

SURVEY AN2:2009:2A & 2B RUBELLA SEROLOGY

Report prepared and collated by: RCPA Serology QAP
Review discussion for and on behalf of RCPA Serology QAP by:
Tony Panayotou, Southern Cross Pathology, VIC



NATA Accredited Proficiency Testing Scheme Provider Number: 14863. This facility is accredited by the National Association of Testing Authorities, Australia and complies with the requirements of ILAC G13. **Site Number: 15003**

Kit Performance

It is up to all users to form their own opinion or conclusions on each kit's performance based on the accumulation of data and information that is supplied by this survey, and other information available to the participant. A variety of samples are used in this Program (straight, undiluted serum; diluted serum and pooled serum) and this can sometimes impact on results and performance of some kits. With serum specimens, occasional artefactual problems are encountered with some kits due to changes in the matrix caused by rethrombinisation of plasma or dilution.

Copyright

This material is copyright and may not be used in any form for advertising, sales promotion or publicity. The material may not be reproduced in whole or in part for any purpose whatsoever (including presentations at meetings and conferences), without the prior written permission of the RCPA Quality Assurance Programs Pty Limited. Permission must be sought in writing from the Program Chair or Program Manager but will not be unreasonably refused.

Confidentiality

RCPA Quality Assurance Programs Pty Ltd keeps all participant details confidential. Such details will not be disclosed to a third party, unless required by legislation, without the prior written consent of the participant.

Request

You are provided with sera from two pregnant women. Each serum requires antenatal screening for rubella. Test in the same manner as patient specimens.

Specimen Details

Samples are of human origin and tested negative for hepatitis C antibody and HIV. (Ref. 2009 SQA Program Plan section AN2 – 2)

2A is serum positive for HBsAg diluted with serum negative for HBsAg. All specimens were converted from plasma by the SQAP.

Source: ARCBS, NSW.

Preliminary testing: ICPMR, Westmead Hospital, NSW.

2B is serum converted from plasma by the SQAP and tested low positive for Rubella IgG.

Source: ARCBS, NSW.

Preliminary testing: ICPMR, Westmead Hospital, NSW.

Analysis of Results

For information on "Analysis of Results" please refer to your Serology QAP Participation Booklet for the current year. The personalised Assessment Report is an indicator for participants to review their results and evaluate their own performance as 'Satisfactory' or 'Unsatisfactory'.

Robust Statistics

Analysis of Results using Robust Statistics is performed on user groups of five (5) or more participants using the same units and are **now available on your personalised Assessment Report.**

In order to calculate the statistics as accurately as possible, results that are presented as < or > are entered into the calculations as the next whole number. For example, <10 is entered into the calculation as 9 and >500 is entered as 501.

To view robust statistics of user groups other than your own, use the RCPA Serology QAP website: <http://www.rcpaqap.com.au/serology> Log into the 'Member Services' section and go to 'Dynamic Graphs of Results'.

Results Reported by Participants

158 participants returned results for rubella.

Survey Results AN2:2009 Rubella

Rubella IgG - Specimen 2A

equ: 1 = 0.66%
 neg: 1 = 0.66%
 not tested: Excluded
 pos/low pos: 150 = 98.68%
 Total Results =152
 Lower 95% Confidence Limit = 86.5%
Consensus: pos/low pos

Rubella IgG - Specimen 2B

equ: 1 = 0.68%
 not tested: Excluded
 pos/low pos: 147 = 99.32%
 Total Results =148
 Lower 95% Confidence Limit = 86.7%
Consensus: pos/low pos

Rubella IgM - Specimen 2A

neg: 36 = 100.00%
 not tested: Excluded
 Total Results =36
 Lower 95% Confidence Limit = 94.1%
Consensus: neg

Rubella IgM - Specimen 2B

neg: 37 = 100.00%
 not tested: Excluded
 Total Results =37
 Lower 95% Confidence Limit = 94.1%
Consensus: neg

Rubella Total Antibody - Specimen 2A

pos: 1 = 100.00%
 Total Results =1
 Lower 95% Confidence Limit = 100%
 Consensus: No

Rubella Total Antibody - Specimen 2B

pos: 1 = 100.00%
 Total Results =1
 Lower 95% Confidence Limit = 100%
 Consensus: No

