


Listing and evaluation of the results

1: Dr. med.Max Mustermann
Laboratory Mustermann
Survey of 11 November 2020

Adviser:

311

Infection Serology - Treponema pallidum Antibodies

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
TPPA (semiquantitative)	61	Titer	<20.0	20.0	ET		<80.0		0	+	
	62		320	640	SV	160	2560		0	+	
AB against Treponema pallidum polyvalent (semiquantitative)	61		0.000								Sample not evaluated
	62		27.0								
AB against Cardiolipin (semiquantitative)	61	Titer	0.000		ET		<1.00		0	+	
	62		0.000		ET		<=2.00		-0,869	+	

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number
TPPA (semiquantitative)	61		<20.0			MA		YN00412
	62		320					
AB against Treponema pallidum polyvalent (semiquantitative)	61	Index	0.000	1.00	228	DO	DO02	332004
	62		27.0	1.00				
AB against Cardiolipin (semiquantitative)	61		0.000	1.00	414	BD		9274714
	62		0.000	1.00				

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
TPPA (qualitative)	61		MA		negative (1)	negative (1)	M	+
	62				positive (3)	positive (3)	M	+
AB against Treponema pallidum polyvalent (qualitative)	61	228	DO	DO02	negative (1)	negative (1)	M	+
	62				positive (3)	positive (3)	M	+
Treponema pallidum IgG - Immunoblot	61	411	MK	MK03	negative (1)	negative (1)	M	+
	62				positive (3)	positive (3)	M	+
Treponema pallidum IgG - Immunoblot bands	61	411	MK	MK03		Sample not evaluated		
	62				Tp47, Tp17	Sample not evaluated		
Treponema pallidum IgM - Immunoblot	61	411	MK	MK03	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
AB against Cardiolipin (qualitative)	61	414	BD		negative (1)	negative (1)	M	+
	62			negative (1)	negative, borderline, positive (1,2,3)	M	+	
diagnostic comment	61				no serological evidence for an infection, suitable for transfusion	no serological evidence for an infection, suitable for transfusion, no serological evidence for an infection + suitable for transfusion	M	+
	62				serological evidence for a past (latent) infection requiring no treatment, not suitable for transfusion	serological evidence for a past (latent) infection requiring no treatment, not suitable for transfusion, serological evidence for a past (latent) infection requiring no treatment + not suitable for transfusion	M	+

Listing and evaluation of the results

1: Dr. med.Max Mustermann
Laboratory Mustermann

Survey of 11 November 2020

312

Infection Serology - Chlamydia trachomatis Antibodies

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Chlamydia trachomatis IgG (semiquantitative)	61		0.000								Sample not evaluated
	62		28.0								Sample not evaluated
AB against Chlamydia trachomatis IgA (semiquantitative)	61		0.000								Sample not evaluated
	62		12.0								Sample not evaluated

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number
AB against Chlamydia trachomatis IgG (semiquantitative)	61	U/ml	0.000	1.00	190	VR	MK02	EL0052
	62		28.0	1.00				
AB against Chlamydia trachomatis IgA (semiquantitative)	61	U/ml	0.000	1.00	190	VR	MK02	EK0039
	62		12.0	1.00				

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Chlamydia trachomatis IgG (qualitative)	61	190	VR	MK02	negative (1)	negative (1)	M	+
	62				positive (3)	borderline, positive (2,3)	M	+
AB against Chlamydia trachomatis IgA (qualitative)	61	190	VR	MK02	negative (1)	negative (1)	M	+
	62				borderline (2)	borderline, positive (2,3)	M	+
diagnostic comment	61				no serological evidence for an infection	no serological evidence for an infection	M	+
	62				serological evidence for a past infection	serological evidence for a past infection, serological evidence for a present infection, serological evidence for a past infection + serological evidence for a present infection	M	+

** BRAVO **

314

Infection Serology - Chlamydia pneumoniae (Chlamydophila) Antibodies

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Chlamydia pneumoniae IgG (semiquantitative)	61		146								Sample not evaluated
	62		0.000								Sample not evaluated
AB against Chlamydia pneumoniae IgA (semiquantitative)	61		1.67								Sample not evaluated
	62		0.000								Sample not evaluated
AB against Chlamydia pneumoniae IgM (semiquantitative)	61		0.000								Sample not evaluated
	62		0.000								Sample not evaluated

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number
AB against Chlamydia pneumoniae IgG (semiquantitative)	61	RU/ml	146	1.00	190	ER	ER99	E200526AM
	62		0.000	1.00				
AB against Chlamydia pneumoniae IgA (semiquantitative)	61	Ratio	1.67	1.00	190	ER	ER99	E200820AM
	62		0.000	1.00				
AB against Chlamydia pneumoniae IgM (semiquantitative)	61	Ratio	0.000	1.00	190	ER	ER99	E200901BN
	62		0.000	1.00				

Listing and evaluation of the results

1: Dr. med. Max Mustermann
Laboratory Mustermann

Survey of 11 November 2020

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Chlamydia pneumoniae IgG (qualitative)	61	190	ER	ER99	positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
AB against Chlamydia pneumoniae IgA (qualitative)	61	190	ER	ER99	positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
AB against Chlamydia pneumoniae IgM (qualitative)	61	190	ER	ER99	negative (1)	negative, borderline, positive (1,2,3)	M	+
	62				negative (1)	negative (1)	M	+
diagnostic comment	61				serological evidence for a past infection	serological evidence for a present infection	M	-
	62				no serological evidence for an infection	no serological evidence for an infection	M	+

317

Infection Serology - Bordetella pertussis Antibodies

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria
AB against Bordetella pertussis IgG (semiquantitative)	61		0.000							Sample not evaluated
	62		82.0							Sample not evaluated

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number	Antigen
AB against Bordetella pertussis IgG (semiquantitative)	61	IU/ml	0.000	1.00	190	ER	ER99	E200402AR	PT
	62		82.0	1.00					

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Bordetella pertussis IgG (qualitative)	61	190	ER	ER99	negative (1)	negative, borderline (1,2)	M	+
	62				positive (3)	borderline, positive (2,3)	M	+
AB against Bordetella pertussis IgA (qualitative)	61	190	ER	ER99	negative (1)	negative, borderline (1,2)	M	+
	62				negative (1)	borderline, positive (3,2)	M	-
diagnostic comment	61				no serological evidence for an infection	no serological evidence for an infection	M	+
	62				serological evidence for a past infection (or immunisation)	serological evidence for a past infection (or immunisation), serological evidence for an acute infection	M	+

324

Infection Serology - Mycoplasma pneumoniae Antibodies

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria
AB against Mycoplasma pneumoniae IgG (semiquantitative)	61		0.000							Sample not evaluated
	62		78.0							Sample not evaluated

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number
AB against Mycoplasma pneumoniae IgG (semiquantitative)	61	RU/ml	0.000	1.00	190	ER	ER99	E200415AQ
	62		78.0	1.00				



Listing and evaluation of the results

1: Dr. med.Max Mustermann
Laboratory Mustermann

Survey of 11 November 2020

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Mycoplasma pneumoniae IgG (qualitative)	61	190	ER	ER99	negative (1)	negative, borderline, positive (1,2,3)	M	+
	62				positive (3)	negative, borderline, positive (1,2,3)	M	+
AB against Mycoplasma pneumoniae IgM (qualitative)	61	190	ER	ER99	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
diagnostic comment	61				no serological evidence for an infection	no serological evidence for an infection, serological evidence for an acute infection, serological evidence for a past infection	M	+
	62				serological evidence for a past infection	no serological evidence for an infection, serological evidence for an acute infection, serological evidence for a past infection	M	+

