA	31-Aug-2019	30-Nov-2019
Kit Regulatory Status	IVD	IVD/CE	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 International Units per mL (IU/mL); positive/reactive results are noted in bold red.
[3]Results are reported as Signal to Cut Off ratio (S/CO); positive/reactive results are noted in bold red.
[4]Results are reported as the mean result of duplicate testing.
RL = Reference Lab; SC = SeraCare; NA = Not available
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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.