Quality of bacteriological infection serology in Germany: analysis of the 2017 proficiency testing trials

Zur Qualität bakteriologisch-infektionsserologischer Verfahren in Deutschland: Auswertung der infektionsserologischen Ringversuche 2017

Abstract

Bacteriological serological tests can detect bacterial antigens and antibodies (IgG and IgM) in samples of body fluids to help diagnose diseases, assess a patient's immune and vaccination status and control the spread of infections. Participation by laboratories in external quality assurance (EQA) enables the comparison of performance and results among different laboratories. This ensures an appropriate quality management for diagnostic testing and, thus, highly precise test results that lead to accurate and rapid treatment. This paper summarizes and discusses the results of the bacteriological infectious serology as part of proficiency testing trials conducted in 2017 and aims to improve the diagnostic management of laboratories in Germany.

Keywords: external quality assurance, EQA, proficiency testing trials, bacteriological infection serology, Germany

Zusammenfassung

Bakteriologisch-serologische Tests können bakterielle Antigene und Antikörper (IgG und IgM) in einer Probe von Körperflüssigkeiten nachweisen, um die Diagnose von Krankheiten zu erleichtern, den Immun- und Impfstatus von Patienten zu untersuchen oder die Ausbreitung von Infektionen zu kontrollieren. Die Teilnahme von Laboratorien an der externen Leistungssicherung (EQA) kann den Vergleich von Leistung und Ergebnissen zwischen verschiedenen Laboratorien ermöglichen, um ein angemessenes diagnostisches Qualitätsmanagement und damit eine hohe Präzision der Testergebnisse zu gewährleisten, die zu einer genauen und schnellen Behandlung führen kann. Der vorliegende Beitrag fasst die Ergebnisse der bakteriologischen Infektionsserologie als Teil der 2017 durchgeführten Ringversuche zusammen und diskutiert sie mit dem Ziel, das diagnostische Management der Laboratorien in Deutschland zu verbessern.

Schlüsselwörter: externe Qualitätssicherung, EQA, Ringversuche, bakteriologische Infektionsserologie, Deutschland

Renata Smit[1,2]
Klaus-Peter Hunfeld[1,2,3]

1 Institute for Laboratory Medicine, Microbiology and Infection Control, Northwest Medical Centre, Academic Teaching Hospital, Medical Faculty, Goethe University, Frankfurt am Main, Germany

2 INSTAND e.V., Düsseldorf, Germany

3 German Society for Hygiene and Microbiology, Safety of Quality commission, Hannover, Germany

Table 1: Study groups and the number of participants included in two proficiency testing trials in Germany, 2017

INSTAND Index No.	Study groups	5/2017 Participants (N)	11/2017 Participants (N)
10	Tetanus toxoid antibodies	138	129
311	*Treponema pallidum* antibodies	333	322
312	*Chlamydia trachomatis* antibodies	248	247
313	*Chlamydia trachomatis* antibodies – direct detection (ELISA/PCR)	14	14
314	*Chlamydia pneumonia* antibodies	218	216
315	*Yersinia* antibodies	227	–
316	*Chlamydia trachomatis* – direct detection (PCR)	23	14
317	*Bordetella pertussis* antibodies	–	202
318	Diphtheria toxoid antibodies	124	121
319	*Campylobacter* antibodies	114	–
320	Procalcitonin	123	128
321	*Streptococcal* antibodies (ASL, aDNase)	293	287
323	Rheumatoid factor	184	183
324	*Mycoplasma pneumonia* antibodies	–	260
325	*Coxiella burnetii* antibodies	–	92
331	Salmonella antibodies (Widal)	72	64
332	*Borrelia burgdorferi* antibodies	389	387
334	*Helicobacter pylori* antibodies	184	171

N=total number of participants with a diagnosis

1 Introduction

Serological tests can be used to detect viral and bacterial antigens and antibodies (IgG and IgM) in a sample of blood, cerebrospinal fluid (CSF) or urine [1]. Serological testing is often used to help diagnose diseases, assess a patient's immune and vaccination status, and control the spread of infection in a certain population [1], [2], [3]. Selecting the appropriate test can lead to a fast, accurate interpretation of the diagnostic findings, as well as proper and immediate treatment [1]. All tests have to meet standard operating procedures and should be validated or verified to comply with the laboratory's quality management. Participation in external quality assurance (EQA) can ensure the accuracy of the diagnostic test results. EQA also allows a comparison of performance and results between different laboratories, the identification of problems associated with equipment, methods and materials, and the improvement of quality management. It also identifies training needs and monitors the role of training and its impact. EQA helps to assure physicians, patients and health authorities that the laboratory is producing reliable results. EQA participation is usually required for accreditation [2], [4]. This paper summarizes and discusses the results of bacteriological infection serology as part of proficiency testing trials conducted in 2017. The findings can help to improve the diagnosis of individual constellations and optimize the test systems used. This paper deals with a standardized form.

2 Methods

2.1 Participants

In 2017, 125,999 laboratories participated in two proficiency testing trials. 10,640 participants were from Germany and 1,450 were from other European countries. One trial was carried out in May and the other in November 2017 (Table 1).

2.2 Sample collection and EQA progress

As the proficiency testing provider, the Society for Promoting Quality Assurance in Medical Laboratories e.V. (INSTAND e.V., Düsseldorf) in Germany sent unknown control samples (31, 32, 61 and 62) for each study group (310–334) to participating laboratories twice per year to test for one or more components present in the samples [5], [6]. All samples were prepared according to standard operating procedures [5], [6]. Samples 31 and 32 were sent to participating laboratories in May 2017, while samples 61 and 62 were sent in November 2017 [5], [6]. The control samples for *Yersinia*, *Bordetella pertussis*, *Campylobacter*, *Mycoplasma pneumonia* and *Coxiella burnetii* were only analyzed once that year [7], [8].

2.3 Target values

The results of all laboratories were compared to the assigned target value that was determined with the highest level of accuracy and precision using a reference measurement procedure in line with the guideline of the German Medical Association (RiLiBÄK). When a uniform target value could not be determined for the quantitative test results, the robust mean of all participants was es-

Table 2: Tetanus toxoid detection during the 2017 proficiency testing trials

		Sample 31		Sample 32		Sample 61		Sample 62	
		Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**ELISA** qual./quant. N=116/N=116	positive	100.0	positive	100.0	positive	100.0	positive	100.0
	Target value [IU/ml]	1.4		0.9		2.9		2.5	
	Target range	(0.86–2.01)	81.5	(0.52–1.22)	96.3	(1.74–4.06)	96.8	(1.49–3.49)	93.5
	Diagnostic N*=134		98.6		99.3		98.5		98.5

N=total number of participants, N*=average number of participants

tablished as the target value. With respect to the qualitative test results, either the mode of the results of the reference laboratories or the mode of the results of the participants was set as the target value [2], [7], [8].

3 Results

3.1 Tetanus toxoid (310)

3.1.1 Sample information

Samples 31, 32, 61 and 62 originated from clinically healthy blood donors.

3.1.2 Determination of the target values

For the tests conducted in May, the mode of the results of all participants was set as the target value for the qualitative test results, while the mode of the results of the reference laboratories was established as the target value for the semi-quantitative test results. For the November tests, the mode of the results of the reference laboratories was set as the target value for the qualitative test results, while the robust mean of all participants was established as the target value for the semi-quantitative test results [7], [8]. The results are listed in Table 2.