** BRAVO **

325

Infection Serology - Coxiella burnetii Antibodies

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria
AB against Coxiella burnetii IgG - Phase II (semiquantitative)	61		0.000							Sample not evaluated
	62		0.000							Sample not evaluated
AB against Coxiella burnetii IgG - Phase I - IFT (semiquantitative)	61	Titer	<10.0	0.000	ET	<80.0			0	+
	62		<10.0	0.000	ET	<80.0			0	+
AB against Coxiella burnetii IgG - Phase II (semiquantitative)	61	Titer	<10.0	0.000	ET	<80.0			0	+
	62		<10.0	0.000	ET	<80.0			0	+
AB against Coxiella burnetii IgM - IFT (semiquantitative)	61	Titer	<10.0	0.000	ET	<20.0			0	+
	62		<10.0	0.000	ET	<20.0			0	+

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number
AB against Coxiella burnetii IgG - Phase II (semiquantitative)	61	U/ml	0.000	1.00	190	VR	MK02	EL0080
	62		0.000	1.00				
AB against Coxiella burnetii IgG - Phase I - IFT (semiquantitative)	61		<10.0			FC		4488W
	62		<10.0					
AB against Coxiella burnetii IgG - Phase II (semiquantitative)	61		<10.0			FC		4488W
	62		<10.0					
AB against Coxiella burnetii IgM - IFT (semiquantitative)	61		<10.0			FC		4290W
	62		<10.0					

Listing and evaluation of the results

1: Dr. med.Max Mustermann
Laboratory Mustermann

Survey of 11 November 2020

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Coxiella burnetii IgG - Phase II (qualitative)	61	190	VR	MK02	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
AB against Coxiella burnetii IgM (qualitative)	61	190	VR	MK02	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
AB against Coxiella burnetii IgG - Phase I - IFT (qualitative)	61		FC		negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
AB against Coxiella burnetii IgG - Phase II (qualitative)	61		FC		negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
AB against Coxiella burnetii IgM - IFT (qualitative)	61		FC		negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
diagnostic comment	61				no serological evidence for an infection	no serological evidence for an infection	M	+
	62				no serological evidence for an infection	no serological evidence for an infection	M	+

** BRAVO **

331

Infection Serology - Salmonella Antibodies

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Salmonella polyvalent (qualitative)	61	190	IT	ER02	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
AB against Salmonella IgA (qualitative)	61	190	IT	ER02	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
diagnostic comment	61				no serological evidence for an infection	no serological evidence for an infection	M	+
	62				no serological evidence for an infection	no serological evidence for an infection	M	+

** BRAVO **

332

Infection Serology - Borrelia burgdorferi Antibodies

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria
AB against Borrelia burgdorferi IgG (semiquantitative)	61		0.000							Sample not evaluated
	62		43.3							Sample not evaluated
AB against Borrelia burgdorferi IgM (semiquantitative)	61		0.000							Sample not evaluated
	62		0.290							Sample not evaluated

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number
AB against Borrelia burgdorferi IgG (semiquantitative)	61	AU/ml	0.000	1.00	228	DO	DO02	331005
	62		43.3	1.00				
AB against Borrelia burgdorferi IgM (semiquantitative)	61	Index	0.000	1.00	228	DO	DO02	120056
	62		0.290	1.00				

Listing and evaluation of the results

1: Dr. med. Max Mustermann
Laboratory Mustermann

Survey of 11 November 2020

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Borrelia burgdorferi IgG (qualitative)	61	228	DO	DO02	negative (1)	negative, borderline (1,2)	M	+
	62				positive (3)	borderline, positive (2,3)	M	+
AB against Borrelia burgdorferi IgM (qualitative)	61	228	DO	DO02	negative (1)	negative (1)	M	+
	62				negative (1)	negative, borderline, positive (1,2,3)	M	+
AB against Borrelia burgdorferi IgG - Blot	61	411	MK	MK01	borderline (2)	negative, borderline (1,2)	M	+
	62				borderline (2)	borderline, positive (2,3)	M	+
AB against Borrelia burgdorferi IgG - Immunoblot bands	61	411	MK	MK01	p41, OspC	Sample not evaluated		
	62				VlsE	Sample not evaluated		
AB against Borrelia burgdorferi IgM - Blot	61	411	MK	MK01	negative (1)	negative (1)	M	+
	62				negative (1)	borderline, positive (2,3)	M	-
AB against Borrelia burgdorferi IgM - Immunoblot bands	61	411	MK	MK01	no specific band	Sample not evaluated		
	62				no specific band	Sample not evaluated		
AB against Treponema pallidum (qualitative)	61	228	DO	DO02	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
diagnostic comment	61				No serological evidence for infection with Borrelia burgdorferi. Early infection however can not be excluded. In case of clinical suspicion control examination after 2-3 weeks is recommended.	No serological evidence for infection with Borrelia burgdorferi. Early infection however can not be excluded. In case of clinical suspicion control examination after 2-3 weeks is recommended.	M	+
	62				The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for a late stage of Lyme disease or serum scar, depending on the clinical context.	The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for an early stage of Lyme disease or serum scar, depending on the clinical context., The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for a late stage of Lyme disease or serum scar, depending on the clinical context.	M	+

334

Infection Serology - Helicobacter pylori Antibodies

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria
AB against Helicobacter pylori IgG (semiquantitative)	61		412							Sample not evaluated
	62		0.000							Sample not evaluated
AB against Helicobacter pylori IgA (semiquantitative)	61		0.000							Sample not evaluated
	62		0.000							Sample not evaluated

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number
AB against Helicobacter pylori IgG (semiquantitative)	61	U/ml	412	1.00	190	VR	MK02	EK0101
	62		0.000	1.00				
AB against Helicobacter pylori IgA (semiquantitative)	61	U/ml	0.000	1.00	190	VR	MK02	EK0169
	62		0.000	1.00				



Listing and evaluation of the results

1: Dr. med.Max Mustermann
Laboratory Mustermann

Survey of 11 November 2020

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Helicobacter pylori IgG (qualitative)	61	190	VR	MK02	positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
AB against Helicobacter pylori IgA (qualitative)	61	190	VR	MK02	negative (1)	negative, borderline, positive (1,2,3)	M	+
	62				negative (1)	negative (1)	M	+
AB against Helicobacter pylori IgG - Immunoblot	61		MK	MK03	positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
AB against Helicobacter pylori IgA - Immunoblot	61		MK	MK03	negative (1)	negative, borderline, positive (1,2,3)	M	+
	62				negative (1)	negative (1)	M	+
diagnostic comment	61				Serological evidence for infection (2)	Serological evidence for infection, further diagnostic analysis recommended, Serological evidence for infection + further diagnostic analysis recommended (2,3,(2,3))	M	+
	62				no evidence for infection (1)	no evidence for infection (1)	M	+

