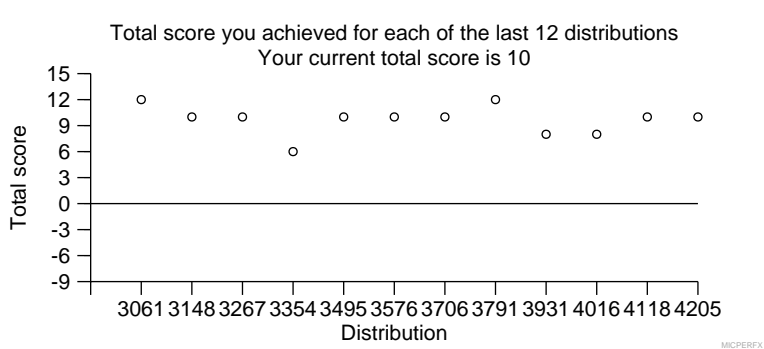
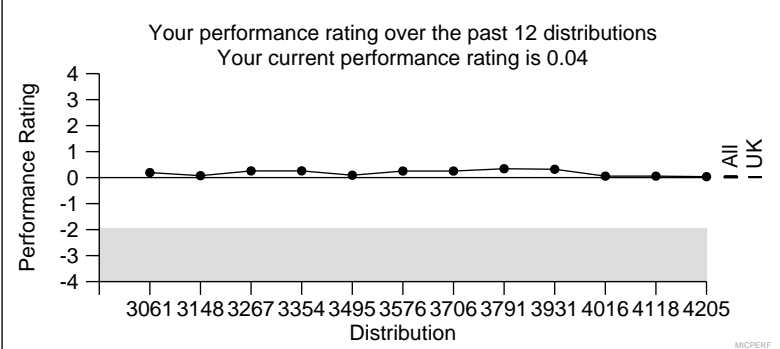


Intended Result	Your Report	Your Score
Specimen 4148 Rubella IgG not designated	Rubella IgG negative (<10 IU/mL)	Not scored
Specimen 4149 Rubella IgG positive (>=10 IU/mL)	Rubella IgG positive (>=10 IU/mL)	2
Specimen 4150 Rubella IgG negative (<10 IU/mL)	Rubella IgG negative (<10 IU/mL)	2
Specimen 4151 Rubella IgG positive (>=10 IU/mL)	Rubella IgG positive (>=10 IU/mL)	2
Specimen 4152 Rubella IgG positive (>=10 IU/mL)	Rubella IgG positive (>=10 IU/mL)	2
Specimen 4153 Rubella IgG positive (>=10 IU/mL)	Rubella IgG positive (>=10 IU/mL)	2

**Cumulative score information**  
 Total number of specimens sent to you for **UK NEQAS for Rubella IgG serology** over the last 2 distributions is 12  
 For these distributions specimen numbers 3878 3879 3881 3882 3883 4149 4150 4151 4152 4153 have been analysed and scored.  
 Number of reports scored 10  
 Number of specimens reported as not examined (not scored) 0  
 Number of specimens received too late for analysis (not scored) 0  
 Number of specimens for which no report was received (not scored) 0  
 Your cumulative score for these specimens was 20 out of a possible total of 20  
 The mean score calculated from the reports returned by **UK** laboratories was 19.97 with a standard error of 0.79.

**Performance rating**  
 Your performance rating for **UK NEQAS for Rubella IgG serology** (i.e. the number of standard errors by which your cumulative score lies above or below the mean) for UK laboratories is 0.04.  
 A performance rating of more than 1.96 standard errors below the mean indicates possible poor performance.  
 Your performance rating may change if other participants' results are amended.  
 No score penalty is incurred for non return of reports. However non return of results may be used as a measure of poor performance.



**AMENDED REPORT:** replaces report dated on 09/02/2018. Specimen 4148 was re-tested with MIKROGEN Rubella IgG assay. Please find more information on pages 4 and 5.

**Comments:** Overall performance was excellent with 99.9% of participants reporting correct results for scored specimens.

**Specimen 4148:** 201/219 participants (91.8%) reported this specimen as rubella IgG negative, with an overall median of 4 IU/ml. 18/219 participants (8.2%) reported a Rubella IgG positive result, with a range of 10-15 IU/ml and a median of 11 IU/ml with the following methods: bioMerieux Vidas (15), Beckman Access (1), Biokit bioelisa (1) and Vircell (1). Please find more information on pages four and five.

