

May
2020



INSTAND

Manual

for Quality Control Tests in
Bacteriology Infection Serology

The products must be handled like patient
samples!

EQAS Online system result entry

Please enter your results in the INSTAND EQAS Online system using the link:

(<https://rv-online.instandev.de/en.html>) => "EQAS Online" =>
"Ordering online and entering results"

This is the entry that you already use for your EQAS registration
with INSTAND e. V.

In case of questions regarding the EQAS Online system, please contact:

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Frankfurt, May 2020

No. 310	<i>Tetanus toxoid</i> -antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 311	<i>Treponema pallidum</i> -antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 312	<i>Chlamydia trachomatis</i> -antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 313	Direct detection - <i>Chlamydia trachomatis</i> (Ag)	Urine control sample	31 and 32 (0.3 mL each)
No. 314	<i>Chlamydophila pneumoniae</i> -antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 315	<i>Yersinia</i> antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 316	Direct detection - <i>Chlamydia trachomatis</i> (IFA)	Slides (fixed)	31 and 32
No. 318	<i>Diphtheria toxoid</i> -antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 319	<i>Campylobacter</i> antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 320	Procalcitonin	Serum control samples	31 and 32 (0.4 mL each)
No. 321	<i>Streptococcal</i> antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 323	Rheumatoid factor	Serum control samples	31 and 32 (0.4 mL each)
No. 331	<i>Salmonella</i> antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 332	<i>Borrelia burgdorferi</i> -antibodies	Serum control samples	31 and 32 (0.4 mL each)
No. 334	<i>Helicobacter pylori</i> -antibodies	Serum control samples	31 and 32 (0.4 mL each)

As samples originate from patients, they must be regarded as *potentially infectious* and must be handled with caution (storage temperature: +2-8° C).

Please, consider the attached test information when performing and evaluating your tests and closely follow the instructions regarding the titration of quantitative or semiquantitative tests.

All participants should indicate **qualitative and quantitative / semiquantitative** results as **units** or **titres** where designated on the corresponding report form.

Certificates for a given test or analysis are issued to the participants only if test results are correctly documented for **both** samples on the evaluation sheet!

To improve clarity of documentation, quantitative or semiquantitative results below the cut-off value should be reported as 0 or with the actual value measured.

Always document the analytical **method, reagents, batch numbers and instruments** used. The manufacturer- and instrument-specific codes are attached.

Correct indication of the performed test methods is essential for the surveys as **target values and ranges** of quantitative or semiquantitative tests **depend on the methods** used. The methods offered for certification can be selected for the individual parameters.

Due to the difficult situation caused by the corona virus for many laboratories, we have extended the processing period for this EQAS.

Deadline for the online entry: 2020-06-05.

In the meantime, we remain with best regards and hope for a continued good cooperation,

Prof. Dr. med. K.-P. Hunfeld, MPH
(EQA Expert)

Implementation and evaluation of serological tests for bacteriologic infection serology (INSTAND-proficiency-testing program)

Where appropriate, this compendium determines the serum starting dilutions and cut-off values for methods detecting specific antibodies by use of geometric serum dilutions (titre tests: IFT, IHAT, CFT etc.). The aim is to improve uniformity when performing and evaluating these assays. Unless otherwise stated, assays should be carried out according to DIN 58967 („Serologische und molekularbiologische Diagnostik von Infektionskrankheiten“, serologic and molecular diagnostics of infectious diseases) or the guidelines of the DGHM for diagnostics in microbiology. The manufacturers' instructions must be also be followed when performing and evaluating ELISA and immunoblot tests.

In order for certificates to be issued, all participants are expected to report quantitative or semiquantitative results along with qualitative results on the evaluation forms, where requested.

For clarity of data processing, quantitative or **semiquantitative** results below the cut-off value should be reported with the actual value measured or as „0“.