3.1.3 Overall diagnostic interpretation and commentary on the test results

Antibody detection has no diagnostic relevance in determining a tetanus infection, but it can be used to assess an individual's immune or vaccination status for tetanus toxoid [1]. Results of this trial show that samples 31, 61 and 62 had tetanus toxoid antibody titers ranging from 1.4 to 2.9 IU/ml, suggesting protective immunity against tetanus toxoid; however, a booster vaccination would be needed in 5 to 10 years to achieve long-term protection. The level of antibodies in sample 32 was 0.9 IU/ml, suggesting that there was protective immunity; however, a booster vaccination would be needed in 2 to 5 years to provide long-term protection. It is important to note that vaccinations should primarily be done in accordance with the recommendations of the German Standing Committee on Vaccination (STIKO) and not based simply on measured antibody levels [3]. Pass rates for ELISA tests were 100% for the qualitative results and 81.5–96.8% for the quantitative results. The pass rate for the overall diagnostic results was between 98.5% and 99.3%.

3.2 Treponema pallidum antibodies (311)

3.2.1 Sample information

Samples 32 and 62 originated from healthy blood donors without clinical evidence of syphilis. Sample 31 was taken from a patient with a known syphilis infection that had been sufficiently treated in the past. Sample 61 was donated during blood donor screening by an individual that had been treated for a syphilis infection several years ago.

3.2.2 Determination of the target values

For the qualitative test results, the mode of the results of the reference laboratories was set as the target value. In the case of the semi-quantitative test results, the mode of the results of all participants was set as the target value for the May tests, while the results of the reference laboratories were stipulated as the target value for November [7], [8]. The results are listed in Table 3.

3.2.3 Overall diagnostic interpretation and commentary on the test results

Samples 32 and 62 showed no clinical or serological evidence of a syphilis infection. In the positive sample 31 (target value (modal): TPPA: 320, VDRL: negative, IgM-FTA-ABS: negative), the results clearly indicated a past infection without the need for further treatment because the IgM-FTA-ABS test was negative. The overall pass rate of all test methods in sample 31 was 77.2%. The positive sample 61 (target value: TPPA: 640, polyval. ELISA: positive, IgG-ELISA: positive, VDRL: negative, FTA-ABS-IgG: 80, FTA-ABS-IgM and IgM-ELISA: negative) indicated a syphilis infection and achieved an overall pass rate for all test methods of 86.9%. The distribution of the immunoblot bands for the positive samples 31 (Figure 1, Figure 2) and 61 (Figure 3) are shown below [7], [8]. The pass rates for the overall diagnostic results of the negative samples 32 and 62 were between 96.4% and 98.8%, whereas the pass rates of the positive samples 31 and 61 were between 77.2% and 86.9%.

Table 3: Treponema pallidum antibody detection during the 2017 proficiency testing trials

			Sample 31		Sample 32		Sample 61		Sample 62	
			Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**ELISA/CLIA/CMIA** qual./quant. Target value [IU/ml] Target range	N=156/N=126	bl./positive 18.2 (11.6–24.7)	90.5 100.0	negative 0.0 (0–0.1)	97.6 100.0	positive 21.3 (13.6–29)	94.4 100.0	negative 0.0 (0–0.09)	97.2 100.0
	TPHA qual./quant. Target value [IU/ml] Target range	N=248/N=182	bl./positive 320 (80–1280)	90.9 97.7	negative 0.0 (0–79.9)	93.2 97.7	positive 320.0 (80–1280)	97.5 87.2	negative 0.0 (0–79.9)	100.0 100.0
	TPPA qual./quant. Target value [IU/ml] Target range	N=84/N=80	bl./positive 320.0 (80–1280)	100.0 86.4	negative 0.0 (0–79.9)	100.0 95.5	positive 640.0 (160–2560)	100.0 100.0	negative 0.0 (0–79.9)	100.0 100.0
	VDRL qual./quant. Target value [IU/ml] Target range	N=238/N=170	negative 0.0 (0–0.99)	87.9 85.0	negative 0.0 (0–0.99)	100.0 92.5	negative 0.0 (0–0.99)	95.1 91.1	negative 0.0 (0–0.99)	100.0 93.3
	Cardiolipin qual./quant. Target value [IU/ml] Target range	N=2/N=18	– 32.0 (8–128)	– 100.0	– 0.0 (0–4.99)	– 100.0	negative 0 (0–0)	100 100	negative 0 (0–0)	100 100
Specific IgG	**ELISA** qual./quant. Target value [IU/ml] Target range	N=30/N=58	bl./positive 21.8 (15.9–27.7)	100.0 100.0	negative 6.5 (4.75–8.26)	100.0 100.0	positive 36.9 (26.9–46.9)	100.0 100.0	negative 0.0 (0–0)	100.0 100.0
	Blot qual.	N=38	bl./positive	100.0	negative	91.7	positive	100.0	negative	100.0
	FTA-ABS qual./quant. Target value [IU/ml] Target range	N=90/N=50	positive 40 (10–160)	73.9 83.3	negative 0.0 (0–4.99)	95.7 100.0	positive 80.0 (20–320)	90.9 69.2	negative 0.0 (0–4.99)	95.5 100.0
Specific IgM	**ELISA** qual.	N=28	negative	100.0	negative	100.0	negative	87.5	negative	87.5
	Blot qual.	N=39	negative	66.7	negative	100.0	negative	87.5	negative	100.0
	FTA-ABS qual./quant. Target value [IU/ml] Target range	N=66/N=54	negative 0.0 (0–4.99)	100.0 100.0	negative 0.0 (0–4.99)	100.0 100.0	negative 0.0 (0–4.99)	100.0 100.0	negative 0.0 (0–4.99)	100.0 100.0
	Diagnostic	N*=328		77.2		96.4		86.9		98.8

N=total number of participants, N*=average number of participants, bl.=borderline

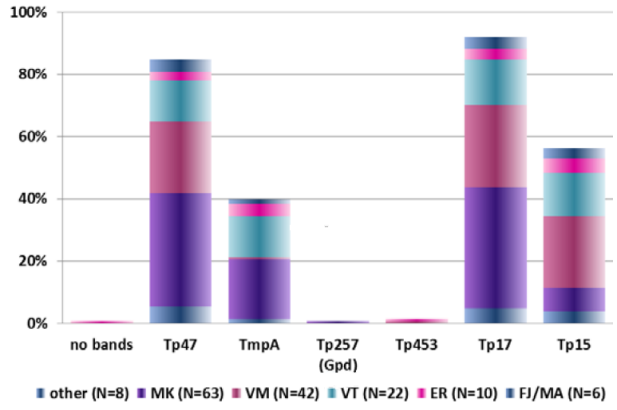

Figure 1: The distribution of the immunoblot bands reported for the positive sample 31 [7], [8]; recovery rate (%) of the submitted IgG immunoblot bands for sample 311/31 (May 2017), participants N=151