Inconsistencies in this Survey

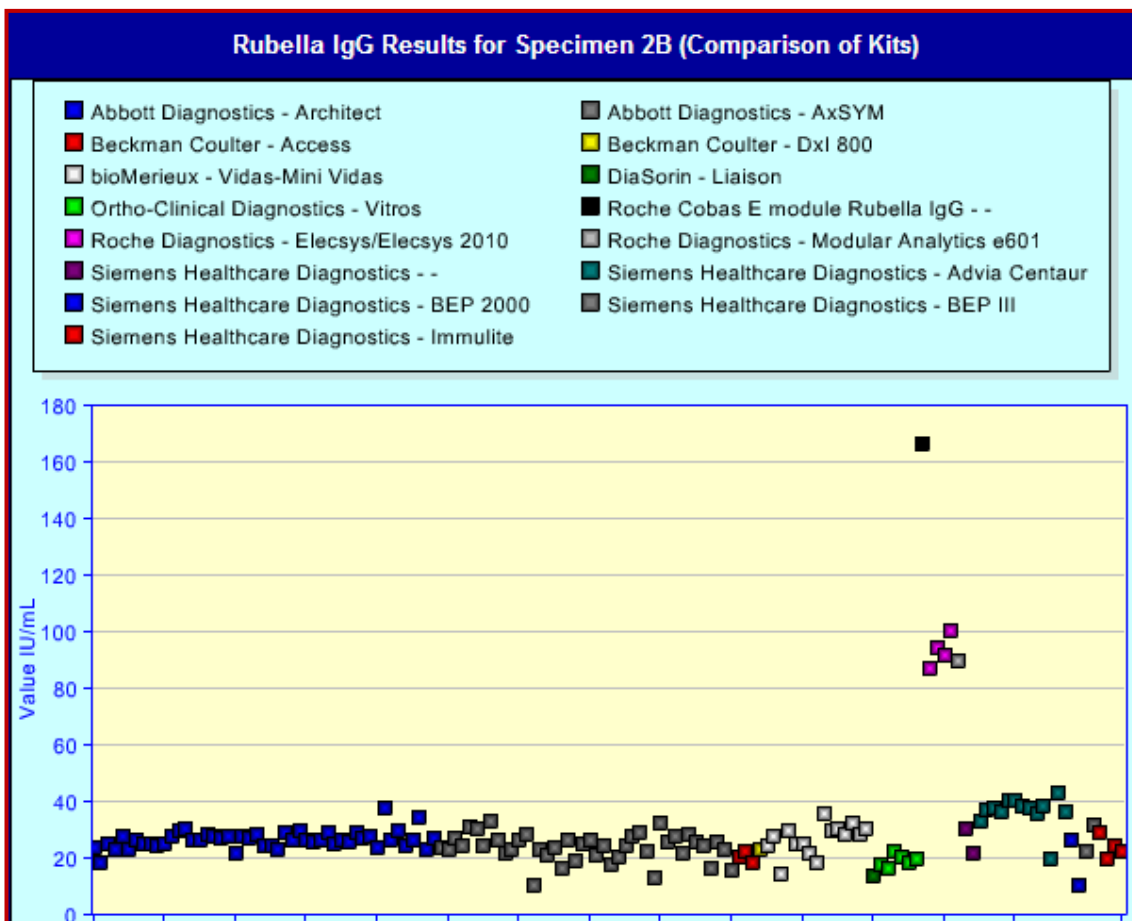
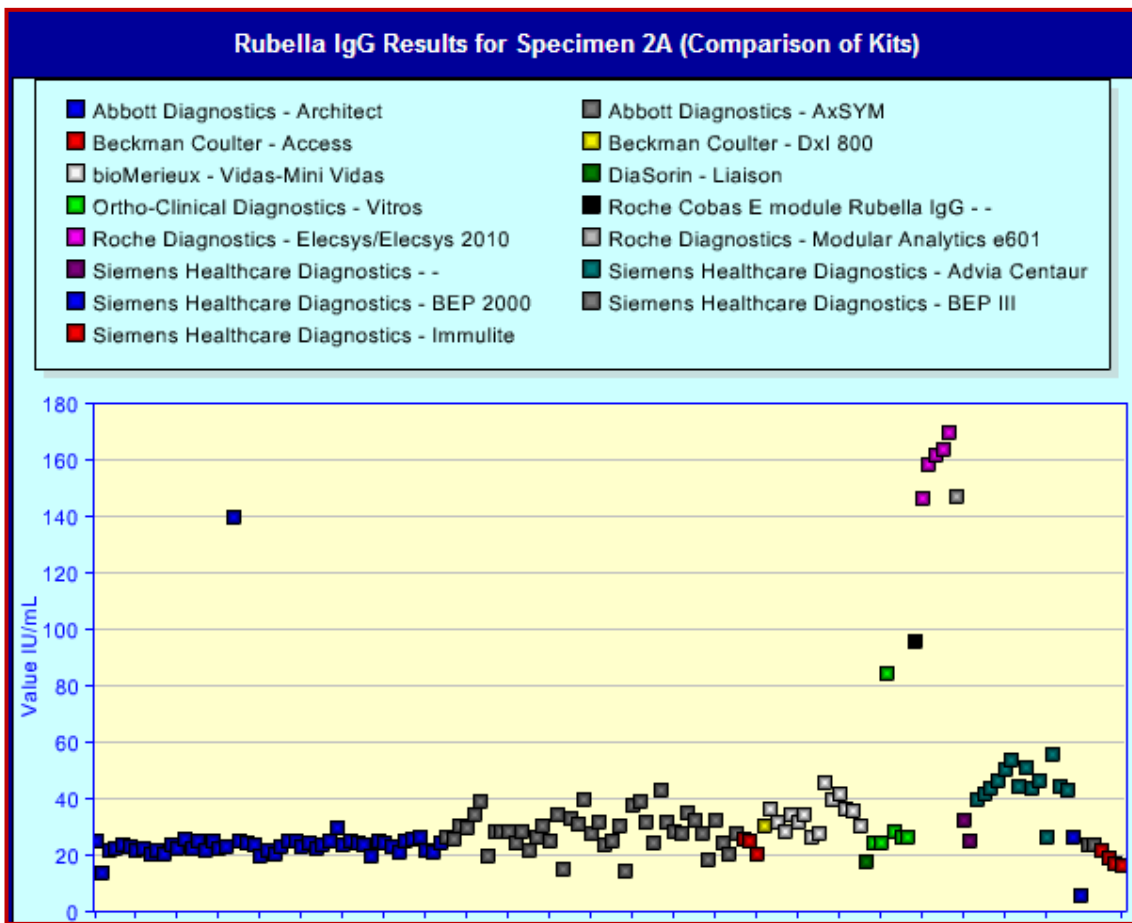
Rubella IgG	Participant	Comment
Specimen 2A & 2B	21267	Specimen result is inconsistent with the low positive range provided.
	31126	Specimen result is inconsistent with the low positive range provided.
	61247	Specimen result is inconsistent with the low positive range provided.
	89003	Low positive range not provided for low positive result.
	89068	Low positive range not provided for low positive result.
	89092	Specimen result is inconsistent with the low positive range provided.
Specimen 2A	21356	Result value is higher than other participants within user group.
	41302	Result value is higher than other participants within user group.
	41432	A transcription error appears to have occurred. Cut-off and specimen values indicate that a correct result should have been returned.
	41432	Result inconsistent with the consensus.
	80030	Result inconsistent with the consensus.
	89061	Low positive range not provided for low positive result.
	89156	Identified a clerical error - no clerical errors featured in this survey.
Specimen 2B	21389	Specimen result is inconsistent with the low positive range provided.
	21489	Specimen result is inconsistent with the low positive range provided.
	89061	Result inconsistent with the consensus.
Rubella IgG	Participant	Comment
Test group	21144	Equivocal and low positive ranges inconsistent with cut-off value provided.

	21164	Equivocal range appears inconsistent with the cut-off value provided.
	21583	Equivocal range appears inconsistent with the cut-off value provided.
	31001	Equivocal range appears inconsistent with the cut-off value provided.
	31440	Equivocal range appears inconsistent with the cut-off value provided.
	41073	Edit - Updated kit according to lot number and result values provided.
	41432	Low positive range is inconsistent with cut-off.
	68646	Cut-off value not provided.
	68646	Edit - Updated kit according to lot number and result values provided.
	80930	Equivocal range appears inconsistent with the cut-off value provided.
	80940	Equivocal and low positive ranges inconsistent with cut-off value provided.
	83618	Equivocal range appears inconsistent with the cut-off value provided.
	89021	Equivocal range appears inconsistent with the cut-off value provided.
	89092	Kit past the expiry date.
	89100	Equivocal range appears inconsistent with the cut-off value provided.
	89102	Kit past the expiry date.
	89102	Low positive range is inconsistent with cut-off.
	89135	Cut-off value provided is inconsistent to others within the user group. Validation data must be retained when differing from the manufacturer's instructions.
	89138	Equivocal range appears inconsistent with the cut-off value provided.
	89139	Equivocal range appears inconsistent with the cut-off value provided.
	89145	Cut-off value provided is inconsistent to others within the user group. Validation data must be retained when differing from the manufacturer's instructions.
	89156	Equivocal range appears inconsistent with the cut-off value provided.
	89157	Equivocal range appears inconsistent with the cut-off value provided.
	89173	Equivocal range appears inconsistent with the cut-off value provided.
	91240	Cut-off value provided is inconsistent to others within the user group. Validation data must be retained when differing from the manufacturer's instructions.
	91267	Equivocal and low positive ranges inconsistent with cut-off value provided.
	91267	Cut-off value provided is inconsistent to others within the user group. Validation data must be retained when differing from the manufacturer's instructions.
	91487	Edit - Updated kit according to lot number and result values provided.
	92006	Edit - Entered 'not tested' for both specimens - entry deleted by SQAP.
	92009	Equivocal range appears inconsistent with the cut-off value provided.
Rubella IgM	Participant	Comment
Test group	21164	Equivocal range appears inconsistent with the cut-off value provided.
	29029	Low positive range is inconsistent with cut-off.
	80030	Equivocal range appears inconsistent with the cut-off value provided.
	80030	Units appear inconsistent with cut-off and result values reported.
	83850	Low positive range is inconsistent with cut-off.