** BRAVO **

Individual summary of results

1: Dr. med. Max Mustermann
Laboratory Mustermann

Survey of 11 November 2020

311

Infection Serology - Treponema pallidum Antibodies

TPPA (semiquantitative) (Titer, N = 142)									
Collective	Sample	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
FUJIREBIO	61		- <80.0			72	87.5	86.1	
	62	640	160 - 2560			72	98.6		
MAST DIAGNOSTICA	61		- <80.0			54	83.3	79.6	
	62	640	160 - 2560			54	96.3		
others	61		- <80.0			16	81.3	81.3	
	62	640	160 - 2560			16	100		

Rate of success: 83,1%

Graphical representation
not useful

AB against Treponema pallidum polyvalent (semiquantitative) (U/ml, N = 138)									
Collective	Sample	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
ELISA	61		Sample not evaluated			7			
	62		Sample not evaluated			7			
CLIA	61		Sample not evaluated			62			
	62		Sample not evaluated			62			
CMIA	61		Sample not evaluated			28			
	62		Sample not evaluated			28			
other methods	61		Sample not evaluated			43			
	62		Sample not evaluated			43			

Graphical representation
not useful

AB against Cardiolipin (semiquantitative) (Titer, N = 164)									
Collective	Sample	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
VDRL-Test, BioMerieux (1)	61		- <1.00	0.667	139	6			
	62		- <=2.00	0.667	139	6			
VDRL-Test, Biokit	61		- <1.00	0.549	120	22	81.8	81.8	
	62		- <=2.00	1.07	86.6	22	95.5		
VDRL-Test, Becton-Dickinson	61		- <1.00	0.000		10	90.0	90.0	
	62		- <=2.00	0.000		10	100		
VDRL-Test, other provider	61		- <1.00	0.000		23	82.6	82.6	
	62		- <=2.00	0.570	115	23	100		
RPR-Card-Test, BioMerieux	61		- <1.00	0.000		9	88.9	88.9	
	62		- <=2.00	0.000		9	100		
RPR-Card-Test, Biokit	61		- <1.00	0.000		47	80.9	78.7	
	62		- <=2.00	0.813	108	47	97.9		
RPR-Card-Test, BioRad	61		- <1.00	0.000		17	94.1	94.1	
	62		- <=2.00	0.000		17	100		
RPR-Card-Test, other provider	61		- <1.00	1.00	0.000	26	84.6	84.6	
	62		- <=2.00	1.00	0.000	26	100		
other methods (1)	61		- <1.00	0.500	131	4			
	62		- <=2.00	5.50	200	4			

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 82,9%

Graphical representation
not useful



Infection Serology - Treponema pallidum Antibodies

TPPA (qualitative) (N = 133, Rate of success: 98,5%)

Sample 61

Collective	negative (1)	total
FUJIREBIO	64 ●	64
MAST DIAGNOSTICA	55 ●	55
others	12 ●	12

Sample 62

Collective	positive (3)	total
FUJIREBIO	66 ●	66
MAST DIAGNOSTICA	55 ●	55
others	12 ●	12

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Treponema pallidum polyvalent (qualitative) (N = 238, Rate of success: 98,7%)

Sample 61

Collective	negative (1)	positive (3)	total
ELISA, Euroimmun	8 ●	0	8
ELISA, other provider	6 ●	0	6
CLIA, Abbott	13 ●	0	13
CLIA, DiaSorin	52 ●	0	52
CLIA, Roche	11 ●	0	11
CLIA, Siemens	16 ●	0	16
CLIA, other provider	2 ●	0	2
CMIA, Abbott	61 ●	0	61
CMIA, other provider	4 ●	0	4
other methods	63 ●	1	64

Sample 62

Collective	negative (1)	positive (3)	total
ELISA, Euroimmun	0	8 ●	8
ELISA, other provider	0	6 ●	6
CLIA, Abbott	0	13 ●	13
CLIA, DiaSorin	0	53 ●	53
CLIA, Roche	0	11 ●	11
CLIA, Siemens	0	16 ●	16
CLIA, other provider	0	2 ●	2
CMIA, Abbott	0	61 ●	61
CMIA, other provider	0	4 ●	4
other methods	1	63 ●	64

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

Treponema pallidum IgG - Immunoblot (N = 168, Rate of success: 93,5%)

Sample 61

Collective	negative (1)	total
Immunoblot, Euroimmun	5 ●	5
Immunoblot, Mikrogen	20 ●	20
Immunoblot, Viramed	35 ●	35
Immunoblot other provider	12 ●	12
Westernblot	7 ●	7
Line Blot, Mikrogen	48 ●	48
Line Blot, Viramed	9 ●	9
Line Blot, Virotech	16 ●	16
Line Blot, other provider	7 ●	7
other methods	6 ●	6

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
Immunoblot, Euroimmun	2	1	2 ●	5
Immunoblot, Mikrogen	0	0	21 ●	21
Immunoblot, Viramed	0	1	34 ●	35
Immunoblot other provider	0	0	13 ●	13
Westernblot	0	2	5 ●	7
Line Blot, Mikrogen	0	2	47 ●	49
Line Blot, Viramed	0	0	9 ●	9
Line Blot, Virotech	0	0	16 ●	16
Line Blot, other provider	0	0	7 ●	7
other methods	0	0	6 ●	6

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

Treponema pallidum IgG - Immunoblot bands (N = 156)

Sample 62 not evaluated

Treponema pallidum IgM - Immunoblot (N = 175, Rate of success: 96,6%)
Sample 61

Collective	negative (1)	total
Immunoblot, Mikrogen	21 ●	21
Immunoblot, Viramed	39 ●	39
Immunoblot, Virotech	6 ●	6
Immunoblot other provider	9 ●	9
Westernblot	7 ●	7
Line Blot, Mikrogen	56 ●	56
Line Blot, Viramed	9 ●	9
Line Blot, Virotech	13 ●	13
Line Blot, other provider	6 ●	6
other methods	8 ●	8

Sample 62

Collective	negative (1)	borderline (2)	total
Immunoblot, Mikrogen	20 ●	1	21
Immunoblot, Viramed	38 ●	1	39
Immunoblot, Virotech	6 ●	0	6
Immunoblot other provider	9 ●	0	9
Westernblot	7 ●	0	7
Line Blot, Mikrogen	55 ●	2	57
Line Blot, Viramed	9 ●	0	9
Line Blot, Virotech	12 ●	0	12
Line Blot, other provider	6 ●	0	6
other methods	8 ●	0	8

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Cardiolipin (qualitative) (N = 197, Rate of success: 98,5%)
Sample 61

Collective	negative (1)	positive (3)	total
VDRL-Test, Biokit	20 ●	0	20
VDRL-Test, Becton-Dickinson	10 ●	0	10
VDRL-Test, other provider	41 ●	1	42
RPR-Card-Test, BioMerieux	7 ●	0	7
RPR-Card-Test, Biokit	49 ●	0	49
RPR-Card-Test, other provider	65 ●	0	65
other methods	3 ●	0	3

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
VDRL-Test, Biokit	11 ●	2 ●	7 ●	20
VDRL-Test, Becton-Dickinson	8 ●	2 ●	0 ●	10
VDRL-Test, other provider	33 ●	1 ●	8 ●	42
RPR-Card-Test, BioMerieux	8 ●	0 ●	0 ●	8
RPR-Card-Test, Biokit	37 ●	3 ●	8 ●	48
RPR-Card-Test, other provider	51 ●	3 ●	11 ●	65
other methods	0 ●	0 ●	3 ●	3