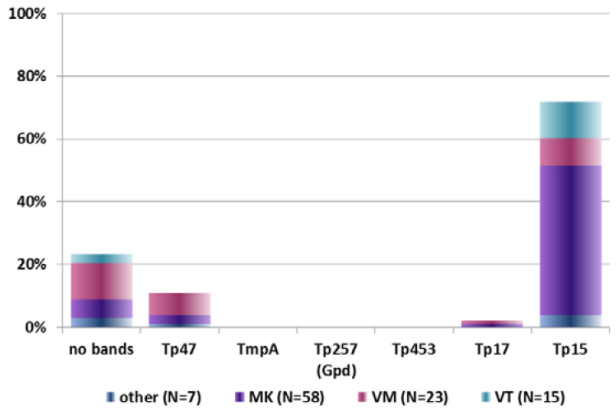

Figure 2: The distribution of the immunoblot bands reported for the positive sample 31 [7], [8]; recovery rate (%) of the submitted IgM immunoblot bands for sample 311/31 (May 2017), participants N=103

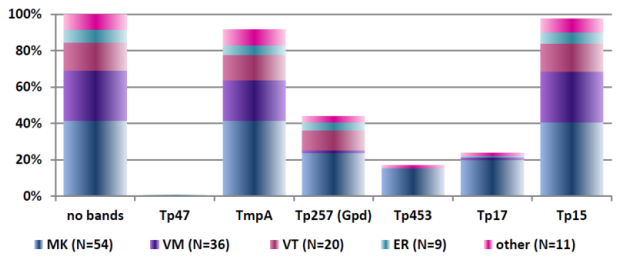

Figure 3: The distribution of the immunoblot bands reported for the positive sample 61 [7], [8]; recovery rate (%) of the submitted IgG immunoblot bands for sample 311/61 (Nov. 2017), participants N=130

Table 4: Chlamydia trachomatis antibody detection during the 2017 proficiency testing trials

			Sample 31		Sample 32		Sample 61		Sample 62	
			Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
Specific IgG	**ELISA** qual.	N=230	bl./positive	50.9	negative	98.1	neg./bl./pos.	100.0	positive	96.8
	ELISA C. spp qual./quant. Target value [IU/ml] Target range	N=16/N=28	positive 56.5 (36.2–76.8)	100.0 100.0	negative 7.35 (4.7–10)	100.0 100.0	positive 10.6 (6.78–14.4)	100.0 100.0	positive 1.67 (1.07–2.27)	100.0 100.0
	Blot qual.	N=16	positive	50.0	negative	100.0	positive	50.0	positive	75.0
	MIFT qual./quant. Target value [IU/ml] Target range	N=54/N=74	bl./positive 80 (20–320)	85.7 75.0	negative 0.0 (0–19.9)	100.0 87.5	neg./bl./pos. 40.0 (0–160)	100.0 85.7	positive 320.0 (80–1280)	92.3 85.7
Specific IgA	**ELISA** qual.	N=170	neg./bl./pos.	100.0	negative	100.0	negative	87	bl./positive	95.7
	ELISA C. spp qual.	N=8	positive	100.0	negative	100.0	negative	100.0	positive	100.0
	Blot qual.	N=20	negative/bl.	100.0	negative	100.0	negative	100.0	bl./positive	100.0
	MIFT qual./quant. Target value [IU/ml] Target range	N=30/N=66	negative/bl. 0.0 (0–20)	100.0 100.0	negative 0.0 (0–19.9)	100.0 100.0	negative 0.0 (0–19.9)	85.7 87.5	bl./positive 80.0 (20–320)	100.0 88.2
Specific IgM	**ELISA** qual.	N=88	negative/bl.	63.6	negative	95.5	negative	95.5	negative	95.5
	ELISA C. spp qual.	N=10	negative	100.0	negative	100.0	negative	100.0	negative	100.0
	Blot qual.	N=40	negative	100.0	negative	100.0	negative	100.0	negative	100.0
	MIFT qual./quant. Target value [IU/ml] Target range	N=66/N=64	negative/bl. 0.0 (0–20)	88.9 94.4	negative 0.0 (0–19.9)	94.4 100.0	negative 0.0 (0–19.9)	100.0 100.0	negative 0.0 (0–19.9)	93.3 100.0
	Diagnostic	N*=248		86.7		98.8		76.1		98.4

N=total number of participants, N*=average number of participants, bl.=borderline

3.3 Chlamydia trachomatis antibodies (312)

3.3.1 Sample information

Samples 31, 32, 61 and 62 originated from clinically healthy blood donors.

3.3.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results, while for the semi-quantitative results, the mode of the results of all participants was set as the target value [7], [8]. The results are listed in Table 4.

3.3.3 Overall diagnostic interpretation and commentary on the test results

Samples 32 and 61 showed no serological evidence of a *C. trachomatis* infection. In sample 31, IgG antibodies by ELISA C. spp and blot as well as IgA-ELISA C. spp were detected, indicating an infection with *C. trachomatis*. In sample 62, IgG and IgA antibodies were detected, suggesting an infection with *C. trachomatis*. In sample 61, the lowest pass rate was 50% for the qualitative detection of IgG antibodies by immunoblot. In sample 31, the lowest pass rates for the qualitative detection of IgG antibodies by immunoblot and ELISA were 50% and 50.9% respectively. The pass rates for the overall diagnostic results of the negative samples (samples 32 and 61) were between 76.1% and 98.8%, while the pass rates for the positive samples (samples 31 and 62) were between 86.7% and 98.4%.

3.4 Chlamydia trachomatis antibodies – direct detection by ELISA/PCR (313)

3.4.1 Sample information

Samples 31, 32, 61 and 62 originated from clinically healthy blood donors.

3.4.2 Determination of the target values

For the qualitative test results, the mode of the results of all participants was set as the target value. In the case of the semi-quantitative test results, the mode of the results of the reference laboratories was established as the target value for the tests conducted in May, while the mode of the results of all participants was stipulated as the target value for November [7], [8]. The results are presented in Table 5.

3.4.3 Overall diagnostic interpretation and commentary on the test results

Samples 31 and 62 showed no clinical or serological evidence of *C. trachomatis*, while samples 32 and 61 tested positive for the pathogen, indicating a *C. trachomatis* infection. The pass rate of all samples for the overall clinical diagnostic results was 100%.

Table 5: Chlamydia trachomatis antibody direct detection by ELISA/PCR during the 2017 proficiency testing trials

			Sample 31		Sample 32		Sample 61		Sample 62	
			Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
313	**ELISA Ag** qual.	N=24	negative	100.0	positive	100.0	positive	83.3	negative	100.0
	DNA hybridization without amplification qual.	N=18	negative	100.0	positive	100.0	positive	100.0	negative	100.0
	Antigen detection techniques (others) qual.	N=30	negative	100.0	positive	83.3	positive	88.9	negative	100.0
	Diagnostic	N*=14		100.0		100.0		100.0		100.0
316	**IFT** qual.	N=74	positive	100.0	negative	91.3	positive	100.0	negative	92.9
	Diagnostic	N*=74		100.0		95.7		100.0		100.0

N=total number of participants, N*=average number of participants

Table 6: Chlamydia pneumonia antibody detection during the 2017 proficiency testing trials