Rubella IgM	Participant	Comment
Test group	89019	Edit - Entered 'not tested' for both specimens - entry deleted by SQAP.
	89021	Cut-off value provided is inconsistent to others within the user group.
	89021	Reported units inconsistent to other participants within the user group.
	89036	Low positive range is inconsistent with cut-off.
	89052	Cut-off value provided is inconsistent to others within the user group. Validation data must be retained when differing from the manufacturer's instructions.
	89055	Equivocal and low positive ranges inconsistent with cut-off value provided.
	89063	Edit - Entered 'not tested' for both specimens - entry deleted by SQAP.
	89096	Equivocal range appears inconsistent with the cut-off value provided.
	89100	Equivocal range appears inconsistent with the cut-off value provided.
	89104	Equivocal range appears inconsistent with the cut-off value provided.
	89135	Cut-off value provided is inconsistent to others within the user group. Validation data must be retained when differing from the manufacturer's instructions.
	89138	Equivocal range appears inconsistent with the cut-off value provided.
	89138	Kit details were entered in the 'Other' section. Please use the drop down list.
	89139	Equivocal and low positive ranges inconsistent with cut-off value provided.
	89156	Equivocal and low positive ranges inconsistent with cut-off value provided.
	89157	Equivocal range appears inconsistent with the cut-off value provided.
	89158	Low positive range is inconsistent with cut-off.
	89173	Equivocal range appears inconsistent with the cut-off value provided.

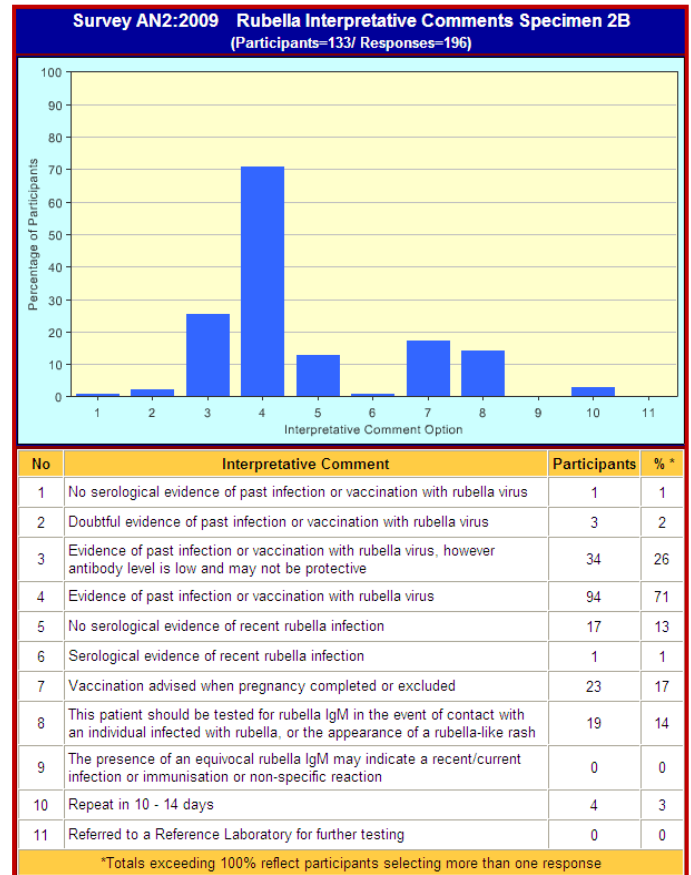
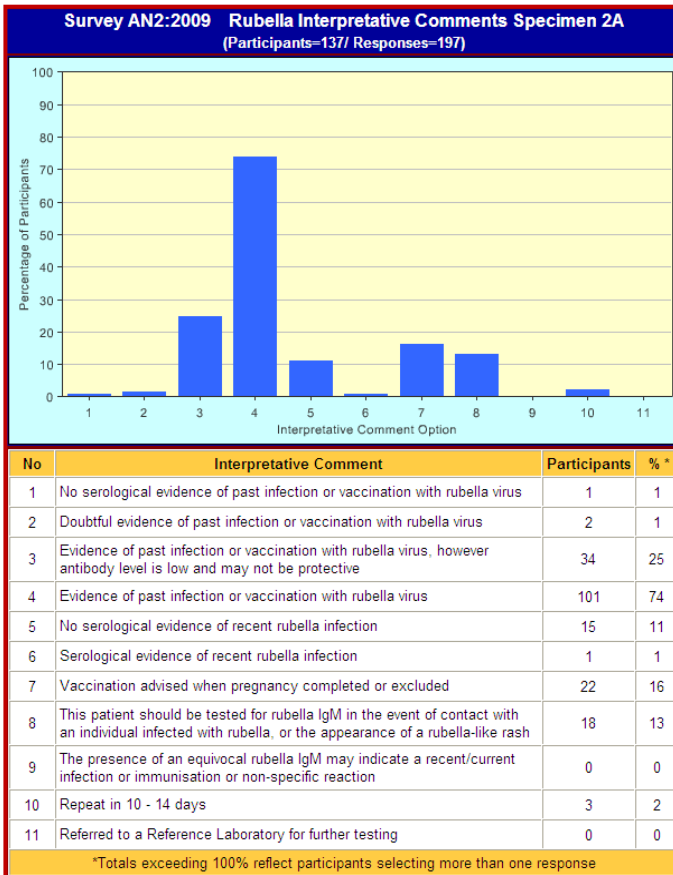
Overall Comparison of Rubella IgG Results by Kit / Methodology

[Only results reported in IU/mL are included on these graphs]



Interpretative Comments

Combination responses have been split into their appropriate option – for example, if a participant chose 3 & 7 they are counted once in each of those options. % is based on the total number of participants and not the total number of comments. Therefore, the total % adds to more than 100%.



Review discussion prepared by: Tony Panayotou, Southern Cross Pathology, VIC

General Overview of Results

Specimen 2A

In this survey, 152 participants performed rubella IgG using 15 different assays or instruments. A consensus rate of 98.68% (pos/low pos) was achieved for rubella IgG which is excellent given the low value of this specimen. From the consensus results, further breakdown shows that 21.3% of participants interpreted the results as low positive and 78.7% as positive.

Participant 89046 in addition to testing for rubella IgG also performed rubella total antibody recording a positive result.

Specimen 2B

In this survey, 148 participants performed rubella IgG using 15 different assays or instruments. A consensus rate of 99.32% (pos/low pos) was achieved for rubella IgG which is excellent given the low value of this specimen. From the consensus results, further breakdown shows that 21.1% of participants interpreted the results as low positive and 78.9% as positive.