**Turn around time:** The time taken to report your results was 0-days. This information is provided for your own use and does not form part of your performance assessment.

**Acknowledgements:** We thank colleagues at PHE - NIS -Public Health Laboratory Manchester, NIBSC and The Royal Free Hospital, London for their assistance with pre-distribution testing.

**Enquiries:** Pre-distribution test results are available should you experience a technical failure and wish to discuss the results. Written enquiries about this distribution should be addressed to Dr Beatrix Kele at the email address below. For repeat specimens please order using the web form or e-mail [organiser@ukneqasmicro.org.uk](mailto:organiser@ukneqasmicro.org.uk) stating your laboratory identification number, the distribution name, distribution number and specimen numbers.

Report authorised by: Dr Sanjiv Rughooputh, Scheme Organiser.

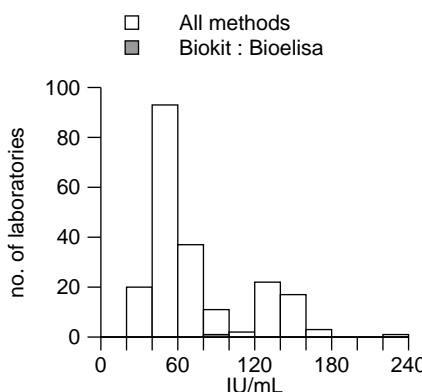
Six specimens were dispatched with requests to screen for immunity to rubella. All specimens were derived from single thrombinised human plasma (serum) donations. Bronidox was added as a preservative at a final concentration of 0.05%.

**Specimen : 4148 Rubella IgG not designated**

	n (UK)	range	median	5%-95%	Number of reports for non-numeric or off-scale results			Quantitative report :			
					Rubella IgG IU/mL	Your method	All methods	Your result : 11 IU/mL	Your method median : 11.0 IU/mL		
All methods	227 (115)	0-15	4	2-11				<b>Qualitative report :</b>			
Abbott : Architect	87 (35)	2-4	3	2-3				Your Report :			
Beckman : Access	8 (8)	8-10	9	8-10				Rubella IgG negative (<10 IU/mL)			
Biokit : Bioelisa	2 (2)	11-11						Your Score : Not scored			
bioMerieux : Vidas	41 (24)	3-12	9	6-11	<5	0	12	Overall Results			
DiaSorin : Liaison	15 (5)	3-4	3	3-4	<10	0	7	UK	All	Score	
Euroimmun	1	5-5						-----			
Roche	43 (27)	4-9	5	4-6				Rubella IgG positive	10	18	NS
Siemens: Immulite	2	6-6						Rubella IgG negative	98	201	NS
Siemens:ADVIA Centaur	13 (11)	1-10	6	1-9				-----			
Siemens:EIA	4 (1)	0-8	5	1-8				Total	108	219	
Unspecified	4 (2)	3-9	8	4-9				% Correct	90.7	91.8	
Virion Serion	2	6-9									

**Specimen : 4149 Rubella IgG positive (>=10 IU/mL)**

	n (UK)	range	median	5%-95%	Number of reports for non-numeric or off-scale results			Quantitative report :			
					Rubella IgG IU/mL	Your method	All methods	Your result : >100 IU/mL	Your method median : 81.0 IU/mL		
All methods	236 (115)	1-737	56	39-168				<b>Qualitative report :</b>			
Abbott : Architect	87 (35)	26-51	45	39-50				Your Report :			
Beckman : Access	8 (8)	61-90	72	62-89				Rubella IgG positive (>=10 IU/mL)			
Biokit : Bioelisa	1 (1)	81-81						Your Score : 2			
bioMerieux : Vidas	40 (23)	40-737	76	64-92				Overall Results			
DiaSorin : Liaison	24 (6)	28-50	42	31-49				UK	All	Score	
Roche	43 (27)	112-166	140	125-151				-----			
Siemens: Immulite	2	79-79						Rubella IgG positive	109	219	2
Siemens:ADVIA Centaur	13 (11)	37-439	348	55-429				Rubella IgG negative	0	0	-1
Siemens:EIA	4 (1)	1-84	72	11-82				-----			
Unspecified	4 (2)	48-80	71	51-79				Total	109	219	
Vircell	1	115-115						% Correct	100	100	
Virion Serion	2	70-77									