			Sample 31		Sample 32		Sample 61		Sample 62	
			Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**CFT** qual./quant. Target value [IU/ml] Target range	N=16/N=18	negative 0 (0–0)	100 100	negative 0 (0–0)	100 100	negative 0 (0–0)	100 100	negative 0 (0–0)	100 100
Specific IgG	**ELISA** qual.	N=184	positive	97.5	negative	95.0	negative	100.0	negative	98.1
	Blot qual.	N=12	positive	66.7	negative	100	negative	100	negative	100
	MIFT qual./quant. Target value [IU/ml] Target range	N=42/N=72	positive 160 (40–640)	87.5 92.9	negative 0 (0–19.9)	87.5 92.9	negative 0 (0–19.9)	100 86.4	negative 0 (0–19.9)	100 86.4
Specific IgA	**ELISA** qual.	N=210	bl./positive	84.6	negative	100.0	negative	100.0	negative	100.0
	Blot	N=16	negative/bl.	100	negative	100	negative	100	negative	100
	MIFT qual./quant. Target value [IU/ml] Target range	N=52/N=68	bl./positive 80 (20–320)	77.8 82.4	negative 0 (0–19.9)	100 100	negative 0 (0–19.9)	100 94.1	negative 0 (0–19.9)	100 94.1
Specific IgM	**ELISA** qual.	N=210	negative	95.9	negative	95.9	negative	96.4	negative	96.4
	Blot qual.	N=50	negative	100	negative	100	negative	100	negative	100
	MIFT qual./quant. Target value [IU/ml] Target range	N=74/N=68	negative 0 (0–19)	66.7 64.7	negative 0 (0–19)	77.8 82.4	negative 0 (0–19)	100 100.0	negative 0 (0–19)	100 100.0
	Diagnostic	N*=217		98.2		96.8		100.0		99.5

N=total number of participants, N*=average number of participants, bl.=borderline

3.5 Chlamydia pneumonia antibodies (314)

3.5.1 Sample information

Samples 31, 32, 61 and 62 were taken from clinically healthy blood donors.

3.5.2 Determination of the target values

For the tests conducted in May, the results of the reference laboratories was set as the target value for the qualitative results, while for the semi-quantitative test results, the mode of the results of the reference laboratories was set as the target value. For November, the mode of the results of the reference laboratories was set as the target value for the qualitative test results, while for the semi-quantitative results, the mode of the results of all participants was set as the target value [7], [8]. The results and pass rates are shown in Table 6.

3.5.3 Overall diagnostic interpretation and commentary on the test results

In samples 32, 61 and 62, no evidence of an infection with *C. pneumoniae* was detected, while the test results for the tested pathogen in sample 31 were positive. In sample 31, IgG was detected, with borderline positive results for IgA antibodies, indicating an infection with *C. pneumoniae*. All samples had qualitative results of 84.6–100% for all ELISA tests. All MIFT tests were between 66.7 and 100% with respect to the qualitative results and in a range of 64.7–100% for the quantitative results. The pass rates for overall diagnostic results of the negative samples 32, 61 and 62 were between 96.8% and 100%, while for the positive sample 31, the pass rate was 98.2%.

Table 7: Yersinia antibody detection during the 2017 proficiency testing trials

			Sample 31		Sample 32	
			Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**Y. enter. 03** qual./quant. Target value [IU/ml] Target range	N=50/N=14	negative 0 (0–99)	96.0 100	negative 0 (0–99)	88.0 100
	Y. enter. 09 qual./quant. Target value [IU/ml] Target range	N=48/N=14	negative 0 (0–99)	100.0 100	negative 0 (0–99)	95.8 100
	Y. pseudotub. qual./quant. Target value [IU/ml] Target range	N=42/N=16	negative 0 (0–99)	100.0 100	negative 0 (0–99)	90.5 87.5
Specific IgG	**ELISA** qual./quant. Target value [IU/ml] Target range	N=40/N=28	negative 126 (80.6–171)	100.0 100.0	positive 7.2 (4.61–9.79)	100.0 100.0
	Blot qual.	N=26	negative	76.9	positive	100
Specific IgM	**ELISA** qual.	N=18	negative	88.9	neg./bl./pos.	88.9
	Blot qual.	N=20	negative	100	positive	70
Specific IgA	**ELISA** qual.	N=38	negative	100.0	positive	94.7
	Blot qual.	N=26	negative	92.3	positive	100
	Diagnostic*	N=227		99.1		87.2

N=total number of participants, N*=average number of participants, bl.=borderline

3.6 Yersinia antibodies (315)

3.6.1 Sample information

Sample 31 was obtained from a healthy blood donor. Sample 32 was donated by a patient with gastroenteritis and arthralgia in his recent medical history.

3.6.2 Determination of the target values

For the tests conducted in May, the mode of the results of all participants was set as the target value for the qualitative test results, while for the semi-quantitative test results, the mode of the results of the reference laboratories was set as the target value. However, in November, the mode of the results of the reference laboratories was set as the target value for the qualitative test results, while the results of the reference laboratories were stipulated as the target value of the semi-quantitative results [7], [8]. The results are listed in Table 7.

3.7 Chlamydia trachomatis antibodies – direct detection by IFT (316)

3.7.1 Sample information

Samples 31, 32, 61 and 62 were taken from clinically healthy blood donors.

3.7.2 Determination of the target values

The mode of the results of all participants was established as the target value for the qualitative test results [7], [8]. The results are listed in Table 5.

3.7.3 Overall diagnostic interpretation and commentary on the test results

Samples 32 and 62 showed no serological evidence of *C. trachomatis*, while samples 31 and 61 tested positive for the pathogen, indicating an infection with *C. trachomatis*. The pass rates for the overall diagnostic results of the negative samples 32 and 62 were between 95.7% and 100% and thus in line with previous years, while the pass rate for the positive samples 31 and 61 was 100%.

3.8 Bordetella pertussis antibodies (317)

3.8.1 Sample information

Samples 61 and 62 were donated by healthy blood donors without evidence of any respiratory infections in their recent medical history.

3.8.2 Determination of the target values

For the qualitative test results, the mode of the results of the reference laboratories was set as the target value, while for the semi-quantitative test results, the robust mean of all participants was established as the target value [7], [8]. The results are listed in Table 8.

3.9 Diphtheria toxoid antibodies (318)

3.9.1 Sample information

Samples 61 and 62 were donated by healthy pre-immunized blood donors, while samples 31 and 32 originated from clinically healthy blood donors.

Table 8: Bordetella pertussis antibody detection during the 2017 proficiency testing trials

		Sample 61		Sample 62	
		Results	Pass rate [%]	Results	Pass rate [%]
Specific IgG	**KBR** quant. N=2 Target value [IU/ml] Target range	 8 (5.12–10.9)	 100	 32 (20.5–43.5)	 100
	ELISA (PT+ FHA) qual. N=30/N=44 Target value [IU/ml] Target range	positive 41.3 (26.4–56.2)	86.7 100.0	negative 4.31 (2.76–5.86)	100.0 100.0
	ELISA (PT) qual. N=110/N=106 Target value [IU/ml] Target range	neg./bl./pos. 55.1 (41.3–68.9)	100 100	negative 0 (0–39.9)	100.0 100.0
	IFT qual./quant. N=6/N=6 Target value [IU/ml] Target range	borderline 210 (134–286)	100 100	negative 16 (10.2–21.8)	100.0 100.0
	Blot qual. N=18	bl./positive	100.0	negative	88.9
Specific IgM	**ELISA** qual. N=38	negative	89.5	negative	94.7
	IFT qual./quant. N=4/N=4 Target value [IU/ml] Target range	negative 0 (0–0)	100 100	negative 0 (0–0)	100 100
	Blot qual. N=6	negative	100	negative	100
Specific IgA	**ELISA (PT+FHA)** qual. N=32	negative	81.3	negative	100
	ELISA (PT) qual. N=192	negative	91.7	negative	96.9
	IFT qual./quant. N=2/N=2 Target value [IU/ml] Target range	negative 0 (0–0)	100 100	negative 0 (0–0)	100 100
	Blot qual. N=32	negative	93.8	negative	100
	Diagnostic N*=202		88.6		99.5

N=total number of participants, N*=average number of participants, bl.=borderline

Table 9: Diphtheria toxoid antibody detection during the 2017 proficiency testing trials

		Sample 31		Sample 32		Sample 61		Sample 62	
		Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**ELISA** qual./quant. N=116/N=84 Target value [IU/ml] Target range	neg./bl./pos. 0 (0–0.1)	100 97.6	positive 0.922 (0.553–1.29)	100 88.1	positive – –	100 –	positive – –	100 –
	Diagnostic N*=123		96.0		100.0		98.3		98.3

N=total number of participants, N*=average number of participants, bl.=borderline

3.9.2 Determination of the target values

In the case of the semi-quantitative test results, the robust mean of all participants was established as the target value. For the qualitative test results, the mode of the results of the reference laboratories was set as the target value for the May tests, while for November, the mode of the results of all participants was set as the target value [7], [8]. The results are shown in Table 9.