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 298, Rate of success: 82,2%)
Sample 61

Collective	no serological evidence for an infection, suitable for transfusion	no serological evidence for an infection	suitable for transfusion	questionable result, follow-up recommended in approx. 2 weeks, no serological evidence for an infection	others	total
all methods	217 ●	74 ●	4 ●	1	2	298

Sample 62

Collective	serological evidence for a past (latent) infection requiring no treatment, not suitable for transfusion	serological evidence for a past (latent) infection requiring no treatment	not suitable for transfusion	serological evidence for a past (latent) infection requiring no treatment, not suitable for transfusion, follow-up recommended in 3 - 6 months after start of treatment	others	total
all methods	161 ●	44 ●	40 ●	9	35	289

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective



312

Infection Serology - Chlamydia trachomatis Antibodies

AB against Chlamydia trachomatis IgG (semiquantitative) (U/ml, N = 213)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	61		Sample not evaluated			149		
	62		Sample not evaluated			149		
CLIA	61		Sample not evaluated			44		
	62		Sample not evaluated			44		
other methods	61		Sample not evaluated			20		
	62		Sample not evaluated			20		

Graphical representation not useful

AB against Chlamydia trachomatis IgA (semiquantitative) (U/ml, N = 157)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	61		Sample not evaluated			107		
	62		Sample not evaluated			107		
CLIA	61		Sample not evaluated			35		
	62		Sample not evaluated			35		
other methods	61		Sample not evaluated			15		
	62		Sample not evaluated			15		

Graphical representation not useful

312

Infection Serology - Chlamydia trachomatis Antibodies

AB against Chlamydia trachomatis IgG (qualitative) (N = 243, Rate of success: 74,9%)

Sample 61

Collective	negative (1)	total
ELISA, DiaSorin	14 ●	14
ELISA, Euroimmun	63 ●	63
ELISA, Mikrogen	10 ●	10
ELISA, Orgentec	9 ●	9
ELISA, Savayon	8 ●	8
ELISA, Vircell	6 ●	6
ELISA, Virion / Serion	37 ●	37
ELISA, other provider	37 ●	37
CLIA, DiaSorin	47 ●	47
CLIA, other provider	6 ●	6
other methods	5 ●	5

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, DiaSorin	0	0 ●	14 ●	14
ELISA, Euroimmun	56	5 ●	2 ●	63
ELISA, Mikrogen	0	0 ●	10 ●	10
ELISA, Orgentec	0	0 ●	9 ●	9
ELISA, Savayon	0	0 ●	9 ●	9
ELISA, Vircell	0	0 ●	6 ●	6
ELISA, Virion / Serion	1	0 ●	36 ●	37
ELISA, other provider	3	7 ●	27 ●	37
CLIA, DiaSorin	0	0 ●	47 ●	47
CLIA, other provider	0	0 ●	6 ●	6
other methods	0	0 ●	5 ●	5

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Chlamydia trachomatis IgA (qualitative) (N = 217, Rate of success: 80,2%)

Sample 61

Collective	negative (1)	borderline (2)	total
ELISA, DiaSorin	12 ●	0	12
ELISA, Euroimmun	61 ●	0	61
ELISA, Mikrogen	10 ●	0	10
ELISA, Orgentec	9 ●	0	9
ELISA, Virion / Serion	34 ●	0	34
ELISA, other provider	43 ●	0	43

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, DiaSorin	6	5 ●	1 ●	12
ELISA, Euroimmun	4	22 ●	35 ●	61
ELISA, Mikrogen	1	0 ●	9 ●	10
ELISA, Orgentec	3	5 ●	1 ●	9
ELISA, Virion / Serion	1	10 ●	23 ●	34
ELISA, other provider	9	7 ●	27 ●	43

Collective	negative (1)	borderline (2)	total
CLIA, Diasorin	35 ●	0	35
CLIA, other provider	7 ●	0	7
other methods	5 ●	1	6

Collective	negative (1)	borderline (2)	positive (3)	total
CLIA, Diasorin	16	12 ●	7 ●	35
CLIA, other provider	1	3 ●	3 ●	7
other methods	1	0 ●	5 ●	6

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 225, Rate of success: 92,4%)

Sample 61

Collective	no serological evidence for an infection	total
all methods	225 ●	225

Sample 62

Collective	no serological evidence for an infection	serological evidence for a past infection	serological evidence for a present infection	serological evidence for a past infection, serological evidence for a present infection	total
all methods	14	68 ●	131 ●	9 ●	222

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

314

Infection Serology - Chlamydia pneumoniae (Chlamydothyla) Antibodies

AB against Chlamydia pneumoniae IgG (semiquantitative) (U/ml, N = 166)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	61		Sample not evaluated			153		
	62		Sample not evaluated			153		
other methods	61		Sample not evaluated			14		
	62		Sample not evaluated			14		

Graphical representation not useful

AB against Chlamydia pneumoniae IgA (semiquantitative) (U/ml, N = 130)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
all methods	61		Sample not evaluated			130		
	62		Sample not evaluated			130		

Graphical representation not useful

AB against Chlamydia pneumoniae IgM (semiquantitative) (U/ml, N = 97)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
all methods	61		Sample not evaluated			97		
	62		Sample not evaluated			97		

Graphical representation not useful

AB against Chlamydia pneumoniae IgG (qualitative) (N = 184, Rate of success: 98,4%)
Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	0	0	59 ●	59
ELISA, Orgentec	0	0	13 ●	13
ELISA, Savayon	0	0	7 ●	7
ELISA, Vircell	1	0	6 ●	7
ELISA, Virion / Serion	0	0	41 ●	41
ELISA, other provider	0	2	48 ●	50
Immunological test (CLIA)	0	0	3 ●	3
other methods	0	0	4 ●	4

Sample 62

Collective	negative (1)	total
ELISA, Euroimmun	59 ●	59
ELISA, Orgentec	13 ●	13
ELISA, Savayon	7 ●	7
ELISA, Vircell	7 ●	7
ELISA, Virion / Serion	41 ●	41
ELISA, other provider	50 ●	50
Immunological test (CLIA)	3 ●	3
other methods	4 ●	4

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Chlamydia pneumoniae IgA (qualitative) (N = 163, Rate of success: 96,9%)
Sample 61

Collective	negative (1)	positive (3)	total
ELISA, Euroimmun	0	56 ●	56
ELISA, Orgentec	0	10 ●	10
ELISA, Virion / Serion	0	38 ●	38
ELISA, other provider	3	49 ●	52
Immunological test (CLIA)	0	3 ●	3
other methods	1	2 ●	3

Sample 62

Collective	negative (1)	total
ELISA, Euroimmun	56 ●	56
ELISA, Orgentec	10 ●	10
ELISA, Virion / Serion	38 ●	38
ELISA, other provider	52 ●	52
Immunological test (CLIA)	3 ●	3
other methods	4 ●	4

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Chlamydia pneumoniae IgM (qualitative) (N = 127, Rate of success: 100%)
Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	35 ●	0 ●	0 ●	35
ELISA, Orgentec	11 ●	0 ●	0 ●	11
ELISA, Virion / Serion	0 ●	0 ●	25 ●	25
ELISA, other provider	29 ●	3 ●	16 ●	48
Immunological test (CLIA)	0 ●	0 ●	3 ●	3
other methods	2 ●	0 ●	3 ●	5