Participant 89046 in addition to testing for rubella IgG also performed rubella total antibody recording a positive result.

Review of Interpretative Comments

Specimen 2A

The most appropriate comments for this specimen are either **4** for a positive rubella IgG, or **3**, **7** and with the option of **8** for a low positive result. Comment **5** should be included from participants who performed rubella IgM with a negative result.

Review of Interpretative Comments

Specimen 2A (continued)

From the 87.3% of participants who provided interpretative comments, 82.3% chose an appropriate comment(s).

Participants 21375 chose comments **2** with **8** and reported a low positive rubella IgG. Comment **3** instead of **2** is more appropriate for this result. Participant 21583 reported a low positive rubella IgG and chose comments **3**, **4** and **7**. Comment **3** and **7** is appropriate for this result as comments **3** with **4** is conflicting. Likewise, Participant 21624 selected comments **3**, **4**, **7** and **10** and reported a positive rubella IgG. Comment **4** instead of **3** is more appropriate for the result reported. Participants 29029 and 41179 reported a low positive rubella IgG and chose comments **4** and **7**. Comment **3** instead of **4** is more appropriate for the result reported. Participant 80030 reported an equivocal rubella IgG and chose comments **3**, **5** and **7**. Comment **2** instead of **3** is more appropriate for the result reported. Participant 83850 reported a positive rubella IgG and curiously chose comment **1**. Presumably, this is a typing error as comment **4** should have been chosen. Participant 89003 reported a low positive rubella IgG and chose comments **3**, **4**, **7** and **8**. Again, comment **3** instead of **4** is appropriate for this result as comments **3** with **4** is conflicting. Finally, Participant 89156 reported a positive rubella IgG and chose comments **2**, **3**, **4**, **6** and **10**. Comments **2**, **3** and **4** together are conflicting. Comment **4** instead of **2** and **3** is more appropriate for this result. This participant should review the low positive range they provided as "15" which is not a range thus causing interpretational problems leading to ambivalent comments. Several participants, as from previous surveys, reported comments **4** and **8**. Comment **8** can be included where rubella IgG is negative, equivocal or low positive indicating that the patient may not have any protection or adequate protection to rubella exposure. That is, in combination with either comments **1**, **2** or **3**.

Specimen 2B

The most appropriate comments for this specimen are either **4** for a positive rubella IgG, or **3**, **7** and with the option of **8** for a low positive result. Comment **5** should be included from participants who performed rubella IgM with a negative result.

From the 86.7% of participants who provided interpretative comments, 84% chose an appropriate comment(s).

Participants 21375 chose comments **2** with **8** and reported a low positive rubella IgG. Comment **3** instead of **2** is more appropriate for this result. Participant 21583 reported a low positive rubella IgG and chose comments **3**, **4** and **7**. Comment **3** and **7** is appropriate for this result as comments **3** with **4** is conflicting. Likewise, Participant 21624 selected comments **3**, **4**, **7** and **10**, and reported a positive rubella IgG. Comment **4** instead of **3** is more appropriate for the result reported. Participants 29029 and 41179 reported a low positive rubella IgG and chose comments **4** and **7**. Comment **3** instead of **4** is more appropriate for the result reported. Participant 83850 reported a positive rubella IgG and curiously chose comment **1**. Presumably, this is a typing error as comment **4** should have been chosen. Participant 89003 reported a low positive rubella IgG and chose comments **3**, **4**, **7** and **8**. Again, comment **3** instead of **4** is appropriate for this result as comments **3** with **4** is conflicting. Finally, Participant 89156 reported a positive rubella IgG and chose comments **2**, **3**, **4**, **6** and **10**. Comments **2**, **3** and **4** together are conflicting. Comment **4** instead of **2** and **3** is more appropriate for this result. This participant should review the low positive range they provided as "15" which is not a range thus causing interpretational problems leading to ambivalent comments. Several participants, as from previous surveys, reported comments **4** and **8**. Comment **8** can be included where rubella IgG is negative, equivocal or low positive indicating that the patient may not have any protection or adequate protection to rubella exposure. That is, in combination with either comments **1**, **2** or **3**.

Review of Results by Methodology

Specimen 2A

The Siemens Advia Centaur and especially the Roche Diagnostics Elecsys/Elecsys 2010 assays are reading higher when compared to the other assays/instruments. Participant 21356 should repeat Specimen 2A as the rubella IgG value submitted is approximately three times higher than the other Ortho-Clinical Diagnostics Vitros users. Apart from Participant 21356, the other Ortho-Clinical Diagnostics Vitros readings were this time in concordance with the majority of the other assays/instruments

The Abbott AxSYM results again appear to have slightly more variation when compared to the Abbott Architect assay (see robust statistics). This could be due to the higher number of batches (14 versus 9 respectively) concurrently in use.

Review of Results by Methodology

Specimen 2B

The Siemens Advia Centaur and especially the Roche Diagnostics assays are reading higher when compared to the other assays/instruments. The Ortho-Clinical Diagnostics Vitros readings were this time in concordance with the majority of the other assays/instruments

The Abbott AxSYM results again appear to have slightly more variation when compared to the Abbott Architect assay (see robust statistics). This could be due to the higher number of batches (14 versus 9 respectively) concurrently in use.

Rubella IgM

It is not necessary to test these specimens for rubella IgM as it was an antenatal screen and no clinical notes were provided to indicate that the patient had been in contact with rubella or exhibited rubella-like symptoms. In this survey, 36 participants for Specimen 2A and 37 participants for Specimen 2B performed rubella IgM using 14 different assays/instruments. A consensus rate of 100% was achieved for both Specimens 2A and 2B. Of these participants, 31/37 (83.8%) also reported interpretative comments. Participants 89051, 89085, 89100, 89135, 89144 and 89155 failed to do so.

Participants 89055, 89065, 89096 and 89144 only performed rubella IgM. The appropriate test for a rubella antenatal screen is rubella IgG or total antibody. These participants should review their testing algorithms and give feedback as to why only rubella IgM is performed.

Review of Results & Conclusion

Again there are numerous inconsistencies and these need to be taken seriously and addressed appropriately, as they can affect the results and interpretation which would reflect on real patient results. This has been demonstrated repeatedly especially with low positive samples.

Equally of concern is the practice of some participants using expired kits. The manufacturers' expiry date is usually determined in real time analysis studies and therefore the use of expired kits can lead to erroneous results.

There are also still a consistent number of participants, who don't report interpretative comments. In addition, only 44.4% for Specimen 2A and 45.9% for Specimen 2B of participants who tested for rubella IgM reported comment 5. It is important to provide interpretative comments and recommend appropriate follow-up testing if required.