3.9.3 Overall diagnostic interpretation and commentary on the test results

Antibody detection against the diphtheria toxin and toxoid (DT) is not suitable for identifying an acute case of diphtheria; it can only be used to assess the immune and vaccination status for diphtheria [3]. Findings suggested that protective immunity did exist in samples 61 and 62, while in sample 31, there was no protective immunity, therefore a booster vaccination was recommended. The titer level (0.922 IU/ml) of sample 32 indicated protective active immunity, however, a booster vaccination would be needed to provide long-term protection. Vaccination recommendations should primarily be made following STIKO recommendations [3]. ELISA tests had qualitative results of 100% and quantitative results of 88.1–97.6%. The pass rates for the overall diagnostic results were in the range of 96.0–100%.

3.10 Campylobacter antibodies (319)

3.10.1 Sample information

Samples 31 and 32 originated from clinically healthy blood donors.

3.10.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results. In

Table 10: Campylobacter antibody detection during the 2017 proficiency testing trials

			Sample 31		Sample 32	
			Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**CFT** qual./quant. Target value [IU/ml] Target range	N=34/N=36	bl./pos. 80.0 (20–320)	64.7 72.2	negative 0.0 (0–20)	100.0 100.0
Specific IgG	**ELISA** qual./quant. Target value [IU/ml] Target range	N=24/N=118	positive 7 (4.48–9.52)	100.0 100	negative 26.3 (16.8–35.8)	91.7 100
	Blot qual.	N=8	positive	100.0	negative	75.0
	IFT qual./quant. Target value [IU/ml] Target range	N=8/N=6	positive 2500.0 (1600–3400)	100 100	negative 0.0 (0–0)	100 100
Specific IgM	**ELISA** qual.	N=8	bl./positive	100	negative	100
	IFT qual./quant. Target value [IU/ml] Target range	N=4/N=4	negative 0.0 (0–0)	100 100	negative 0.0 (0–0)	100 100
Specific IgA	**ELISA** qual.	N=24	neg./bl./pos.	100	negative	100
	Blot qual.	N=8	bl./positive	75.0	negative	100
	IFT qual./quant. Target value [IU/ml] Target range	N=6/N=4	negative 160.0 (102–218)	100.0 100	negative 0.0 (0–0)	100 100
	Diagnostic	N*=114		86.8		96.5

N=total number of participants, N*=average number of participants, bl.=borderline

Table 11: Procalcitonin detection during the 2017 proficiency testing trials

			Sample 31		Sample 32		Sample 61		Sample 62	
			Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**Procalcitonin** qual.	N=20/15	negative	100	positive	100	negative	100	positive	100
	Procalcitonin semi-quant [ng/ml]	N=19/16	<0.5 ng/ml	100	2–10 ng/ml, >10 ng/ml	100	<0.5 ng/ml	93.8	>10 ng/ml, 2–10 ng/ml	93.8
	Procalcitonin quant. Target value [IU/ml] Target range	N=69/68	 0 (0–0.5)	 100	 20.3 (15.2–25.4)	 92.8	 0 (0–0.5)	 100	 6.34 (4.63–8.05)	 95.6
	Diagnostic	N*=126		100		89.50		99.2		96.9

N=total number of participants, N*=average number of participants

the case of the semi-quantitative test results, the mode of the results of all participants was set as the target value for the May tests; however, the robust mean of all participants was established as the target value [7], [8] for November. The results are listed in Table 10.

3.10.3 Overall diagnostic interpretation and commentary on the test results

Specific IgG, IgM and IgA antibodies were detected using the commercially available ELISA, immunoblot and IFT tests. No evidence of an infection with *C. jejuni* was detected in sample 32, while sample 31 tested positive for IgG antibodies against the tested pathogen, indicating a *Campylobacter* infection. In sample 31, qualitative and quantitative results for ELISA were 100% for IgG, IgM and IgA antibodies, while in sample 32 they ranged from 91.7–100%. The pass rate for the overall diagnostic results of sample 32 was 96.52%, while it was 86.8% for sample 31.

3.11 Procalcitonin (320)

3.11.1 Sample information

Samples 31, 32, 61 and 62 were donated by healthy blood donors.

3.11.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results, while the robust mean of all participants was established as the target value for the semi-quantitative test results [7], [8]. The results are presented in Table 11.

3.11.3 Overall diagnostic interpretation and commentary on the test results

The findings of samples 32 and 66 indicated the likelihood of systemic inflammatory reaction (sepsis), while the findings of samples 31 and 61 indicated that systemic infection is unlikely. The qualitative result in all four

Table 12: Streptococci antibody detection during the 2017 proficiency testing trials

		Sample 31		Sample 32	
		Results	Pass rate [%]	Results	Pass rate [%]
Streptococcus-O-Lysin	**All methods** qual./quant. N=2/N=2	positive	100.0	negative	100
	Target value [IU/ml]	300		0	
	Target range	(228–372)	100.0	(0–0)	100
	Method 1 qual./quant. N=4/N=4	positive	100.0	negative	100
	Target value [IU/ml]	436		24.8	
	Target range	(331–541)	100	(18.8–30.8)	100
	Method 2 quant. N=2				
	Target value [IU/ml]	155		0	
	Target range	(118–192)	100	(0–0)	100
Streptodornase	**Method 1** qual./quant. N=4/N=4	negative	100	negative	100
	Target value [IU/ml]	123		45	
	Target range	(93.5–153)	100	(34.2–55.8)	100
	Method 3 qual./quant. N=6/N=6	negative	33.3	negative	100
	Target value [IU/ml]	200		0	
	Target range	(152–248)	33.3	(0–0)	66.7

N=total number of participants; method 1: nephelometry, dead stop; method 2: kinetic nephelometry; method 3: latex-agglutination

Table 13: Rheumatoid factor detection during the 2017 proficiency testing trials

	Sample 31		Sample 32	
	Results	Pass rate [%]	Results	Pass rate [%]
All methods qual. N=2	positive	100.0	negative	100.0
Method 1 qual./quant. N=4/N=4	negative	50.0	negative	100.0
Target value [IU/ml]	36		0	
Target range	(28.8–43.2)	50.0	(0–0)	50.0

N=total number of participants; method 1: nephelometry, dead stop

samples was 100%. The quantitative test results in samples 31 and 61 were 100%, while they were 92.8% in sample 32, and 95.6% in sample 62. The semi-quantitative results in samples 31 and 32 were 100%, while they were 93.8% in samples 61 and 62. The overall diagnostic evaluation of all four samples was between 89.5 and 100%.