Sample 62

Collective	negative (1)	total
ELISA, Euroimmun	35 ●	35
ELISA, Orgentec	11 ●	11
ELISA, Virion / Serion	25 ●	25
ELISA, other provider	48 ●	48
Immunological test (CLIA)	3 ●	3
other methods	5 ●	5

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 204, Rate of success: 74%)
Sample 61

Collective	no serological evidence for an infection	serological evidence for a past infection	serological evidence for a present infection	total
all methods	3	48	158 ●	209

Sample 62

Collective	no serological evidence for an infection	serological evidence for a present infection	total
all methods	202 ●	1	203

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective



317

Infection Serology - Bordetella pertussis Antibodies

AB against Bordetella pertussis IgG (semiquantitative) (N = 208)								
Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Antigen: Pertussis Toxin	61		Sample not evaluated			169		
	62		Sample not evaluated			169		
Antigen: PT plus FHA	61		Sample not evaluated			37		
	62		Sample not evaluated			37		
without Antigen indication	(1) 61		Sample not evaluated			5		
	62		Sample not evaluated			5		

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Graphical representation not useful

317

Infection Serology - Bordetella pertussis Antibodies

AB against Bordetella pertussis IgG (qualitative) (N = 216, Rate of success: 95,8%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
Pertussis Toxin, ELISA, Diasorin	10 ●	0 ●	0	10
Pertussis Toxin, ELISA, Euroimmun	52 ●	0 ●	0	52
Pertussis Toxin, ELISA, Orgentec	11 ●	0 ●	0	11
Pertussis Toxin, ELISA, Virion / Serion	26 ●	1 ●	0	27
Pertussis Toxin, ELISA, Virotech	22 ●	0 ●	0	22
Pertussis Toxin, ELISA, other providers	18 ●	1 ●	1	20
Pertussis Toxin, other methods	29 ●	0 ●	0	29
PT plus FHA, ELISA, Virion / Serion	17 ●	0 ●	0	17
PT plus FHA, ELISA, Virotech	13 ●	0 ●	0	13
PT plus FHA, ELISA, other providers	4 ●	0 ●	1	5
PT plus FHA, other methods	2 ●	0 ●	1	3
without Antigen indication	6 ●	0 ●	0	6

Sample 62

Collective	positive (3)	borderline (2)	negative (1)	total
Pertussis Toxin, ELISA, Diasorin	3 ●	7 ●	0	10
Pertussis Toxin, ELISA, Euroimmun	41 ●	10 ●	1	52
Pertussis Toxin, ELISA, Orgentec	11 ●	0 ●	0	11
Pertussis Toxin, ELISA, Virion / Serion	4 ●	22 ●	1	27
Pertussis Toxin, ELISA, Virotech	17 ●	5 ●	0	22
Pertussis Toxin, ELISA, other providers	10 ●	7 ●	3	20
Pertussis Toxin, other methods	18 ●	11 ●	1	30
PT plus FHA, ELISA, Virion / Serion	15 ●	2 ●	0	17
PT plus FHA, ELISA, Virotech	13 ●	0 ●	0	13
PT plus FHA, ELISA, other providers	5 ●	0 ●	0	5
PT plus FHA, other methods	2 ●	1 ●	0	3
without Antigen indication	3 ●	2 ●	0	5

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Bordetella pertussis IgA (qualitative) (N = 201, Rate of success: 63,2%)

Sample 61

Collective	negative (1)	borderline (2)	total
Pertussis Toxin, ELISA, Diasorin	7 ●	0 ●	7
Pertussis Toxin, ELISA, Euroimmun	47 ●	0 ●	47
Pertussis Toxin, ELISA, Orgentec	12 ●	0 ●	12
Pertussis Toxin, ELISA, Virion / Serion	25 ●	0 ●	25
Pertussis Toxin, ELISA, Virotech	18 ●	1 ●	19
Pertussis Toxin, ELISA, other providers	14 ●	0 ●	14

Sample 62

Collective	positive (3)	negative (1)	borderline (2)	total
Pertussis Toxin, ELISA, Diasorin	5 ●	1	1 ●	7
Pertussis Toxin, ELISA, Euroimmun	31 ●	11	5 ●	47
Pertussis Toxin, ELISA, Orgentec	12 ●	0	0 ●	12
Pertussis Toxin, ELISA, Virion / Serion	5 ●	19	1 ●	25
Pertussis Toxin, ELISA, Virotech	3 ●	16	0 ●	19
Pertussis Toxin, ELISA, other providers	1 ●	14	0 ●	15

Collective	negative (1)	borderline (2)	total
Pertussis Toxin, other methods	35 ●	0 ●	35
PT plus FHA, ELISA, Virion / Serion	15 ●	0 ●	15
PT plus FHA, ELISA, Virotech	11 ●	0 ●	11
PT plus FHA, ELISA, other providers	7 ●	0 ●	7
Antigen: PT plus FHA	3 ●	0 ●	3
without Antigen indication	5 ●	0 ●	5

Collective	positive (3)	negative (1)	borderline (2)	total
Pertussis Toxin, other methods	26 ●	6 ●	3 ●	35
PT plus FHA, ELISA, Virion / Serion	12 ●	3 ●	0 ●	15
PT plus FHA, ELISA, Virotech	9 ●	0 ●	2 ●	11
PT plus FHA, ELISA, other providers	6 ●	1 ●	0 ●	7
Antigen: PT plus FHA	1 ●	1 ●	1 ●	3
without Antigen indication	2 ●	2 ●	1 ●	5

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 207, Rate of success: 88,9%)

Sample 61

Collective	no serological evidence for an infection	serological evidence for a past infection (or immunisation)	serological evidence for an acute infection	total
others	195 ●	5 ●	7 ●	207

Sample 62

Collective	no serological evidence for an infection	serological evidence for a past infection (or immunisation)	serological evidence for an acute infection	total
others	8 ●	110 ●	86 ●	204

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

324

Infection Serology - Mycoplasma pneumoniae Antibodies

AB against Mycoplasma pneumoniae IgG (semiquantitative) (U/ml, N = 223)

Collective	Sample	Target value	Target range	Participants collective		Rate (%)	
				AVG	CV	Num.	Sam. total
ELISA	61		Sample not evaluated			157	
	62		Sample not evaluated			157	
CLIA	61		Sample not evaluated			60	
	62		Sample not evaluated			60	
other methods (1)	61		Sample not evaluated			7	
	62		Sample not evaluated			7	

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Graphical representation not useful

324

Infection Serology - Mycoplasma pneumoniae Antibodies

AB against Mycoplasma pneumoniae IgG (qualitative) (N = 256, Rate of success: 100%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	7 ●	25 ●	13 ●	45
ELISA, Orgentec	20 ●	1 ●	0 ●	21
ELISA, Virion / Serion	51 ●	3 ●	2 ●	56
ELISA, Virotech	29 ●	0 ●	0 ●	29
ELISA	15 ●	8 ●	13 ●	36
CLIA, Diasorin	58 ●	1 ●	0 ●	59
CLIA, other providers	1 ●	0 ●	7 ●	8
other methods	2 ●	0 ●	0 ●	2