Test	Assay	Serum-Starting dilution	Cut-off	Qualitative evaluation
1. Tetanus toxoid antibodies (310)	EIA	XXXX	0.01 IU/mL	P: ≥0.01 IU/mL; N: <0.01 IU/mL
	PHA	XXXX		
	Diagnostic evaluation:			
	<0.1 IU/mL	No protective active immunity		
	0.1-0.5 IU/mL	Existing protective immunity, booster vaccination provides long term immunity		
>0.5-1.1 IU/mL	Protective active immunity, booster vaccination in 2 to 5 years			
>1.1-5.0 IU/mL	Protective active immunity, booster vaccination in 5 to 10 years			
>5.0 IU/mL	Protective active immunity, booster vaccination in 10 years			
2. Treponema pallidum antibodies (311)	TPHA	1:20	80(SE)	P: ≥80; N: <80
	TPPA	1:20	80(SE)	P: ≥80; N: <80
	VDRL	1:1	1	P: ≥1; N: <1
	Card.-CFT	1:5	5 (SE)	P: ≥5; N: <5
	FTA-ABS-IgG	XXXX	5 (SE)	P: ≥5; N: <5
	FTA-ABS-IgM	XXXX	5 (SE)	P: ≥5; N: <5
3. Chlamydia trachomatis and Chlamydia pneumoniae antibodies (312/314)	CFT	1:5	10 (SE)	P: ≥10; N: <10
	MIF-IgG	1:10	20 (SE)	P: ≥20; N: <20
	MIF-IgM	1:10	20 (SE)	P: ≥20; N: <20
	MIF-IgA	1:10	20 (SE)	P: ≥20; N: <20
4. Yersinia-Serology (Widal) (315)	O-agglutination	1 :50	100 (SE)	P: >100; BL: 100; N: <50
	(O)H-agglutination	1 :50	100 (SE)	P: >100; BL: 100; N: <50
5. Diphtheria toxoid antibodies (318)	EIA	XXXX	0.01 IU/mL	P: ≥0.01 IU/mL; N: <0.01 IU/mL
	Diagnostic evaluation:			
	0.01 – <0.1 IU/mL	No protective active immunity		
0.1 – <1.0 IU/mL	Existing protective immunity, booster vaccination provides long term immunity			
>1.0 IU/mL	Protective active immunity, booster vaccination in 5 to 10 years			
6. Campylobacter antibodies (319)	CFT	1:5	10 (SE)	P: > 10 N: < 10

SE: final dilution of serum; P: positive; BL: border line; N: negative

Test	Assay	Serum-starting dilution	Cut-off	Qualitative evaluation
7. Procalcitonin (320)		XXXX	0.5 ng/mL	P: ≥ 0.5ng/mL N:<0.5ng/mL
8. Streptococcal antibodies (321)	Streptolysin-O	XXXX	200 IU/mL	P: > 200 IU/mL BL: 200 IU/mL N: <200 IU/mL
	aDNase	XXXX	200 IU/mL	P: > 200 IU/mL BL: 200 IU/mL N: <200 IU/mL
9. Rheumatoid factor (323)	Rheumatoid factor	XXXX10 IU/mL		P: ≥ 20 IU/mL BL: 10-19 IU/mL N: <10IU/mL
10. Salmonella antibodies (Widal) (331)	O-agglutination	1:25	100 (SE)	P: ≥ 200; BL: 100; N: ≤ 50
	(O)H-agglutination	1:25	100 (SE)	P: ≥ 200; BL: 100; N: ≤ 50
11. Borrelia burgdorferi antibodies (332)	PHA	1:20	80 (SE)	P: ≥80; N: <80
	IFAT-IgG	1:5	40 (SE)	P: ≥40; N: <40
	IFAT-IgM	1:10	20 (SE)	P: ≥20; N: <20

SE: final dilution of serum; P: positive; BL: border line; N: negative

Literature:

Hunfeld, K.-P., Brade, V.

Ringversuche in der bakteriologischen Infektionsserologie – Standortbestimmung und Auswertung des Ringversuchs X/99. Der Mikrobiologe (2000), 10: 135-144.