3.12 Streptococci antibodies (321)

3.12.1 Sample information

Samples 31 and 32 were donated by healthy blood donors.

3.12.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results, while in the case of the semi-quantitative test results, the robust mean of all participants was established as the target value [7], [8]. The results are displayed in Table 12.

3.12.3 Overall diagnostic interpretation and commentary on the test results

In the qualitative results, titers of streptococcal antibodies above the cut-off value (200 IU/ml) indicated an infection with *Streptococcus*. Titers between 200 and 400 indicated a past or recent infection [5]. A much higher titer occurs when there is severe infection or an acute secondary disease. The latex agglutination method used to detect Streptococcus-O-lysine antibodies had a qualitative and quantitative test result of 33.3% in sample 31, while in sample 32, the quantitative test result was 66.7%. The overall pass rate of Streptococcus-O-lysine antibody detection was 100%, while the overall pass rate of streptodornase detection was between 33.3% and 100%.

3.13 Rheumatoid factor (323)

3.13.1 Sample information

Samples 31 and 32 were taken from clinically healthy blood donors.

3.13.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results, while in the case of the semi-quantitative test results, the robust mean of all participants was established as the target value [7], [8]. The results are indicated in Table 13.

3.13.3 Overall diagnostic interpretation and commentary on the test results

The qualitative test results for both samples for all methods were 100%. The qualitative and quantitative test results for sample 31 for method 1 was 50%, while

Table 14: Mycoplasma pneumonia antibody detection during the 2017 proficiency testing trials

			Sample 61		Sample 62	
			Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**ELISA-IgA+IgM** qual.	N=20	positive	100.0	positive	100.0
	PHA qual./quant. Target value [IU/ml] Target range	N=22/N=12	neg./bl./pos. 80.0 (0–320)	90.9 100.0	bl./positive 160.0 (40–640)	63.6 66.7
Specific IgG	**ELISA** qual./quant. Target value [IU/ml] Target range	N=98/N=84	bl./positive 23.8 (15.2–32.4)	89.8 100.0	neg./bl./pos. 14.7 (9.41–20)	100.0 100.0
	Blot qual.	N=8	negative	100.0	negative	100.0
	CLIA qual./quant. Target value [IU/ml] Target range	N=96/N=84	bl./positive 12.7 (8.13–17.3)	85.4 100.0	neg./bl./pos. 6.21 (3.97–8.45)	100.0 100.0
	IFT qual./quant. Target value [IU/ml] Target range	N=12/N=8	negative 0 (0–0)	100.0 100.0	positive 0 (0–0)	100.0 100.0
Specific IgM	**ELISA** qual.	N=124	negative	91.9	negative	88.7
	Blot qual.	N=8	negative	100.0	negative	100.0
	CLIA qual.	N=114	negative	94.7	negative	96.5
	IFT qual./quant. Target value [IU/ml] Target range	N=10/N=8	negative 35.7 (22.8–48.6)	100.0 100.0	negative 35.2 (22.5–47.9)	100.0 100.0
Specific IgA	**ELISA** qual.	N=90	neg./bl./pos.	100.0	negative/bl.	68.9
	Blot qual.	N=10	positive	100.0	negative	100.0
	IFT qual./quant. Target value [IU/ml] Target range	N=4/N=2	negative 0 (0–0)	100.0 100.0	negative 0 (0–0)	100.0 100.0
	Diagnostic	N*=260		100.0		82.7

N=total number of participants, N*=average number of participants, bl.=borderline

the quantitative test result for sample 32 for method 1 was 50%.

3.14 Mycoplasma pneumonia antibodies (324)

3.14.1 Sample information

Samples 61 and 62 originated from patients with several known respiratory infections in their recent medical history.

3.14.2 Determination of the target values

The mode of the results for all participants was set as the target value for the qualitative and semi-quantitative test results [7], [8]. The results are presented in Table 14.

3.14.3 Overall diagnostic interpretation and commentary on the test results

Evidence of an infection with *M. pneumonia* was detected in both samples. In both samples both the reference laboratories and most participants found variable results and weak IgG and IgA seroreactivity [7], [8]. The pass rate for the overall diagnostic results was 100% for sample 61 and 82.7% for sample 62.

3.15 Coxiella burnetii antibodies (325)

3.15.1 Sample information

Sample 61 was donated by a healthy blood donor who showed no evidence of a recent infection. Sample 62 was donated by a patient a few months after having acute *C. burnetii* pneumonia.

3.15.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results, while the mode of the results of all participants was set as the target value for the semi-quantitative test results [7], [8]. The results are shown in Table 15.

3.15.3 Overall diagnostic interpretation and commentary on the test results

Sample 61 tested negative for *C. burnetii*, while sample 62 tested positive. Sample 61 exhibited IgG phase I IFT titers of 5120 (median), IgG phase II IFT titers of 2560 (median) as well as weakly reactive IgM and IgA results. These results suggested a relatively recent case of pneumonia. Most participants and expert laboratories made variable clinical comments as to whether the test constellation should be interpreted as an acute or chronic *Coxiella* infection [7], [8].

Table 15: Coxiella burnetii antibody detection during the 2017 proficiency testing trials

			Sample 61		Sample 62	
			Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**CFT Phase I** qual./quant. Target value [IU/ml] Target range	N=2/N=4	negative 0.0 (0–19.9)	100.0 100.0	positive 320.0 (80–1280)	100.0 100.0
	CFT Phase II qual./quant. Target value [IU/ml] Target range	N=2/N=2	negative 0.0 (0–19.9)	100.0 100.0	positive 160.0 (40–640)	100.0 100.0
Specific IgG	**ELISA Phase I** qual.	N=58	negative	100.0	positive	100.0
	ELISA Phase II qual.	N=20	negative	100.0	positive	90.0
	IFT Phase I qual./quant. Target value [IU/ml] Target range	N=80/N=92	negative 0.0 (0–79.9)	100.0 97.7	positive 5120.0 (1280–20480)	100.0 87.0
	IFT Phase II qual./quant. Target value [IU/ml] Target range	N=80/N=92	negative 0.0 (0–79.9)	100.0 97.7	positive 2560.0 (640–10240)	100.0 87.0
Specific IgM	**ELISA** qual.	N=20	negative	100.0	positive	90.0
	IFT qual./quant. Target value [IU/ml] Target range	N=76/N=82	negative 0.0 (0–19.9)	100.0 89.7	bl./positive 80.0 (20–320)	92.1 80.5
Specific IgA	**ELISA** qual.	N=44	negative	100.0	negative/bl.	86.4
	IFT qual./quant. Target value [IU/ml] Target range	N=18/N=22	negative 0.0 (0–19.9)	88.9 63.6	bl./positive 80.0 (20–320)	88.9 81.8
	Diagnostic	N*=92		100.0		89.0

N=total number of participants, N*=average number of participants, bl.=borderline

The pass rate for the overall diagnostic results of sample 61 was 100%, while the pass rate of sample 62 was 89.0%.

3.16 Salmonella antibodies (331)

3.16.1 Sample information

Samples 31, 32, 61 and 62 originated from clinically healthy blood donors.

3.16.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results, while the results of the reference laboratories were stipulated as the target value of the semi-quantitative results [7], [8]. The results are listed in Table 16.