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	2 ●	0 ●	43 ●	45
ELISA, Orgentec	20 ●	0 ●	1 ●	21
ELISA, Virion / Serion	2 ●	0 ●	54 ●	56
ELISA, Virotech	27 ●	2 ●	0 ●	29
ELISA	7 ●	1 ●	28 ●	36
CLIA, Diasorin	58 ●	0 ●	1 ●	59
CLIA, other providers	0 ●	1 ●	7 ●	8
other methods	2 ●	0 ●	0 ●	2

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Mycoplasma pneumoniae IgM (qualitative) (N = 286, Rate of success: 97,9%)
Sample 61

Collective	negative (1)	positive (3)	total
ELISA, Euroimmun	46 ●	1	47
ELISA, Orgentec	23 ●	0	23
ELISA, Virion / Serion	58 ●	0	58
ELISA, Virotech	27 ●	0	27
ELISA, other providers	37 ●	1	38
CLIA, Diasorin	71 ●	0	71
CLIA, other providers	11 ●	0	11
other methods	8 ●	2	10

Sample 62

Collective	negative (1)	borderline (2)	total
ELISA, Euroimmun	45 ●	1	46
ELISA, Orgentec	23 ●	0	23
ELISA, Virion / Serion	58 ●	0	58
ELISA, Virotech	27 ●	0	27
ELISA, other providers	39 ●	0	39
CLIA, Diasorin	71 ●	0	71
CLIA, other providers	11 ●	0	11
other methods	10 ●	0	10

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 254, Rate of success: 98,8%)
Sample 61

Collective	no serological evidence for an infection	serological evidence for an acute infection	serological evidence for a past infection	total
all providers	192 ●	12 ●	47 ●	251

Sample 62

Collective	no serological evidence for an infection	serological evidence for an acute infection	serological evidence for a past infection	total
all providers	119 ●	2 ●	133 ●	254

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

325
Infection Serology - Coxiella burnetii Antibodies
AB against Coxiella burnetii IgG - Phase II (semiquantitative) (U/ml, N = 47)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA, Virion / Serion	61		Sample not evaluated			33		
	62		Sample not evaluated			33		
ELISA, other providers	61		Sample not evaluated			6		
	62		Sample not evaluated			6		
other methods	61		Sample not evaluated			9		
	62		Sample not evaluated			9		

Graphical representation not useful

AB against Coxiella burnetii IgG - Phase I - IFT (semiquantitative) (Titer, N = 33)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Focus	61		- <80.0			19	100	100
	62		- <80.0			19	100	100
Vircell	61		- <80.0			7	100	100
	62		- <80.0			7	100	100
other providers	61		- <80.0			7	85.7	85.7
	62		- <80.0			7	85.7	85.7

Rate of success: 97%

Graphical representation not useful

AB against Coxiella burnetii IgG - Phase II (semiquantitative) (Titer, N = 32)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Focus	61		- <80.0			19	100	94.7
	62		- <80.0			19	94.7	94.7
Vircell	61		- <80.0			7	100	71.4
	62		- <80.0			7	71.4	71.4
other providers	61		- <80.0			6	100	83.3
	62		- <80.0			6	83.3	83.3

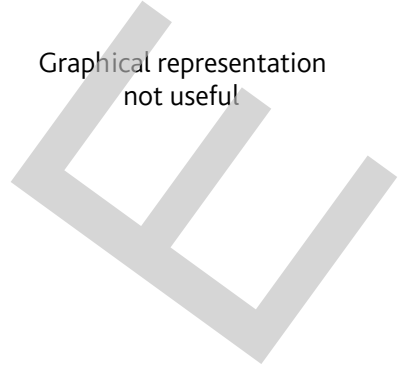
Rate of success: 87,5%

Graphical representation not useful

AB against Coxiella burnetii IgM - IFT (semiquantitative) (Titer, N = 31)									
Collective	Sample	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Focus	61		- <20.0			19	94.7	94.4	
	62		- <20.0			19	94.7		
Vircell	61		- <20.0			7	85.7	85.7	
	62		- <20.0			7	85.7		
other providers	61		- <20.0			6	83.3	83.3	
	62		- <20.0			6	83.3		

Rate of success: 90,3%

Graphical representation not useful



325 Infection Serology - Coxiella burnetii Antibodies

AB against Coxiella burnetii IgG - Phase II (qualitative) (N = 54, Rate of success: 88,9%)

Sample 61

Collective	negative (1)	positive (3)	total
ELISA, Virion / Serion	36 ●	0	36
ELISA, other providers	11 ●	1	12
other methods	6 ●	0	6

Sample 62

Collective	negative (1)	positive (3)	total
ELISA, Virion / Serion	36 ●	0	36
ELISA, other providers	6 ●	5	11
other methods	6 ●	0	6

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Coxiella burnetii IgM (qualitative) (N = 62, Rate of success: 91,9%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Vircell	5 ●	0	0	5
ELISA, Virion / Serion	39 ●	0	1	40
ELISA, other providers	5 ●	1	3	9
other methods	8 ●	0	0	8

Sample 62

Collective	negative (1)	borderline (2)	total
ELISA, Vircell	5 ●	0	5
ELISA, Virion / Serion	40 ●	0	40
ELISA, other providers	5 ●	4	9
other methods	8 ●	0	8

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Coxiella burnetii IgG - Phase I - IFT (qualitative) (N = 40, Rate of success: 90%)

Sample 61

Collective	negative (1)	borderline (2)	total
Focus	20 ●	1	21
Vircell	9 ●	0	9
other providers	10 ●	0	10

Sample 62

Collective	negative (1)	positive (3)	total
Focus	20 ●	1	21
Vircell	8 ●	1	9
other providers	9 ●	1	10

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Coxiella burnetii IgG - Phase II (qualitative) (N = 39, Rate of success: 82,1%)

Sample 61

Collective	negative (1)	borderline (2)	total
Focus	20 ●	1	21
Vircell	9 ●	0	9
other providers	9 ●	0	9

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
Focus	18 ●	2	1	21
Vircell	7 ●	1	1	9
other providers	8 ●	0	1	9

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Coxiella burnetii IgM - IFT (qualitative) (N = 38, Rate of success: 97,4%)
Sample 61

Collective	negative (1)	total
Focus	19 ●	19
Vircell	9 ●	9
other providers	9 ●	9

Sample 62

Collective	negative (1)	total
Focus	19 ●	19
Vircell	9 ●	9
other providers	10 ●	10

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 94, Rate of success: 90,4%)
Sample 61

Collective	no serological evidence for an infection	serological evidence for an acute infection	serological evidence for a past infection	total
others	89 ●	4	1	94

Sample 62

Collective	no serological evidence for an infection	serological evidence for a past infection	serological evidence for a chronic infection	total
others	87 ●	6	1	94

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

331
Infection Serology - Salmonella Antibodies
AB against Salmonella polyvalent (qualitative) (N = 39, Rate of success: 97,4%)
Sample 61

Collective	negative (1)	positive (3)	total
Human	13 ●	0	13
IMTEC	22 ●	1	23
other provider	3 ●	0	3

Sample 62

Collective	negative (1)	total
Human	13 ●	13
IMTEC	23 ●	23
other provider	3 ●	3

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Salmonella IgA (qualitative) (N = 25, Rate of success: 100%)
Sample 61