Further reading

Best, J. M. et al (2002). Interpretation of Rubella Serology in Pregnancy Pitfalls and Problems. *BMJ*; 325:147-148 (20 July)

Pustowoit, B. & Liebert, U. G. (1998). Predictive Value of Serological Tests in Rubella Virus Infection during Pregnancy. *Intervirology*; 41: 170-177

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – Interpretations

Part.	Comment 2A	Comment 2B	Part.	Comment 2A	Comment 2B	Part.	Comment 2A	Comment 2B	Part.	Comment 2A	Comment 2B
20008	4	4	31126	4	4	61076	4	3,7,8	89065	5	5
20009	4	4	31171	4	4	61247	4	4	89068	3	3
21147	3,7	3,7	31221	4	4	61253	3	3	89073	4	4
21164	4	4	31234	4	4	61360	3,7,8	3,7,8	89078	4,5	4,5
21189	4	4	31252	4	4	61396	4	4	89096	5	5
21207	4	4	31293	4	4	61455	3	3	89101	3,5,7	4,5
21229	4	4	31342	3,7	4	68646	4	4	89104	4	4
21238	4	4	31369	4	4	71131	3,7,8	3,7,8	89107	4	4
21267	4,8	4,8	31378	4	4	71246	3,7	3,7	89113	3,7	3,7
21292	3,7,8	3,7,8	31409	4,8	4,8	71358	3,7,8	4,8	89125	4	4
21338	4	4	31433	4	4	71683	4	3	89138	4	4
21347	4,7,8	4,7,8	31440	4	4	80030	3,5,7	4,5	89139	4	4
21356	4	4	31466	4,8	3,7,8	80756	3	3	89156	2,3,4,6,10	2,3,4,6,10
21375	2,8	2,8	31702	4	4	80800	4	4	89157	4,5	4,5
21389	4	3,7	31722	4	4	80930	3,5,7,8,10	3,5,7,8,10	89158	4	4
21398	3,8	3,8	31750	4	4	80940	4,5	4,5	89173	12	5
21401	3,7,8	3,7,8	40075	4	4	81325	4	4	91119	4	4
21412	4	4	41062	3,7,8	3,7,8	83555	4	4	91159	4	4
21439	4	4	41073	3	3	83618	4	4	91240	4	4
21452	4	4	41125	3	3	83667	4	4	91267	3,7	3,7
21470	4	4	41133	3,7,8	3,7,8	83850	1	1	91317	4	4
21489	4	3,7	41179	4,7	4,7	89000	4	4	91427	3	3
21500	4,8	4,8	41183	4	4	89003	3,4,7,8	3,4,7,8	91431	4,8	4,8
21583	3,4,7	3,4,7	41302	4	4	89012	4,5	4,5	91458	4	4
21624	3,4,7,10	3,4,7,10	49000	3	3	89019	4	4	91461	3,7	3,7
21721	4	4	51007	4	4	89021	4,5	4,5	91462	4	12
21763	3	3	51044	4	4	89036	4,5	4,5	91465	4	12
21767	4	4	51058	4	4	89041	4,5	4,5	91469	4	4
29029	4,7	4,7	51063	4	4	89045	4,8	4,8	91482	4	12
29033	4	4	51077	4	4	89046	4,5	4,5	91487	4	12
31001	3	3	51434	4	4	89052	4	5	91493	4	4
31008	4	4	51632	4	4	89055	5	5	92009	4	4
31013	3	3	59000	4	4	89058	5	5	92010	4	12
31043	3	4	59006	4	4	89061	3	2,7,10			
31089	4	4	61033	4	3	89063	4	4	41302	2A/B add- This level of antibody is consistent with immunity.	

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Equivocal Range	Cut Off	Low Positive Range	Value 2A	Result 2A	Value 2B	Result 2B
21238	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL		5.0		25.45	pos	24.45	pos
21267	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-09	IU/mL	5.0-9.9	10	10-30	14.2	pos	19.0	pos
21292	Abbott Diagnostics	Rubella IgG	CMIA	Architect	30014UN07	Jul-10	IU/mL		10	10 - 40	22	low pos	26	low pos
21375	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL		10	10-25	23.1	low pos	23.4	low pos
21401	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5- 9.9	10	10 - 30	24.6	low pos	28.1	low pos
21412	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	5-9.9	10	-	23.4	pos	23.6	pos
21439	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5.0-9.9	10		22.2	pos	26.8	pos
29029	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	8-10	10	10-40	22.9	low pos	25.4	low pos
31001	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26963UN08	Feb-10	IU/mL	5-9	5	6-30	21	low pos	26	low pos
31013	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	5.0-9.9	10	10-29	22	low pos	25	low pos
31252	Abbott Diagnostics	Rubella IgG	CMIA	Architect	30014UN09	Jul-10	IU/mL	5-9	10	10-20	24	pos	28	pos
31234	Abbott Diagnostics	Rubella IgG	CMIA	Architect	30014UN09	Jul-10	IU/mL	5.0-9.9	10		20.9	pos	25.8	pos
31293	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26963UN08	Feb-10	IU/mL	5.0-9.9	10	N/A	23	pos	30	pos
31342	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26933UN08	Feb-10	IU/mL	5-9.99	10	10-30	26.3	low pos	30.7	pos
41062	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL		10	10-29	23.2	low pos	27.3	low pos
41073	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL		9	10-29	25.6	low pos	26.8	low pos
41125	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5-9	10		22	pos	28.8	pos
41133	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26933UN08	Feb-10	IU/mL	5.0 - 9.9	10	10 - 30	26	low pos	28	low pos
41179	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5-10	10	10-30	23.0	low pos	27.7	low pos
41183	Abbott Diagnostics	Rubella IgG	CMIA	Architect	30014UN09	Jul-09	IU/mL	5 - 9.9	10		23.5	pos	28.4	pos
41302	Abbott Diagnostics	Rubella IgG	CMIA	Architect	30014UN09	Jul-10	IU/mL	5-9.9	10	10-19	140	pos	22	pos
49000	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL		10	10-30	26	low pos	28	low pos
51044	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5.0 - 9.9	10.0		24.73	pos	27.86	pos
51077	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	5-9.99	10		24	pos	29	pos
61247	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	n/a	10	10-30	20	pos	25	pos
61253	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	5-10	10	11-30	22.5	low pos	24.8	low pos
61360	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL		10	10-30	21.1	low pos	23.5	low pos
61455	Abbott Diagnostics	Rubella IgG	CMIA	Architect	24749UN08	Oct-09	IU/mL		10	10-30	23.9	low pos	29.5	low pos
71131	Abbott Diagnostics	Rubella IgG	CMIA	Architect	30014UN09	Jul-10	IU/mL	5 - 9.9	10	10 - 30	25.5	low pos	27.1	low pos
71358	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5.0-10.0	10.0	10-30	25.9	low pos	30.2	pos
81325	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL		10		23.9	pos	26.9	pos
83555	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26933UN08	Feb-10	IU/mL	5.0-10	10.0		24.7	pos	26.6	pos
89000	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL		10		23.3	pos	27.3	pos
89003	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5.0-9.9	10		24.1	low pos	29.5	low pos
89012	Abbott Diagnostics	Rubella IgG	CMIA	Architect	24749UN08	Oct-09	IU/mL		10.0		25.6	pos	25.6	pos
89058	Abbott Diagnostics	Rubella IgG	CMIA	Architect	69339LF00	Aug-09	IU/mL	5-9.9	10.0		30.3	pos	27.3	pos
89073	Abbott Diagnostics	Rubella IgG	CMIA	Architect	68196LF00	Jul-09	IU/mL		4.9		24.0	pos	26.5	pos
89138	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5.0-9.9	5.0		25.9	pos	29.8	pos
89139	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5.0-9.9	5.0	10.0	24.9	pos	27.8	pos