3.16.3 Overall diagnostic interpretation and commentary on the test results

No evidence of a *Salmonella* infection was detected in all samples. The pass rates for all samples for the overall diagnostic results were between 94.4% and 98.4%.

3.17 Borrelia burgdorferi antibodies (332)

3.17.1 Sample information

Samples 31 and 61 originated from a healthy blood donor without evidence of a tick bite or clinical Lyme borreliosis in his medical history. Sample 32 was donated by a patient with past Lyme arthritis treated several years ago and confirmed by culture and PCR. Sample 62 was donated two years after the infection by a patient with successfully treated Lyme arthritis.

3.17.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results [7], [8]. The results are listed in Table 17.

3.17.3 Overall diagnostic interpretation and commentary on the test results

No evidence of an infection with *B. burgdorferi* was detected in samples 31 and 61, while pathogens were detected in samples 32 and 62, indicating an infection with *B. burgdorferi*. Samples 32 and 62 showed high IgG antibody titers together with borderline reactive IgM test results, suggesting a late phase of the borrelia-specific immune response. Figure 4 and Figure 5 show the distribution of specific IgG and IgM borrelia immunoblot bands for sample 32 [7], [8]. The distribution of the immunoblot

Table 16: Salmonella antibody detection during the 2017 proficiency testing trials

		Sample 31		Sample 32		Sample 61		Sample 62	
		Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
S. Typhi O-Ag	**WIDAL** qual./quant. N=98/N=96 Target value [IU/ml] Target range	negative 0 (0–99)	91.7 91.3	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	96.0 96.0	negative 0 (0–99)	96.0 96.0
S. Typhi (O)H-Ag	**WIDAL** qual./quant. N=108/N=106 Target value [IU/ml] Target range	negative 0 (0–99)	96.2 96.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0
S. Enterit. (O)H-Ag	**WIDAL** qual./quant. N=70/N=66 Target value [IU/ml] Target range	negative 0 (0–99)	100.0 93.3	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0
S. O-Ag, Gr. A	**WIDAL** qual./quant. N=66/N=68 Target value [IU/ml] Target range	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0
S. O-Ag, Gr. B	**WIDAL** qual./quant. N=70/N=74 Target value [IU/ml] Target range	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0
S. parat. B (O)H-Ag	**WIDAL** qual./quant. N=104/N=102 Target value [IU/ml] Target range	negative 0 (0–99)	96.0 95.8	negative 0 (0–99)	96.0 95.8	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 96.3
S. typhim. (O)H-Ag, Gr. B	**WIDAL** qual./quant. N=70/N=68 Target value [IU/ml] Target range	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–109)	100.0 100.0
S. O-Ag, Gr. C	**WIDAL** qual./quant. N=58/N=58 Target value [IU/ml] Target range	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0	negative 0 (0–99)	100.0 100.0
ELISA	**Polyvalent** N=18	negative	100.0	negative	100.0	negative	100.0	negative	100.0
	IgA N=20	negative	100.0	negative	100.0	negative	87.5	negative	100.0
	Diagnostic N*=68		94.4		97.2		95.3		98.4

N=total number of participants, N*=average number of participants

Table 17: Borrelia burgdorferi antibody detection during the 2017 proficiency testing trials

		Sample 31		Sample 32		Sample 61		Sample 62	
		Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
Specific polyvalent test system	**PHA** qual./quant. N=28/N=32 Target value [IU/ml] Target range	negative 0.0 (0–79.9)	100.0 100.0	positive 640.0 (320–1280)	100.0 100.0	negative 0.0 (0–0)	100.0 100.0	positive 15200.0 (9728–20672)	100.0 100.0
	ELISA qual. N=14	negative	100.0	positive	100.0	negative	100.0	positive	100.0
	Line-Immunoblot qual. N=18	negative	75.0	positive	75.0	negative	100.0	positive	100.0
Specific IgG	**ELISA** qual. N=200	negative	95.8	positive	97.9	negative	100.0	positive	100.0
	Blot qual. N=174	negative	92.9	positive	92.9	negative	97.7	positive	97.7
	CLIA qual./quant. N=24/N=20 Target value [IU/ml] Target range	negative 0.0 (0–4.99)	100.0 100.0	positive 933.0 (597–1269)	100.0 100.0	negative 0.0 (0–4.99)	100.0 100.0	positive 500.0 (400–600)	100.0 100.0
	IFT qual./quant. N=48/N=36 Target value [IU/ml] Target range	negative 0.0 (0–39.9)	100.0 100.0	positive 1280.0 (320–5120)	100.0 100.0	negative 0.0 (0–39.9)	100.0 100.0	bl./positive 640.0 (160–2560)	100.0 100.0
Specific IgM	**ELISA** qual. N=220	negative	98.2	neg./bl./pos.	98.2	negative	98.2	neg./bl./pos.	100.0
	Blot qual. N=180	negative/bl.	97.7	neg./bl./pos.	97.7	negative	100.0	negative/bl.	89.1
	CLIA qual. N=26	negative	85.7	neg./bl./pos.	85.7	negative	100.0	negative/bl.	100.0
	IFT qual./quant. N=34/N=34 Target value [IU/ml] Target range	negative 0.0 (0–19.9)	100.0 100.0	neg./bl./pos. 0.0 (0–40)	100.0 100.0	negative 0.0 (0–19.9)	100.0 100.0	negative 0.0 (0–19.9)	100.0 100.0
	Diagnostic N*=388		98.2		82.5		98.7		94.8

N=total number of participants, N*=average number of participants, bl.=borderline

bands reported for the positive sample 62 is depicted in Figure 6.

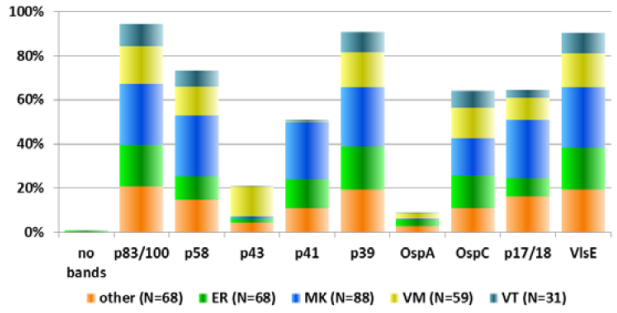

Figure 4: The distribution of the immunoblot bands reported for sample 32 [7], [8]; recovery rate (%) of the submitted IgG immunoblot bands for sample 332/32 (May 2017), participants N=314

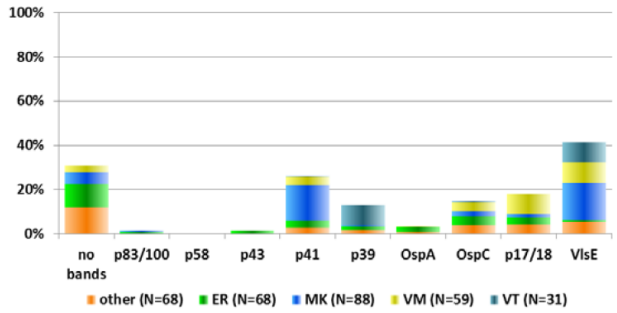

Figure 5: The distribution of the immunoblot bands reported for sample 32 [7], [8]; recovery rate (%) of the submitted IgM immunoblot bands for sample 332/32 (May 2017), participants N=285

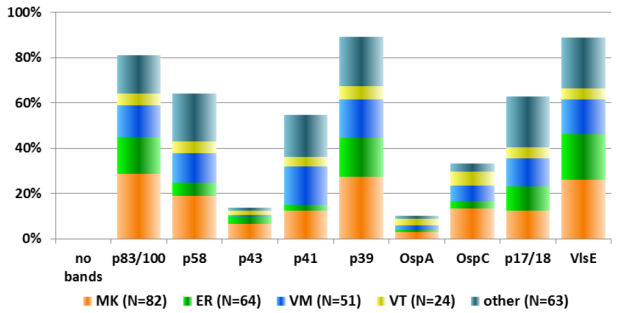

Figure 6: The distribution of the immunoblot bands reported for sample 62 [7], [8]; recovery rate (%) of the submitted IgG immunoblot bands for sample 332/62 (Nov 2017), participants N=284

The pass rates for the overall diagnostic results of the negative samples 31 and 61 were between 98.2% and 98.7%, while for the positive samples 32 and 62 they were between 82.5% and 94.8%.

3.18 Helicobacter pylori antibodies (334)

3.18.1 Sample information

Samples 31, 32 and 61 originated from clinically healthy blood donors. Sample 62 was taken from a helicobacter-positive patient shortly after finishing eradication therapy.

3.18.2 Determination of the target values

The mode of the results of the reference laboratories was set as the target value for the qualitative test results. The results are shown in Table 18.

3.18.3 Overall diagnostic interpretation and commentary on the test results

There was no evidence of an infection with *H. pylori* in samples 32 and 61. Samples 31 and 62 showed positive IgG and IgA antibody reactivity by ELISA and immunoblot, indicating an infection or colonization with *H. pylori*. In sample 61, the qualitative result for IgA blot was 60%, while for IgG blot it was 71.4%. The pass rates for the overall diagnostic results of the positive samples 31 and 62 were between 91.3% and 93.0%, while for the negative samples 61 and 32 they were between 82.5% and 95.7%.

4 Discussion and conclusion

EQA can be used as a tool in improving diagnostic processes in laboratories. It leads to more reliable and prompt diagnostic results, which sustain the quality and efficiency of patient care. The results of the EQA presented in this report generally show moderate to very good diagnostic quality. However, some special comments on serology need to be made:

Regarding the *Treponema pallidum* serology (311), sample 31 had low pass rates of 66.7% for the qualitative detection of IgM antibodies by immunoblot and 73.9% for the detection of IgG antibodies by FTA-ABS. These contributed to the poor overall pass rate of 77.2% for all test methods. Generally, laboratory results in 2017 showed better pass rates compared to the results in 2016. In the case of *Chlamydia trachomatis* serology (312), the overall pass rate was between 50% and 100% for all tests in sample 31. A pass rate of 50% was observed for the qualitative detection of IgG antibodies by immunoblot. Next, pass rates of 50.9% and 63.6% were observed for the qualitative detection of IgG and IgM antibodies respectively, both detected by ELISA in the above-mentioned sample. In sample 61, the lowest pass rate of 50% was observed for the qualitative detection of IgG antibodies by immunoblot, while in sample 62 the lowest pass rate was 75% for the same method. With regard to *Chlamydia pneumonia* serology (314), the overall pass rate was between 64.7% and 100% for all tests in sample 31. A pass rate of 66.7% was observed for the qualitative detection and 64.7% for the quantitative detection of IgM antibodies by MIFT. A pass rate of 77.8% was observed for the qualitative detection of IgA antibodies, also by MIFT, and a pass rate of 66.7% was recorded for the qualitative detection of IgG antibodies by immunoblot in the above-mentioned sample. In sample 32, the lowest pass rate of 77.8% was observed for the qualitative detection of IgM antibodies by MIFT.

Table 18: Helicobacter pylori antibody detection during the 2017 proficiency testing trials

		Sample 31		Sample 32		Sample 61		Sample 62	
		Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]	Results	Pass rate [%]
Specific IgG	**ELISA** qual./quant. N=190/N=150 Target value [IU/ml] Target range	positive 3.17 (2.03–4.31)	98.1 100	negative 701 (449–953)	88.7 100	negative 3.83 (2.45–5.21)	100.0 100	positive 46.3 (29.6–63)	95.2 100
	Blot qual. N=34	positive	100	negative	90	negative	71.4	positive	100
Specific IgA	**ELISA** qual. N=120	bl./positive	87.1	negative	100.0	negative	96.6	bl./positive	96.6
	Blot qual. N=26	bl./positive	100	negative	100	negative	60	positive	80
	Diagnostic N*=178		91.3		95.7		82.5		93.0

N=total number of participants, N*=average number of participants, bl.=borderline

Generally, the pass rates were lower in 2017 compared to the results in 2016. In the case of *Yersinia* antibody serology (315), the lowest pass rate of 76.9% was observed for the qualitative detection of IgG antibodies by immunoblot in sample 31. Sample 32 recorded the lowest pass rate of 70% for the qualitative detection of IgM antibodies by immunoblot. In the case of *Campylobacter* serology (319), the lowest pass rate of 64.7% was observed for qualitative and 72.2% for quantitative detection by CFT in sample 31. In the same sample, a pass rate of 75% was detected for the qualitative detection of IgA by immunoblot. Sample 32 recorded the lowest pass rate of 75% for the qualitative detection of IgG antibodies by immunoblot. With respect to *Streptococci* serology (321), the pass rate was 33.3% for qualitative and quantitative detection by latex agglutination in sample 31, while in sample 32, a pass rate of 66.7% for quantitative detection by latex agglutination was observed. Generally, the pass rates were lower in 2017 than in 2016. Regarding rheumatoid factor serology (323), the pass rate was 50% for qualitative and quantitative detection using the nephelometry method in sample 31, while a pass rate of 50% for quantitative detection by the same method mentioned above was observed in sample 32. With regard to *Mycoplasma pneumonia* serology (324), the pass rate was 63.6% and 66.7% for qualitative and quantitative detection respectively, using PHA in sample 62. In the same sample, the pass rate was 68.9% for the quantitative detection of IgA antibodies by ELISA. With respect to the *Coxiella burnetii* serology (325), the overall pass rate was 100% in the diagnostic assessment of sample 61. The lowest pass rate for quantitative detection of IgA by IFT was 63.6%, showing poorer laboratory results than the pass rate in 2016. In the case of the *Borrelia burgdorferi* serology (332), both samples 31 and 32 showed the lowest pass rate of 75% in the qualitative detection by line immunoblot. In the diagnostic assessment of sample 31, an overall pass rate of 98.2% was recorded, while in sample 32, it was 82.5%. In the *Helicobacter pylori* serology (334), the overall pass rate for sample 61 was between 60% and 100%. In terms of the qualitative result, the pass rate was 71.4% for IgG detection and 60% for IgA detection, both by immunoblot.

The above-mentioned findings and comments show, as in previous years, the need for further improvement in certain diagnostic procedures. This will achieve more standardized and higher quality testing in Germany to ensure even better diagnostic test results in the routine clinical setting. This will maintain quality and efficiency in patient care.

Notes

Competing interests

The authors declare that they have no competing interests.

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Corresponding author:
Dr. Renata Smit
Institute for Laboratory Medicine, Microbiology and Infection Control, Northwest Medical Centre, Academic Teaching Hospital, Medical Faculty, Goethe University, Steinbacher Hohl 2–26, 60488 Frankfurt am Main, Germany
renata_smit@t-2.net

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