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Externe Qualitätskontrolle in der bakteriologischen Infektionsserologie: Ringversuchsauswertung September 2001. Der Mikrobiologe (2002), 12: 96-108

Müller, I., Besier, S., Hintereder, G., Brade, V., Hunfeld, K.-P.

Zur Qualität der bakteriologischen Infektionsserologie in Deutschland: eine Metaanalyse der infektionsserologischen Ringversuche des Jahres 2006 – Beitrag der Qualitätssicherungskommission der DGHM. GMS Zeitschrift zur Förderung der Qualitätssicherung in medizinischen Laboratorien, (2009), Vol. 1; Open Access online <http://www.egms.de/static/pdf/journals/lab/2009-1/lab000004.pdf>

**Codes for devices - proficiency testing program
in bacteriologic infection serology**

Device	Code
Abbott Architect	AB20
Abbott: other devices	AB99
Axis-Shield - NycoCard System	AH02
Axon Lab: other devices	AY99
BECKMAN (OLYMPUS) AU-Systems	OL01
BECKMAN (OLYMPUS): other devices	OL99
Beckman Access	BE85
Beckman Immage-Systems	BE51
Beckman Synchron CX-Systems	BE80
Beckman Synchron LX-Systems	BE81
Beckman Unicel DX-Systems	BE82
Beckman: other devices	BE99
Binding Site Optilite	BS02
BioMérieux Vidas	AX01
BioMérieux: other devices	AX99
Bio-Rad: other devices	BR99
Brahms Kryptor	HN01
Brahms: other devices	HN99
Diasorin Liaison	DO01
Diasorin Liaison XL	DO02
Diasorin Liaison XS	DO05
Diasorin: other devices	DO99
Diasys respons 910	DS01
Euroimmun: Analyzer I	ER02
Euroimmun: other devices	ER99
Euroimmun: Euroscan	ER01
Günther Keul Hem-o-test 5000 CRP	KG01
Horiba ABX/AXON-Lab (Roche) Micros CRP 100/200	HO02
Horiba ABX/AXON-Lab (Roche): other devices	HO99
Horiba Microsemi CRP	HO07
IDS-iSYS	ID01
Instrumentation Laboratory: other devices	IL99
Johnson & Johnson: Vitros 250	JJ03
Johnson & Johnson: Vitros other devices	JJ99
Konelab: all devices	KN98
Mikrogen Dynex DSX	MK02
Mikrogen Profiblot	MK01
Mikrogen: other devices	MK99
Orgentec Alegria	OC01
Orgentec: other devices	OC99
Orion Quikread	ON01
Orion Quikread 101	ON02

Device	Code
Orion Quikread go	ON03
Orion: other devices	ON99
Qiagen: other devices	QG99
Qiagen: RotorGene	QG01
Radiometer AQT 90	RA09
Roche Cobas (6000) System (c501/502/e601)	RO56
Roche Cobas (8000) System (c701/702)	RO71
Roche Cobas (8000) System (e801)	RO88
Roche Cobas 4000 System	RO73
Roche Cobas e411	RO87
Roche Elecsys-Systems/Cobas e602	RO50
Roche Hitachi-Systems	RO24
Roche Integra-Systems	RO46
Roche Modular-Systems	RO55
Roche: Amplicor	RO90
Roche: other devices	RO99
Roche: Cobas 4800	RO96
Roche: TaqMan	RO60
Siemens (Bayer Healthcare) Advia	BG07
Siemens (Bayer Healthcare) Advia 1800	BG08
Siemens (Bayer Healthcare) Centaur	BG17
Siemens (Bayer Healthcare): other devices	BG99
Siemens (Dade Behring) Turbitimer	BW07
Siemens (Dade-Behring) Atellica NEPH 630	BW24
Siemens (Dade-Behring) BEP III	BW03
Siemens (Dade-Behring) BN Prospec	BW08
Siemens (Dade-Behring) Dimension Vista	BW13
Siemens (Dade-Behring) Dimension+	BW09
Siemens (Dade-Behring) Nephelometer	BW04
Siemens (Dade-Behring): other devices	BW99
Siemens (DPC Biermann) Immulite	DG01
Siemens (DPC Biermann) Immulite 2000	DG02
Siemens (DPC Biermann): other devices	DG99
Siemens (Kone): other devices	KN99
Siemens Advia Centaur XP	BG60
Siemens: Atellica CH	SI02
Siemens: Atellica IM	SI03
Siemens: Atellica NEPH 630	SI05
Tecan Genesis	TN03
Tecan RPM	TN02
Tecan Sunrise	TN01
Tecan: other devices	TN99
Other devices	ZY99