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Equivocal Range	Cut Off	Low Positive Range	Value 2A	Result 2A	Value 2B	Result 2B
91240	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	9.5-15.0	15.1		24.6	pos	28.2	pos
91267	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	15-20	15	20-25	20	low pos	24	low pos
91317	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26921UN08	Feb-10	IU/mL		10		26	pos	38	pos
91427	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5-9.9	10	10-30	25	low pos	27	low pos
91431	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26933UN08	Feb-10	IU/mL	5-9	10		23.4	pos	30.2	pos
91458	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	5.0-9.9	10.0	10.0-15.0	21.5	pos	24.8	pos
91461	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL	10-29	10	10-29	26	low pos	27	low pos
91462	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26933UN08	Feb-10	IU/mL	5.0-9.9	10	na	26.6	pos		not tested
91469	Abbott Diagnostics	Rubella IgG	CMIA	Architect	26921UN08	Feb-10	IU/mL	5-9.9	10		26.9	pos	35.1	pos
91487	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	28365UN08	May-10	IU/mL	5-10	10	NA	22.30	pos		not tested
91493	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28365UN08	May-10	IU/mL		10	10-14	21.9	pos	23.8	pos
92009	Abbott Diagnostics	Rubella IgG	CMIA	Architect	28354UN08	May-10	IU/mL	5 - 10	5		24.9	pos	27.9	pos
21147	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	74326M100	Sep-09	IU/mL		10	30	26.7	low pos	24.6	low pos
21189	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL		10		26.5	pos	23.4	pos
21389	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M100	Jul-09	IU/mL	5-9.9	10	10-30	31.2	pos	27.6	pos
21398	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	74326M100	Sep-09	IU/mL	5.0-9.9	10		30.0	pos	24.8	pos
21470	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL	5 - 9.9	10		35.1	pos	31.5	pos
21500	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M100	Jul-09	IU/mL		10.0	10.0-19.9	39.9	pos	31.2	pos
21583	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	73080M101	Sep-09	IU/mL	5-10	4.99	10-30	20.2	low pos	25.0	low pos
31043	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL	5.0-9.9	10	10-30	29	low pos	33.7	pos
31369	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL		10	10-20	29	pos	27	pos
31378	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M101	Jul-09	IU/mL		10	10-29	29	low pos	22	low pos
31409	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL	5-9.9	10.0		25.2	pos	23.8	pos
31702	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	71417M200	Jul-09	IU/mL	5-9.9	10	10.1-20	29.1	pos	27.2	pos
31750	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	74326M100	Sep-09	IU/mL	5.0 - 9.9	10.0		22.3	pos	29	pos
41432	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL	5-9.9	10.0	5.1	26.8	neg	10.7	pos
51007	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	71417M200	Jul-09	IU/mL	5.0-9.9	10.0		30.9	pos	23.7	pos
51058	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	74326M100	Sep-09	IU/mL	5-10	10	11-20	25.6	pos	21.5	pos
51434	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	73080M101	Sep-09	IU/mL		10	10-20	35	pos	24	pos
59000	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL	5.0-9.9	10.0		15.4	pos	17.1	pos
59006	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	70510M100	Jul-09	IU/mL	5-9.99	10	10-20	33.8	pos	27.2	pos
61033	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL	5 to 10	10	10 to 30	31.8	pos	19.8	low pos
61076	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	74326M100	Aug-09	IU/mL	5 to 10	10.0	10 to 30	40.2	pos	25.9	low pos
80021	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M100	Jul-09	IU/mL	n/a	10.0	n/a	28.6	pos	26.7	pos
80800	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M100	Jul-09	IU/mL	5.0-9.9	10.0		32.5	pos	21.5	pos
80930	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	73080M100	Sep-09	IU/mL	5 - 10	5		24.6	pos	25.3	pos
80940	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M101	Jul-09	IU/mL	5.0-9.0	10.0	9.1-11.0	25.7	pos	18.3	pos
83850	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983MIQQ	Jul-09	IU/mL	5.0 - 9.9	10.0	10.0	30.8	pos	20.9	pos

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Equivocal Range	Cut Off	Low Positive Range	Value 2A	Result 2A	Value 2B	Result 2B
89021	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M100	Jul-09	IU/mL	5.0-9.9	5	-	14.8	pos	25.3	pos
89036	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M100	Jul-09	IU/mL	5-10	10	10	38.5	pos	28.2	pos
89041	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M100	Jul-09	IU/mL	5-10	10.0		39.6	pos	29.4	pos
89046	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M100	Jul-09	IU/mL	5-9.9	10	10 -14.9	32.1	pos	23.1	pos
89052	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67969M101	Apr-09	IU/mL	5.0	5.0		25.2	pos	13.6	pos
89063	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M101	Jul-09	IU/mL	5.0-9.9	10.0		43.6	pos	32.7	pos
89078	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL	5-9.9	10		32.4	pos	26.1	pos
89091	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67233M101	May-09	IU/mL		5		28.8	pos	28.5	pos
89092	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	63329M201	Feb-09	IU/mL	11-15	10	16-35	28.1	pos	22.1	pos
89102	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	57577M201	Aug-08	IU/mL	5-9.9	10	5	35.7	pos	29.0	pos
89107	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M101	Jul-09	IU/mL	5 to 9.9	10		33.0	pos	26.2	pos
89117	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M101	Jun-09	IU/mL		10		28.1	pos	25.3	pos
89125	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M100	Jul-09	IU/mL		10.0		19.0	pos	16.8	pos
89133	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M100	Jul-09	IU/mL		10		33.3	pos	26.1	pos
89135	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	6796M100	Apr-09	IU/mL		1		24.9	pos	23.5	pos
89145	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67978M100	Jul-09	IU/mL		15.0		21.2	pos	16.6	pos
92010	Abbott Diagnostics	Rubella IgG	MEIA	AxSYM	67983M100	Jul-09	IU/mL	5 - 10	10		28	pos		not tested
21144	Beckman Coulter	Rubella IgG	ChLEIA	Access	890215	May-09	IU/mL	10-15	10	15-20	26.3	pos	21.3	pos
31126	Beckman Coulter	Rubella IgG	ChLEIA	Access	890215	May-10	IU/mL	10-15	15	15-25	26	pos	23	pos
31440	Beckman Coulter	Rubella IgG	ChLEIA	Access	890298	Aug-09	IU/mL	10-15	10		21	pos	19	pos
21721	Beckman Coulter	Rubella IgG	ChLEIA	Dxl 800	890215	May-10	IU/mL		10.0	10-15	31.2	pos	23.9	pos
89019	Biokit	bioelisa Rubella IgG	ELISA	-	E-0208	Jun-09	OD	n/a	0.218	n/a	0.372	pos	0.292	pos
21489	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	830441201	Sep-09	IU/mL	10-15	15	15-25	37	pos	25	pos
31008	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	829870201	Dec-09	IU/mL	10-14	15		32	pos	28	pos
31433	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	829870201	Dec-09	IU/mL	10-14	15	n/a	29	pos	15	pos
31722	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	829870201	Dec-09	IU/mL		10	10-24	35	pos	30	pos
71683	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	830441201	Sep-09	IU/mL	10-14	15	15-30	32	pos	26	low pos
83618	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	830441201	Sep-09	IU/mL	11-14	10		35	pos	26	pos
89051	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	828059501	Nov-09	IU/mL	10-15	15		27	pos	22	pos
89113	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	827638901	Oct-09	IU/mL	10 - 14	15		28	pos	19	pos
89155	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	831129501	Feb-10	IU/mL	10-15	15		46	pos	36	pos
89156	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	090601-0	Jun-09	IU/mL	10 - 14	9	15	40	pos	30	pos
89157	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	823538201	May-09	IU/mL	10-14	9		42	pos	31	pos
89158	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	090601-0	Jun-09	IU/mL	10 - 14	15	15	37	pos	29	pos
89173	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	100303-0	Mar-10	IU/mL	10-15	10			not tested	33	pos
91119	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	829870201	Dec-09	IU/mL	10-15	15	15-20	36	pos	29	pos