**Specimen : 4150 Rubella IgG negative (<10 IU/mL)**

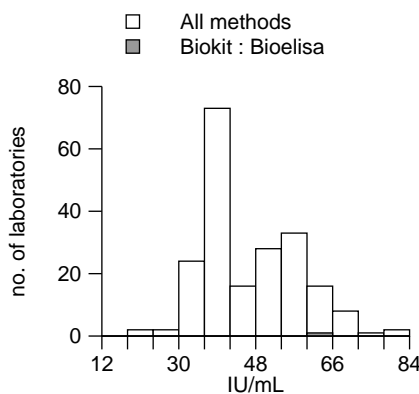
	n (UK)	range	median	5%-95%	Number of reports for non-numeric or off-scale results			Quantitative report :			
					Rubella IgG IU/mL	Your method	All methods	Your result : 6 IU/mL	Your method median : 5.5 IU/mL		
All methods	213 (112)	0-10	3	2-6				<b>Qualitative report :</b>			
Abbott : Architect	88 (36)	1-4	3	2-3				Your Report :			
Beckman : Access	8 (8)	5-6	6	5-6				Rubella IgG negative (<10 IU/mL)			
Biokit : Bioelisa	2 (2)	5-6						Your Score : 2			
bioMerieux : Vidas	41 (25)	4-6	5	4-6	<5	0	28	Overall Results			
DiaSorin : Liaison	2	3-3			<10	0	6	UK	All	Score	
Roche	43 (27)	0-5	2	2-3				-----			
Siemens:ADVIA Centaur	13 (11)	0-10	5	1-9				Rubella IgG positive	0	0	-1
Siemens:EIA	4 (1)	0-6	4	1-6				Rubella IgG negative	109	220	2
TGS TA	1	1-1						-----			
Unspecified	4 (2)	3-6	5	3-6				Total	109	220	
Vircell	1	6-6						% Correct	100	100	
Virion Serion	2	4-5									



Six specimens were dispatched with requests to screen for immunity to rubella. All specimens were derived from single thrombinised human plasma (serum) donations. Bronidox was added as a preservative at a final concentration of 0.05%.

**Specimen : 4151 Rubella IgG positive ( $\geq 10$  IU/mL)**

	n (UK)	range	median	5%-95%
All methods	238 (116)	1-844	46	33-81
Abbott : Architect	88 (35)	24-46	40	36-45
Beckman : Access	8 (8)	39-67	57	42-65
Biokit : Bioelisa	2 (2)	65-844		
bioMerieux : Vidas	40 (23)	34-81	63	53-75
DiaSorin : Liaison	24 (6)	24-42	34	28-41
Roche	43 (27)	42-63	54	47-59
Siemens: Immulite	2	52-52		
Siemens:ADVIA Centaur	13 (11)	10-118	109	39-118
Siemens:EIA	4 (1)	1-55	52	8-55
Unspecified	4 (2)	42-73	56	43-71
Vircell	1	106-106		
Virion Serion	2	59-61		



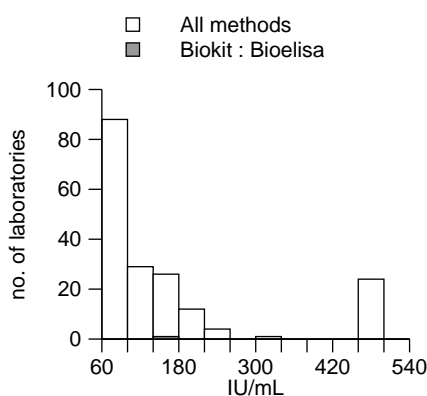
**Quantitative report :**  
Your result : 844 IU/mL  
Your method median : 454.5 IU/mL

**Qualitative report :**  
Your Report :  
Rubella IgG positive ( $\geq 10$  IU/mL)  
Your Score : 2

Overall Results	UK	All	Score
Rubella IgG positive	109	220	2
Rubella IgG negative	0	0	-1
Total	109	220	
% Correct	100	100	