Collective	negative (1)	total
Human	10 ●	10
IMTEC	14 ●	14
other provider	1 ●	1

Sample 62

Collective	negative (1)	total
Human	10 ●	10
IMTEC	14 ●	14
other provider	1 ●	1

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 60, Rate of success: 93,3%)
Sample 61

Collective	no serological evidence for an infection	serological evidence for a past infection	total
ELISA	36 ●	1	37
WIDAL	22 ●	1	23

Sample 62

Collective	no serological evidence for an infection	serological evidence for an acute infection	serological evidence for a past infection	total
ELISA	37 ●	0	0	37
WIDAL	2	13 ●	10 ●	25

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective



332

Infection Serology - Borrelia burgdorferi Antibodies

AB against Borrelia burgdorferi IgG (semiquantitative) (U/ml, N = 340)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	61		Sample not evaluated			185		
	62		Sample not evaluated			185		
CLIA	61		Sample not evaluated			151		
	62		Sample not evaluated			151		
other methods	(1) 61		Sample not evaluated			6		
	62		Sample not evaluated			6		

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Graphical representation not useful

AB against Borrelia burgdorferi IgM (semiquantitative) (Titer, N = 275)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	61		Sample not evaluated			137		
	62		Sample not evaluated			137		
CLIA	61		Sample not evaluated			104		
	62		Sample not evaluated			104		
other methods	61		Sample not evaluated			35		
	62		Sample not evaluated			35		

Graphical representation not useful

332

Infection Serology - Borrelia burgdorferi Antibodies

AB against Borrelia burgdorferi IgG (qualitative) (N = 403, Rate of success: 79,9%)

Sample 61

Collective	negative (1)	positive (3)	borderline (2)	total
ELISA, BioMerieux	16 ●	0	0 ●	16
ELISA, Siemens	12 ●	0	1 ●	13
ELISA, Euroimmun	9 ●	36	42 ●	87
ELISA, Mikrogen	15 ●	2	4 ●	21
ELISA, Orgentec	9 ●	0	0 ●	9
ELISA, Virion / Serion	28 ●	3	0 ●	31
ELISA, Virotech	2 ●	15	5 ●	22
ELISA, other provider	23 ●	8	1 ●	32
CLIA, DiaSorin	151 ●	2	1 ●	154
CLIA, other provider	7 ●	0	0 ●	7
other methods	9 ●	1	1 ●	11

Sample 62

Collective	positive (3)	borderline (2)	negative (1)	total
ELISA, BioMerieux	17 ●	0 ●	0	17
ELISA, Siemens	12 ●	1 ●	0	13
ELISA, Euroimmun	15 ●	61 ●	11	87
ELISA, Mikrogen	11 ●	9 ●	1	21
ELISA, Orgentec	8 ●	0 ●	1	9
ELISA, Virion / Serion	28 ●	0 ●	3	31
ELISA, Virotech	22 ●	0 ●	0	22
ELISA, other provider	25 ●	2 ●	5	32
CLIA, DiaSorin	153 ●	0 ●	1	154
CLIA, other provider	7 ●	0 ●	0	7
other methods	8 ●	2 ●	1	11

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Borrelia burgdorferi IgM (qualitative) (N = 413, Rate of success: 98,1%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, BioMerieux	17 ●	0	0	17
ELISA, Siemens	13 ●	0	0	13
ELISA, Euroimmun	89 ●	1	1	91
ELISA, Mikrogen	21 ●	0	0	21
ELISA, Orgentec	9 ●	0	0	9
ELISA, Virion / Serion	29 ●	0	3	32

Sample 62

Collective	negative (1)	positive (3)	borderline (2)	total
ELISA, BioMerieux	0 ●	4 ●	12 ●	16
ELISA, Siemens	0 ●	12 ●	1 ●	13
ELISA, Euroimmun	17 ●	26 ●	48 ●	91
ELISA, Mikrogen	0 ●	20 ●	1 ●	21
ELISA, Orgentec	9 ●	0 ●	0 ●	9
ELISA, Virion / Serion	4 ●	19 ●	9 ●	32



Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Virotech	22 ●	0	0	22
ELISA, other provider	32 ●	0	1	33
CLIA, DiaSorin	158 ●	0	0	158
CLIA, other provider	7 ●	0	0	7
other methods	10 ●	0	0	10

Collective	negative (1)	positive (3)	borderline (2)	total
ELISA, Virotech	6 ●	9 ●	7 ●	22
ELISA, other provider	12 ●	19 ●	2 ●	33
CLIA, DiaSorin	157 ●	1 ●	0 ●	158
CLIA, other provider	2 ●	2 ●	3 ●	7
other methods	3 ●	2 ●	5 ●	10

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Borrelia burgdorferi IgG - Blot (N = 324, Rate of success: 80,6%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
Immuno- and Westernblot, Euroimmun	34 ●	1 ●	16	51
Immuno- and Westernblot, Mikrogen	3 ●	18 ●	2	23
Immuno- and Westernblot, Viramed	63 ●	1 ●	0	64
Immuno- and Westernblot, Virotech	9 ●	0 ●	0	9
Immuno- and Westernblot, other provider	12 ●	0 ●	0	12
Line Blot, Euroimmun	28 ●	0 ●	6	34
Line Blot, Mikrogen	11 ●	60 ●	2	73
Line Blot, Viramed	9 ●	0 ●	0	9
Line Blot, Virotech	21 ●	1 ●	0	22
Line Blot, other provider	2 ●	1 ●	0	3
other methods	16 ●	1 ●	0	17

Sample 62

Collective	positive (3)	borderline (2)	negative (1)	total
Immuno- and Westernblot, Euroimmun	46 ●	2 ●	5	53
Immuno- and Westernblot, Mikrogen	21 ●	2 ●	2	25
Immuno- and Westernblot, Viramed	49 ●	14 ●	1	64
Immuno- and Westernblot, Virotech	1 ●	2 ●	6	9
Immuno- and Westernblot, other provider	9 ●	3 ●	1	13
Line Blot, Euroimmun	35 ●	0 ●	1	36
Line Blot, Mikrogen	51 ●	21 ●	1	73
Line Blot, Viramed	7 ●	3 ●	0	10
Line Blot, Virotech	2 ●	6 ●	14	22
Line Blot, other provider	3 ●	0 ●	0	3
other methods	12 ●	5 ●	0	17

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Borrelia burgdorferi IgG - Immunoblot bands (N = 323)

Sample 61 not evaluated

Sample 62 not evaluated

AB against Borrelia burgdorferi IgM - Blot (N = 321, Rate of success: 76,9%)

Sample 61

Collective	negative (1)	borderline (2)	total
Immuno- and Westernblot, Euroimmun	49 ●	0	49
Immuno- and Westernblot, Mikrogen	23 ●	0	23
Immuno- and Westernblot, Viramed	63 ●	0	63
Immuno- and Westernblot, Virotech	8 ●	1	9
Immuno- and Westernblot, other provider	12 ●	0	12
Line Blot, Euroimmun	35 ●	0	35
Line Blot, Mikrogen	72 ●	0	72
Line Blot, Viramed	9 ●	0	9
Line Blot, Virotech	19 ●	3	22