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Equivocal Range	Cut Off	Low Positive Range	Value 2A	Result 2A	Value 2B	Result 2B
91159	bioMerieux	Rubella IgG II	ELFA	Vidas-Mini Vidas	829870201	Dec-09	IU/mL	5-10	10.	11-20	31	pos	31	pos
89061	DiaSorin	Liaison Rubella IgG	ChLEIA	Liaison	036047	Sep-09	IU/mL	10 - 15	15		18	low pos	14	equ
89100	Human	Rubella IgG	ELISA	Personal Lab	08001	Oct-10	OD	0.21-0.28	0.242		0.394	pos	0.454	pos
21207	Ortho-Clinical Diagnostics	Rubella IgG	ECi	Vitros	0650	Jul-09	IU/mL		10	10 - 14.9	25	pos	18	pos
21338	Ortho-Clinical Diagnostics	Rubella IgG	ECi	Vitros	0670	Aug-09	IU/mL	10-15	15	15	25	pos	17	pos
21356	Ortho-Clinical Diagnostics	Rubella IgG	ECi	Vitros	0630	May-09	IU/mL		10	11-15	84.8	pos	22.7	pos
21452	Ortho-Clinical Diagnostics	Rubella IgG	ECi	Vitros	0640	May-09	IU/mL		10.0	10.0-14.9	28.9	pos	20.8	pos
31089	Ortho-Clinical Diagnostics	Rubella IgG	ECi	Vitros	0650	Jul-09	IU/mL	10-15	15		26.7	pos	19	pos
71246	Ortho-Clinical Diagnostics	Rubella IgG	ECi	Vitros	0630	May-09	IU/mL		10	10-30	27	low pos	20	low pos
39036	Roche Cobas E module Rubella IgG	-	-	-	00153183	Dec-09	IU/mL		10		96.08	pos	166.8	pos
20008	Roche Diagnostics	Rubella IgG	ECi	Elecsys/Elecsys 2010	00151701	Aug-09	IU/mL	5-10	10	10-15	146.7	pos	87.66	pos
29033	Roche Diagnostics	Rubella IgG	ECi	Elecsys/Elecsys 2010	00151701	Aug-09	IU/mL	5-10	10	10-15	159	pos	95	pos
89085	Roche Diagnostics	Rubella IgG	ECi	Elecsys/Elecsys 2010	15115301	Jul-09	IU/mL		10		162.5	pos	92.43	pos
89104	Roche Diagnostics	Rubella IgG	ECi	Elecsys/Elecsys 2010	151701	Aug-09	IU/mL		10		164.3	pos	100.9	pos
91482	Roche Diagnostics	Rubella IgG	ECi	Elecsys/Elecsys 2010	00153183	Dec-09	IU/mL	5-10	10		170.2	pos		not tested
31171	Roche Diagnostics	Rubella IgG	ECLIA	Modular Analytics e601	151701-01	Aug-09	IU/mL		10	<50	147.4	pos	90.31	pos
20009	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	152	Oct-09	IU/mL	5-9.9	10.0	10-30	40.3	pos	33.4	pos
21767	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	152	Oct-09	IU/mL	5-10	10.0	10-30	42.2	pos	37.9	pos
31221	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	152	Oct-09	IU/mL	5-10	10	10 - 30	44.3	pos	38.6	pos
40075	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	153	Dec-09	IU/mL		10	10-29	47	pos	37	pos
51063	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	153	Jun-09	IU/mL	5-9.9	10		50.9	pos	40.9	pos
51632	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	35846152	Oct-09	IU/mL	5 - 9.99	10		54.2	pos	41.1	pos
61396	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	153	Dec-09	IU/mL		10	10-40	45	pos	39	low pos
68646	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgG	EIA	BEP III	152	Oct-09	IU/mL	10-30	n/a		52	pos	38	pos
83667	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	152	Oct-09	IU/mL	5-10	10	NA	44	pos	36	pos
89045	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	068152	Oct-09	IU/mL	5-9.99	10		47	pos	39	pos
89068	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	068152	Oct-09	IU/mL	10	10		27.0	low pos	20.6	low pos
91089	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	152	Oct-09	IU/mL	NA	10	10-30	56.2	pos	43.6	pos
91418	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	068151	Jul-09	IU/mL	10-30	10		45.2	pos	36.8	pos
91465	Siemens Healthcare Diagnostics	Rub G	ChLEIA	Advia Centaur	068152	Oct-09	IU/mL	5-9	10		43.4	pos		not tested

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Equivocal Range	Cut Off	Low Positive Range	Value 2A	Result 2A	Value 2B	Result 2B
21164	Siemens Healthcare Diagnostics	Rubella IgG Quant	ChLEIA	Immulite	262	Sep-09	IU/mL	5-10	5		22.5	pos	29.6	pos
21763	Siemens Healthcare Diagnostics	Rubella IgG Quant	ChLEIA	Immulite	235	Oct-09	IU/mL	5-10	10	10-30	19.7	low pos	20.2	low pos
61400	Siemens Healthcare Diagnostics	Rubella IgG Quant	ChLEIA	Immulite	209	Nov-09	IU/mL	5-10	10	10-20	17.6	low pos	25.1	pos
80756	Siemens Healthcare Diagnostics	Rubella IgG Quant	ChLEIA	Immulite	209	Nov-09	IU/mL	5-9.9	10	na	16.8	pos	23	pos
21229	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgG	EIA	BEP III	38116	Sep-09	IU/mL	4-9.9	9.99	10-15	24	pos	23	pos
21347	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgG	EIA	BEP 2000	38116	Sep-09	IU/mL		10	10-40	27	low pos	27	low pos
21624	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgG	EIA	-	38376	Oct-09	IU/mL	9-10	10	11-20	33	pos	31	pos
31466	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgG	EIA	-	37941	Jul-09	IU/mL		10	10-25	26	pos	22	low pos
80030	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgG	EIA	BEP 2000	38116	Sep-09	IU/mL		10		6.4	equ	11.3	pos
89101	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgG	EIA	BEP III	38116	Sep-09	IU/mL		10	10-25	24	low pos	32	pos

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – Total Antibody

Part	Manufacturer	Kit Name	Method	Lot No.	Expiry Date	Units	Cut Off	Value 2A	Result 2A	Value 2B	Result 2B
89046	In house	-	HAI	400107B	Sep-09	titre	8	32	pos	16	pos

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – IgM

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Equivocal Range	Cut Off	Low Pos Range	Value 2A	Result 2A	Value 2B	Result 2B
89012	Abbott Diagnostics	Rubella IgM	CMIA	Architect	681964LF00	Jul-09	S/CO		1.20		0.10	neg	0.10	neg
89058	Abbott Diagnostics	Rubella IgM	CMIA	Architect	66423LF00	Jun-09	S/CO	0.75-0.99	1.00		0.08	neg	0.08	neg
89073	Abbott Diagnostics	Rubella IgM	CMIA	Architect	26933UN08	Feb-10	S/CO		1.20		0.11	neg	0.29	neg
21398	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	66574M100	Jul-09	S/CO	0.60-0.79	0.8		0.078	neg	0.121	neg
29029	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	72679M100	Jan-10	Index		0.8	0.6	0.08	neg	0.14	neg
80930	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	63693M100	May-09	S/CO	0.600-0.79	0.800		0.175	neg	0.223	neg
80940	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	66574M100	Jul-09	S/CO	0.60-0.799	0.800	-	0.082	neg	0.119	neg
89021	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	65307M200	Jul-09	OD	0.6-0.799	0.6		0.090	neg	0.103	neg
89036	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	63693M100	May-09	S/CO	0.600-0.79	0.800	0.8	0.082	neg	0.116	neg
89041	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	69925M100	Dec-09	S/CO	0.600-08	0.800		0.101	neg	0.126	neg
89052	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	63693M100	May-09	S/CO		1.0		0.090	neg	0.126	neg
89065	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	68302M100	Jul-09	S/CO	0.6-0.799	0.800	na	0.099	neg	0.142	neg
89078	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	63373M200	May-09	S/CO	0.6 - 0.79	0.8		0.130	neg	0.193	neg
89107	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	65307M200	Jul-09	S/CO	.6 to .799	0.800		0.085	neg	0.131	neg
89125	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	69925M100	Dec-09	S/CO	0.60-0.79	0.8		0.099	neg	0.151	neg
89135	Abbott Diagnostics	Rubella IgM	MEIA	AxSYM	68302M100	Jul-09	S/CO		1		0.122	neg	0.153	neg
89055	Biokit	bioelisa Rubella IgM	ELISA	Personal Lab	080408	Jul-09	OD	1.0-1.2	0.282	1.2	0.042	neg	0.142	neg
89051	bioMerieux	Rubella IgM	ELFA	Vidas-Mini Vidas	829118701	Sep-09	S/CO	0.8 -1.20	1.20		0.15	neg	0.08	neg
89138	BioMerieux	Rubella IgM	ELFA	Vidas-Mini Vidas	826121901	Jun-09	S/CO	0.8-1.19	0.8		0.07	neg	0.03	neg
89139	bioMerieux	Rubella IgM	ELFA	Vidas-Mini Vidas	82612901	Jun-09	S/CO	0.80-1.19	0.80	1.20	0.08	neg	0.04	neg
89155	bioMerieux	Rubella IgM	ELFA	Vidas-Mini Vidas	827254701	Jul-09	S/CO	0.80-1.20	1.20		0.12	neg	0.04	neg
89156	bioMerieux	Rubella IgM	ELFA	Vidas-Mini Vidas	090617-0	Jun-09	S/CO	0.80-1.19	0.79	1.20	0.09	neg	0.07	neg
89157	bioMerieux	Rubella IgM	ELFA	Vidas-Mini Vidas	828294401	Aug-09	S/CO	0.80-1.19	0.79		0.15	neg	0.12	neg
89158	bioMerieux	Rubella IgM	ELFA	Vidas-Mini Vidas	090617-0	Jun-09	S/CO	0.80-1.19	1.20	1.20	0.10	neg	0.05	neg
89173	bioMerieux	Rubella IgM	ELFA	Vidas-Mini Vidas	091105-0	Nov-09	S/CO	0.8-1.1	0.8			not tested	<0.8	neg
89144	BioRad	Platelia Rubella IgM	EIA	-	7L2020	May-09	S/CO	1 - 0.8	1		0.087	neg	0.103	neg
89061	DiaSorin	Liaison Rubella IgM	ChLEIA	Liaison	037070	Sep-09	AU/mL		25		<10	neg	<10	neg
83850	DRG International	Rubella IgM	ELISA	-	RN -29963	Jul-09	S/CO	0.91-0.99	1.0	1.0	0.66	neg	0.58	neg
89100	Human	Rubella IgM	ELISA	Personal Lab	09002	Aug-10	OD	0.21-0.28	0.242		0.020	neg	0.061	neg
89096	Radim	Rubella IgM	EIA	-	00821A	Oct-09	IU/mL	0.605-0.74	0.673		0.188	neg	0.181	neg

Survey AN2:2009:2A & 2B Antenatal Rubella Serology – IgM

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Equivocal Range	Cut Off	Low Pos Range	Value 2A	Result 2A	Value 2B	Result 2B
89085	Roche Diagnostics	Rubella IgM Recomb	EIA	Cobas Core II	15115301	Oct-09	S/CO		1.0		0.244	neg	0.216	neg
89104	Roche Diagnostics	Rubella IgM	ECi	Modular Analytics E170	152408	Oct-09	S/CO	0.8-0.9	1.0		0.248	neg	0.247	neg
83667	Siemens Healthcare Diagnostics	Rub M	ChLEIA	Advia Centaur	143	Sep-09	S/CO		1.0		0.0	neg	0.09	neg
80030	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgM	EIA	BEP 2000	38509	Jan-10	S/CO	0.1 - 0.2	0.10		0.001	neg	0.002	neg
89046	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgM	EIA	-	38224	Oct-09	OD	0.1-0.2	0.201	NA	-0.01	neg	0.003	neg
89101	Siemens Healthcare Diagnostics	Enzygnost Anti-Rubella IgM	EIA	BEP III	38224	Oct-09	OD	0.1-0.2	0.200		0.001	neg	0.001	neg
21164	Siemens Healthcare Diagnostics	Rubella IgM	ChLEIA	Immulin	141	Dec-09	IU/mL	0.85-1.15	0.85		0.53	neg	0.65	neg