**Specimen : 4152 Rubella IgG positive ( $\geq 10$  IU/mL)**

	n (UK)	range	median	5%-95%
All methods	209 (100)	2-1520	120	80-500
Abbott : Architect	88 (35)	58-105	87	78-97
Beckman : Access	8 (8)	167-329	216	181-294
Biokit : Bioelisa	1 (1)	164-164		
bioMerieux : Vidas	39 (22)	115-222	156	136-195
DiaSorin : Liaison	24 (6)	73-177	124	99-160
Roche	27 (22)	500-1520	500	500-1366
Siemens: Immulite	2	148-162		
Siemens:ADVIA Centaur	2 (2)	158-500		
Siemens:EIA	4 (1)	2-134	121	18-133
Unspecified	4 (2)	91-192	161	98-191
Vircell	1	224-224		
Virion Serion	2	159-167		



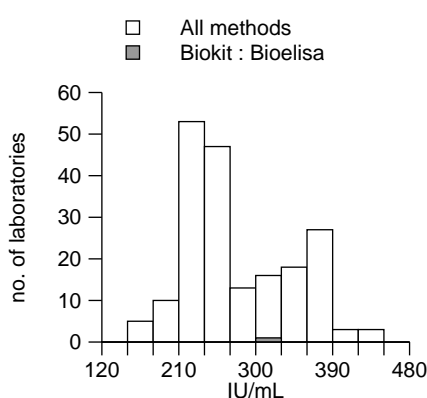
**Quantitative report :**  
Your result :  $>100$  IU/mL  
Your method median : 164.0 IU/mL

**Qualitative report :**  
Your Report :  
Rubella IgG positive ( $\geq 10$  IU/mL)  
Your Score : 2

Overall Results	UK	All	Score
Rubella IgG positive	109	220	2
Rubella IgG negative	0	0	-1
Total	109	220	
% Correct	100	100	

**Specimen : 4153 Rubella IgG positive ( $\geq 10$  IU/mL)**

	n (UK)	range	median	5%-95%
All methods	218 (102)	2-500	258	188-384
Abbott : Architect	88 (35)	165-305	241	210-274
Beckman : Access	8 (8)	265-432	358	285-427
Biokit : Bioelisa	1 (1)	319-319		
bioMerieux : Vidas	36 (20)	198-382	300	216-369
DiaSorin : Liaison	24 (6)	154-319	228	174-308
Luminex xTAG	1	294-294		
Roche	43 (27)	318-450	364	325-410
Siemens:ADVIA Centaur	3 (3)	50-500	364	81-486
Siemens:EIA	3	2-341	200	22-327
Unspecified	3 (1)	228-389	236	229-374
Vircell	1	270-270		
Virion Serion	1	320-320		



**Quantitative report :**  
Your result :  $>100$  IU/mL  
Your method median : 319.0 IU/mL

**Qualitative report :**  
Your Report :  
Rubella IgG positive ( $\geq 10$  IU/mL)  
Your Score : 2

Overall Results	UK	All	Score
Rubella IgG positive	108	219	2
Rubella IgG negative	1	1	-1
Total	109	220	
% Correct	99.1	99.5	



**Comments on distribution 4205**

Specimen 4148 was derived from thrombinised human plasma (serum) donation. Pre-distribution test results for specimen 4148 are shown in the table below. This specimen gave a negative result (<10 IU/mL) with Biokit Rubagen, Roche Cobas and Abbott Architect assays however it gave positive result ( $\geq 10$  IU/mL) with SRH and Biokit: Bioelisa.

Specimen Number	SRH IU/mL	Biokit Bioelisa		Biokit Rubagen* IU/mL	Roche Cobas IU/mL	Abbott Architect IU/ml
		IU/mL	OD			
4148	20.0	11.0	0.33	<10.0	8.4	2.8
<b>Cut-off</b>	<b>15</b>	<b>10</b>		<b>10</b>	<b>10</b>	<b>10</b>

SRH: Single Radial Haemolysis

\*: Total antibody

Images of MIKROGEN recomBlot Rubella line assay of specimen 4148 as tested in UK NEQAS Microbiology



Specimen No. 4148

recomBlot Rubella IgG band profile: **E1-E2 +/-; c -; E1+; E2-**



**Interpretation of test results (according to the Mikrogen kit insert):**

Specimen 4148: New infection in the last few days cannot be excluded.



Antibodies present against Rubella antigens:

- a) New infection possible
- b) No formation of antibodies against E2
- c) Delayed antibody formation against E2 following vaccination or infection

It has been confirmed that IgG antibodies against Rubella were present in specimen 4148.  
Due to discrepant pre-distribution test results, specimen 4148 was not scored.