**Codes for reagents (providers) - proficiency testing program
in bacteriologic infection serology**

Reagent	Code
ABBOTT	AB
AESKU DIAGNOSTICS	AE
AID	AA
ALERE (INVERNESS MEDICAL)	VV
AXIS-SHIELD AG	AH
BAG Health Care	BA
BAYER HEALTH (Siemens)	BG
BECKMAN (OLYMPUS)	OL
BECKMAN COULTER	BE
BECTON DICKINSON	BN
BINDING SITE, THE	BS
BIOKIT	BB
BIOMED	BD
BIOMERIEUX	AX
BIOPHARM	BZ
BIORAD	BR
BIOS	BQ
BIOTEST	BT
BIOTRIN	BL
DADE BEHRING (Siemens)	BW
DEMEDITEC	DT
DENKA SEIKEN	DK
DIAGAST	DJ
DIALAB	DF
DIAMED	DM
DIAPRO	DR
DIASORIN	DO
DIESSE DIAGNOSTICA	DE
DPC BIERMANN (Siemens)	DG
DRG INSTRUMENTS	DI
EUREKA LAB DIVISION	EU
EURO IMMUN	ER
FEINCHEMIE SEBNITZ	FS
FOCUS	FC
FORTRESS DIAGNOSTICS	FD
FUJIREBIO	FJ
FUJIZOKI (Fujirebio)	FU
GENBIO	GB
GEN-PROBE	GX

Reagent	Code
GENZYME GmbH	GD
HAIN LIFESCIENCE	HA
HUMAN	HU
IBL	IB
IMMUNOLAB	IN
IMTEC	IT
INNOGENETICS	IS
INSTRUMENTATION LAB.	IL
LAB21	LZ
LABOR DIAGNOSTIKA	LD
MACHEREY-NAGEL	MG
MAST DIAGNOSTICA	MA
MEDAC	MC
MERIDIAN BIOSCIENCE	MR
MICROGEN BIOPRODUCTS	MF
MIKROGEN	MK
MOLTER	MO
NAL VON MINDEN	MV
NOVAGNOST (Siemens)	NX
NOVATEC	NO
NUCLEAR LASER MEDICINE S.r.l	NL
OMEGA	OA
OMEGA DIAG. (Allergo Pharma)	AL
ORGENTEC	OC
OXOID	OD
PHADIA (Thermo Fisher Scientific)	PH
PROGEN	PR
QIAGEN	QG
RANDOX	RX
RAVO DIAGNOSTICA	RV
R-BIOPHARM	RB
REMEL	RL
ROCHE DIAGNOSTICS	RO
SACACE BIOTECHNOLOGIE	SG

Reagent	Code
SANOFI PASTEUR	PS
SAVAYON	SV
Sentinel	SL
SERAMUN	SU
SIEMENS MED.SOLUT.DIAG	SI
SIFIN	SF
SPINREACT	SN
STAGO / TCOAG	TB
TECAN	TN
TEST-LINE	TT
TRINITY BIOTECH	TR

Reagent	Code
VECTOR BEST	VB
VIENNA LAB	VL
VIRAMED	VM
VIRCELL	VC
VIRIMMUN	VI
VIRION/SERION	VR
VIRO-IMMUN LAB.DIAGN.	VO
VIROTECH DIAGNOSTICS GmbH	VT
ZEUS SCIENTIFIC	ZS
IN-HOUSE PRODUCTION	ZX
OTHER MANUFACTURERS	ZY