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
Immuno- and Westernblot, Euroimmun	7	12 ●	31 ●	50
Immuno- and Westernblot, Mikrogen	6	1 ●	18 ●	25
Immuno- and Westernblot, Viramed	10	4 ●	50 ●	64
Immuno- and Westernblot, Virotech	5	0 ●	4 ●	9
Immuno- and Westernblot, other provider	5	1 ●	6 ●	12
Line Blot, Euroimmun	3	3 ●	29 ●	35
Line Blot, Mikrogen	8	5 ●	59 ●	72
Line Blot, Viramed	1	0 ●	9 ●	10
Line Blot, Virotech	13	1 ●	8 ●	22

Collective	negative (1)	borderline (2)	total
Line Blot, other provider	4 ●	0	4
other methods	18 ●	0	18

Collective	negative (1)	borderline (2)	positive (3)	total
Line Blot, other provider	0	0 ●	4 ●	4
other methods	9	2 ●	7 ●	18

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Borrelia burgdorferi IgM - Immunoblot bands (N = 308)

Sample 61 not evaluated

Sample 62 not evaluated

AB against Treponema pallidum (qualitative) (N = 120, Rate of success: 94,2%)

Sample 61

Collective	negative (1)	total
ELISA	3 ●	3
CLIA	34 ●	34
CMIA	12 ●	12
other methods	68 ●	68

Sample 62

Collective	negative (1)	positive (3)	total
ELISA	3 ●	0	3
CLIA	35 ●	0	35
CMIA	13 ●	0	13
other methods	65 ●	2	67

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 347, Rate of success: 78,7%)

Sample 61

Collective	No serological evidence for infection with Borrelia burgdorferi. Early infection however can not be excluded. In case of clinical suspicion control examination after 2-3 weeks is recommended.	The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for an early stage of Lyme disease or serum scar, depending on the clinical context.	The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for a late stage of Lyme disease or serum scar, depending on the clinical context.	total
all methods	295 ●	12	38	345

Sample 62

Collective	No serological evidence for infection with Borrelia burgdorferi. Early infection however can not be excluded. In case of clinical suspicion control examination after 2-3 weeks is recommended.	The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for an early stage of Lyme disease or serum scar, depending on the clinical context.	The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for a late stage of Lyme disease or serum scar, depending on the clinical context.	total
all methods	25	226 ●	93 ●	344

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

334

Infection Serology - Helicobacter pylori Antibodies

AB against Helicobacter pylori IgG (semiquantitative) (N = 142)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Siemens	61		Sample not evaluated			13		
	62		Sample not evaluated			13		
Euroimmun	61		Sample not evaluated			42		
	62		Sample not evaluated			42		
Mikrogen	61		Sample not evaluated			13		
	62		Sample not evaluated			13		
Virion / Serion	61		Sample not evaluated			27		
	62		Sample not evaluated			27		
Sekisui Virotech	61		Sample not evaluated			16		
	62		Sample not evaluated			16		
other providers	61		Sample not evaluated			31		
	62		Sample not evaluated			31		

Graphical representation not useful

AB against Helicobacter pylori IgA (semiquantitative) (N = 96)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Siemens	(1) 61		Sample not evaluated			6		
	62		Sample not evaluated			6		
Euroimmun	61		Sample not evaluated			29		
	62		Sample not evaluated			29		

Graphical representation not useful



Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Mikrogen	61		Sample not evaluated			10		
	62		Sample not evaluated			10		
Virion / Serion	61		Sample not evaluated			21		
	62		Sample not evaluated			21		
Sekisui Virotech	61		Sample not evaluated			16		
	62		Sample not evaluated			16		
other providers	61		Sample not evaluated			14		
	62		Sample not evaluated			14		

334

Infection Serology - Helicobacter pylori Antibodies

AB against Helicobacter pylori IgG (qualitative) (N = 155, Rate of success: 96,8%)

Sample 61

Collective	negative (1)	positive (3)	total
CLIA	0	6 ●	6
ELISA, Euroimmun	0	35 ●	35
ELISA, Mikrogen	0	12 ●	12
ELISA, Virion / Serion	0	25 ●	25
ELISA, Virotech	0	16 ●	16
ELISA, other providers	2	31 ●	33
Immuno fluorescence	0	5 ●	5
Immunochromatography	3	4 ●	7
other methods	0	16 ●	16

Sample 62

Collective	negative (1)	total
CLIA	6 ●	6
ELISA, Euroimmun	35 ●	35
ELISA, Mikrogen	12 ●	12
ELISA, Virion / Serion	25 ●	25
ELISA, Virotech	16 ●	16
ELISA, other providers	33 ●	33
Immuno fluorescence	5 ●	5
Immunochromatography	7 ●	7
other methods	16 ●	16

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Helicobacter pylori IgA (qualitative) (N = 102, Rate of success: 99%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Siemens	0 ●	1 ●	4 ●	5
ELISA, Euroimmun	27 ●	1 ●	0 ●	28
ELISA, Mikrogen	0 ●	0 ●	9 ●	9
ELISA, Virion / Srion	4 ●	15 ●	1 ●	20
ELISA, Virotech	3 ●	10 ●	3 ●	16
ELISA, other providers	5 ●	0 ●	8 ●	13
other providers	8 ●	0 ●	3 ●	11

Sample 62

Collective	negative (1)	borderline (2)	total
ELISA, Siemens	5 ●	0	5
ELISA, Euroimmun	27 ●	1	28
ELISA, Mikrogen	9 ●	0	9
ELISA, Virion / Srion	20 ●	0	20
ELISA, Virotech	16 ●	0	16
ELISA, other providers	13 ●	0	13
other providers	11 ●	0	11

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against Helicobacter pylori IgG - Immunoblot (N = 101, Rate of success: 91,1%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
EURO IMMUN	2	0	9 ●	11
MIKROGEN	0	0	37 ●	37
VIRAMED	0	2	32 ●	34
VIROTECH DIAGNOSTICS GmbH	0	0	9 ●	9
others	0	0	9 ●	9

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
EURO IMMUN	9 ●	2	0	11
MIKROGEN	37 ●	0	1	38
VIRAMED	34 ●	0	0	34
VIROTECH DIAGNOSTICS GmbH	9 ●	0	0	9
others	9 ●	0	0	9

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective



AB against Helicobacter pylori IgA - Immunoblot (N = 83, Rate of success: 98,8%)

Sample 61

Collective	positive (3)	negative (1)	borderline (2)	total
EURO IMMUN	5 ●	1 ●	4 ●	10
MIKROGEN	2 ●	24 ●	1 ●	27
VIRAMED	30 ●	2 ●	0 ●	32
VIROTECH DIAGNOSTICS GmbH	5 ●	0 ●	0 ●	5
others	8 ●	1 ●	0 ●	9

Sample 62

Collective	negative (1)	total
EURO IMMUN	10 ●	10
MIKROGEN	27 ●	27
VIRAMED	31 ●	31
VIROTECH DIAGNOSTICS GmbH	5 ●	5
others	9 ●	9

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 158, Rate of success: 96,2%)

Sample 61

Collective	Serological evidence for infection (2)	further diagnostic analysis recommended (3)	no evidence for infection, further diagnostic analysis recommended (1, 3)	Serological evidence for infection, further diagnostic analysis recommended (2, 3)	total
all providers	58 ●	14 ●	1	85 ●	158

Sample 62

Collective	no evidence for infection (1)	Serological evidence for infection (2)	further diagnostic analysis recommended (3)	total
all providers	154 ●	1	4	159

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective