Quality Assessment Schemes Program

2027



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ESfEQA GmbH
Siemensstraße 38
69123 Heidelberg
GERMANY
phone +49(0)6221-4166-700
fax +49(0)6221-4166-790
info@esfeqa.eu
www.esfeqa.eu

INTRODUCTION

A high quality standard is essential for every medical laboratory since test results are the basis for medical decisions and have an important impact on the wellbeing and treatment of patients. There are different approaches to maintain and improve quality in medical laboratories.

ESfEQA – European Society for External Quality Assessment – supports laboratories to assess the quality of their analytical results and ultimately improve their performance by providing well-designed external quality assessment programs. ESfEQA offers a wide range of External Quality Assessment Schemes. ESfEQA was founded in Heidelberg, Germany in 2013 and is accredited according to the standard ISO 17043:2023 by the German national accreditation body DAkkS. Since its foundation, ESfEQA has expanded its program portfolio and at the same time the number of laboratories participating in ESfEQA's external quality assessment schemes.

Extension of Accreditation Scope

Due to the flexible scope of the ESfEQA ISO 17043 accreditation the number of accredited EQA programs in our portfolio has increased.

Non-accredited programs / analytes are highlighted in our catalog as follows: "This program / parameter is not accredited according to DIN EN ISO/ IEC 17043."

Registration and Sample Ordering

ESfEQA offers EQA schemes worldwide and cooperates with reliable regional distributors. They are the direct business partners of participants, responsible for the ordering process, invoicing and local shipment of survey samples. ESfEQA offers programs with 2, 4 or 12 surveys per year. Participants generally sign up for a subscription for an entire calendar year.

Survey Calendar

The dates when participants can enter results and the deadlines are published in this catalogue and on the ESfEQA website (www.esfeqa.eu).

The testing periods of our proficiency test programs are synchronized in order to make the samples of a year available to participants in as few shipments as possible. Thus, a maximum of 4 shipments per year are required per participant.

Survey samples are sent to the participants in good time, usually at the beginning of the respective testing period. In order to keep the logistical, environmental and financial effort as low as possible, the samples of the first and second quarters of the monthly and quarterly programs are sent together; as well as the samples for the third and fourth quarters. This procedure is chosen for samples with sufficient stability for a period of at least 6 months. Samples with a shorter shelf life, as well as the samples for the semi-annual programs are sent quarterly.

Submission of Results, Survey Reports and Certificates

Participants submit their results online via the TEQA 2.0 web-application. Requests for new method, instrument and reagent codes can be made online. The subscription to any ESfEQA program allows participants to submit up to three results obtained from a single control set using different devices. Reports and certificates are provided online as pdf- files within 3 weeks (within one week for monthly programs) after the deadline of result submission.

Report files and certificates can be stored electronically, forwarded and printed.

Educational Programs

The CASE and CASE-T present in each case study a different hypothetical patient case.

The CASE-T program is intended for medical laboratory technicians to strengthen analytical competence. The CASE program is intended for clinicians to strengthen diagnostic acumen. Participants can join the CASE or CASE-T programs at any time of the year. Please contact your distributor or ESfEQA (info@esfeqa.eu) to register.

New Programs

Based on the feedback of our participants, ESfEQA will offer new proficiency testing programs in 2027. These include further programs in the field of:

Autoimmunity

ANA: Antinuclear Antibodies

Biochemistry

LIPID: Lipids

Stool Antigens

ADROTAg: Adenovirus & Rotavirus Stool Antigen
CDIFFAg: Clostridioides difficile Stool Antigen
NOROAg: Norovirus Stool Antigen

Molecular Diagnostics

HPVM: Human Papillomavirus
STIM: Sexually Transmitted Infections Molecular

We appreciate your participation in the ESfEQA External Quality Assement surveys.
Please contact us for further suggestions on new programs.

Heidelberg, September 2026

BIOCHEMISTRY PROGRAMS

BLOOD GAS AND ELECTROLYTES — BG

Program: BG12: 12 surveys/year x 1 sample
BG4: 4 surveys/year x 2 samples
Material: Liquid buffered aqueous solution or serum-based samples (minimum 2 mL)
Evaluation: Quantitative

Analytical parameters:

Bicarbonate (HCO^-_3)	Glucose	pH	Urea
Calcium	Lactate	pO2	
Chloride	Magnesium	Potassium	
Creatinine	pCO2	Sodium	

CARDIAC MARKER — CM

Program: CM12: 12 surveys/year x 1 sample
CM4: 4 surveys/year x 2 samples
CM2: 2 surveys/year x 2 samples
Material: Lyophilized samples of human sera with added analytes of human origin (minimum 1 mL)
Evaluation: Quantitative
Analytical devices that are intended for whole blood only are not suitable for these samples.

Analytical parameters:

BNP	Homocysteine	NT-proBNP
CK-MB (mass)	hsCRP	Troponin I
CK-MB (activity)	Myoglobin	Troponin T

CARDIAC MARKER POCT — CM-POCT

Program: CM-POCT12: 12 surveys/year x 1 sample
CM-POCT4: 4 surveys/year x 2 samples
CM-POCT2: 2 surveys/year x 2 samples
Material: Lyophilized samples of human sera with added analytes of human origin (minimum 1mL)
Evaluation: Quantitative and qualitative*
Analytical devices that are intended for whole blood only are not suitable for these samples.

Analytical parameters:

BNP	Myoglobin	Troponin T
CK-MB (mass)	NT-proBNP	
CK-MB (activity)	Troponin I	

*Thequalitativeparameters are not accredited accordingtoDINEN ISO/ IEC 17043.

CLINICAL CHEMISTRY CC

Program:CC12: 12surveys/year x 1 sample
CC4: 4 surveys/year x 2 samples
CC2: 2 surveys/year x 2 samples
Material: Lyophilized samples of human sera with added enzymes and proteins of human origin (5 mL)
Evaluation: Quantitative

Analytical parameters:

- Albumin
- ALP Alkaline phosphatase
- ALT/GPT
- α-Amylase
- Amylase pancreatic
- AST/GOT
- Bilirubin, direct
- Bilirubin, total
- Bilirubin conjugated*
- Bilirubin non-conjugated*
- Calcium
- Calcium (ionized)
- Chloride
- Cholesterol
- Cholinesterase
- CK Creatinkinase
- Creatinine
- Copper
- Gamma GT
- Glucose
- HDL Cholesterol
- Iron
- Lactate
- LDH Lactate Dehydrogenase
- LDL Cholesterol
- Lipase
- Lithium
- Magnesium
- Phosphate
- Potassium
- Sodium
- TIBCTotalIron Binding Capacity
- Total protein
- Triglycerides
- UIBCUnsaturated Iron Binding Capacity
- Urea
- Uric acid
- Zinc

*This parameter is not accredited according to DINENISO/IEC 17043.

COAGULATION COA

Program:COA12: 12 surveys/year x 1 sample
COA4: 4 surveys/year x 2 samples
COA2: 2 surveys/year x 2 samples
Material: Lyophilized samples of human plasma (1 mL)
Evaluation: Quantitative

Analytical parameters:

- aPTT (activated Partial Thromboplastin Time)
- Antithrombin III
- D-Dimer
- Fibrinogen
- PT (prothrombin time)
- Protein C
- Protein S
- Thrombin Time

CO-OXIMETRY OXI

Program:OXI:4 surveys/year x 2 samples
Material: Purified bovine hemoglobin solution treated with carbon monoxide (minimum 1,0 mL)
Evaluation: Quantitative

Analytical parameters:

- Oxyhemoglobin
- Desoxyhemoglobin
- Carboxyhemoglobin
- Methemoglobin
- Total Hemoglobin

CSF DIAGNOSTICS — CSF

Program: CSF: 4 surveys/year x 2 samples
Material: Liquid samples made from human serum and other human and chemical components (minimum 1 mL)
Evaluation: Quantitative
This program is not accredited according to DIN EN ISO/ IEC 17043

Analytical parameters:

Albumin	IgG	Sodium
Chloride	IgM	Proteins
Glucose	Lactate	
IgA	LDH	

DRUGS OF ABUSE — DAT

Program:DAT12: 12 surveys/year x 1 sample
DAT4: 4 surveys/year x 2 samples
Material: Liquid samples of filtered human urines with added drugs for qualitative analysis (minimum 2 mL)
Evaluation: Qualitative

New: K3/AB-Pinaca

Analytical parameters:

Acetylmorphine	Cannabinoids	MDMA	Synthetic Cannabinoids K2/Spice
Amphetamines	Cocaine and metabolites	Methadone	Synthetische Cannabinoide K3/AB-Pinaca
Barbiturates	EDDP	Metamphetamines	
Benzodiazepines	Fentanyl	Opiates	Tramadol
Buprenorphine	Ketamine	Phencyclidine	Tricyclic Antidepressants

ETHANOL, AMMONIA AND BICARBONATE — ETH

Program:ETH12: 12 surveys/year x 1 sample
ETH4: 4 surveys/year x 2 samples
Material: Liquid samples with added compounds (minimum 1 mL)
Evaluation: Quantitative

Analytical parameters:

Ethanol	Ammonia	Bicarbonate

FECAL OCCULT BLOOD — FOB

Program:FOB: 2 surveys/year x 2 samples
Material: Liquid samples simulating extracted stool samples (minimum 0,5 mL)
Evaluation:Qualitative and quantitative

Analytical parameters:

Human Hemoglobin (qualitative and quantitative)

GLUCOSE POC - WHOLE BLOOD — GLUWB

Program: 4surveys/year x 2 samples
GLUWB: Registration of 1-3 measuring systems
GLUWB 6 DEVICES: Registration of up to 6 measuring systems
GLUWB 9 DEVICES: Registration of up to 9 measuring systems
Material: Simulated whole blood (minimum 1 mL)
Evaluation: Quantitative

Analytical parameters:

Glucose

GLYCATED HEMOGLOBIN (HbA1c) — GHB

Program:GHB12: 12 surveys/year x 1sample
GHB4: 4 surveys/year x 2 samples
Material: Lyophilized samples of hemolysate of human blood (minimum 0,5 mL)
Evaluation: Quantitative

Analytical parameters:

HbA1c

LIPIDS — LIPID

Program:LIPID: 4 surveys/year x 2 samples
Material: Lyophilized samples of human plasma (minimum 3 mL)
Evaluation: Quantitative

New Program

Analytical parameters:

Apolipoproteins	Cholesterol, LDL	Lipoprotein(a)
Cholesterol, HDL	Cholesterol, total	Triglycerides

PROTHROMBIN TIME (INR)-POCT — INR-POCT

Program: 4 surveys/year x 2samples
I NR-POCT: Registration of 1-3 measuring systems
I NR-POCT 6 DEVICES: Registration of up to 6 measuring systems
INR-POCT 9 DEVICES: Registration of up to 9 measuring systems
Material: Liquid samples (minimum 0,3 mL)
Evaluation: Quantitative
Suitable for POCT analyzers, e.g. Roche Coaguchek, Siemens Xprecia Stride, Abbott iStat.

Analytical parameters:

Prothrombin Time (INR)

QUALITATIVE URINE ANALYSIS (URINE STICK) US

Program: US4: 4 surveys/year x 2 samples
US2: 2 surveys/year x 2 samples
Material: Liquid or lyophilized samples of urine preparation of human origin with added preservatives and stabilizers (minimum 10 mL)
Evaluation: Semi-quantitative

Analytical parameters:

Bilirubin	Ketone bodies	pH
Glucose	Leucocytes	Specific Gravity
hCG	Microalbumin	Total Protein
Hemoglobin	Nitrite	Urobilinogen

THERAPEUTIC DRUGS TDM

Program:TDM: 4 surveys/year x2samples
Material: Liquid samples with added compounds (minimum 2 mL)
Evaluation: Quantitative

Analytical parameters:

Amikacin	Gentamicin	Primidone
Carbamazepine	Lidocain	Salicylate
Chinidine	Paracetamol	Theophylline
Digoxin	Phenobarbital	Valproic Acid
Ethosuximide	Phenytoin	Vancomycin

URINE CHEMISTRY UC

Program:UC:4 surveys/year x 2 samples
Material: Liquid or lyophilized samples of human urine (minimum 5 mL)
Evaluation: Quantitative

Analytical parameters:

Amylase	Glucose	Phosphate	Urea
Calcium	Magnesium	Potassium	Uric acid
Chloride	Microalbumin	Total protein	
Creatinine	Osmolality*	Sodium	

*This parameter is not accredited according to DINENISO/IEC 17043.

URINE SEDIMENT FOR LIGHT SCATTERING METHODS USEDL

Program: USEDL4: 4 surveys/year x 2 samples
USEDL2: 2 surveys/year x 2 samples
Material: Liquid samples of human urine (minimum 5 mL)
Evaluation: Qualitative, quantitative and semi-quantitative
This program is suitable for light scattering methods, e.g. Sysmex UF-5000/4000/1500.

Analytical parameters:

Bacteria qual., semi-quant., quant.	Red cells qual., semi-quant., quant.
Casts qual., semi-quant., quant.	White cells qual., semi-quant., quant.
Crystals qual., semi-quant., quant.	

URINE SEDIMENT FOR MICROSCOPIC METHODS USEDM

Program: USEDM4: 4 surveys/year x 2 samples
USEDM2: 2 surveys/year x 2 samples
Material: Liquid samples of human urine (minimum 5 mL)
Evaluation: Qualitative, quantitative and semi-quantitative
This program is suitable for manual microscopy and automated microscopy, e.g. Siemens Atellica, Beckman Coulter Iris, Roche Cobas u 701, Menarini Sedimax, 77 Elektronika UriSed, Dirui FUS, Analyticon Urilyzer Cell, Mindray EH Series, Mindray EU series.

Analytical parameters:

Bacteria qual., semi-quant., quant.
Casts qual., semi-quant., quant.
Crystals qual., semi-quant., quant.
Red cells qual., semi-quant., quant.
White cells qual., semi-quant., quant.

IMMUNOASSAY PROGRAMS

ANTINUCLEAR ANTIBODIES — ANA

Program: ANA: 2 surveys/year x3 samples
Material: Liquid samples of human defibrinated plasma or serum (minimum 0,5 mL)
Evaluation: Qualitative, semiquantitative and quantitative
This program is not accredited according to DIN EN ISO/ IEC 17043

New Program

Analytical parameters:

ANA screen/detection
ANA - IFA Hep-Cell Pattern
ANA-Titer (dominant pattern) - semi-quant.
ANA quantitative
ANAidentification:Anti-CENP-A,Anti-CENP-B,Anti-dsDNA,Anti-Jo1,anti-RNP,Anti-Scl70, Anti-Sm, Anti-SS-A/Ro60, Anti-SS-B/La

CYCLIC CITRULLINATED PEPTIDE ANTIBODIES — CCP

Program: CCP: 2 surveys/yearx2 samples
Material: Liquid samples of human defibrinated plasma (minimum 0,5 mL)
Evaluation: Quantitative and qualitative

Analytical parameters:

anti-CCP (anti-cyclic citrullinated peptide)

HCG IN SERUM — HCG

Program: hCG: 4 surveys/year x 1 sample
Material: Lyophilized or liquid sample of human serum with added analytes of human origin (minimum 1 mL)
Evaluation: Qualitative

Analytical parameters:

hCG qualitative

HORMONES HOR

Program: HOR12: 12 surveys/year x 1 sample
HOR4: 4 surveys/year x 2 samples
Material: Lyophilized samples of human sera with added analytes (minimum 3 mL)
Evaluation: Quantitative

Analytical parameters:

17-OH-Progesterone	FSH	Prolactin
Aldosterone	hCG (qualitative and quantitative)	SHBG
AMH	Homocysteine	T3, free
Androstenedione	Human Growth Hormone	T3, total
Calcitonin	IgE	T4, free
C-Peptide	IGF-1	T4, total
Cortisol	Insulin	Testosterone Total
DHEA-S	LH (Luteinizing Hormone)	Thyroglobulin
Estradiol	Methylmalonic Acid	TSH
Ferritin	PTH	Vitamin B12
Folate	Progesterone	Vitamin D (25-OH)

PROCALCITONIN PCT

Program: PCT: 4 surveys/year x 2 samples
Material: Lyophilized samples of human sera with added analyte (minimum 0,5 mL)
Evaluation: Quantitative

Analytical parameters:

Procalcitonin

SPECIFIC PROTEINS SP

Program: SP12: 12 surveys/year x 1 sample
SP4: 4 surveys/year x 2 samples
Material: Liquid or lyophilized samples of human sera with added analytes of human origin (minimum 1 mL)
Evaluation: Quantitative

Analytical parameters:

Albumin	Ceruloplasmin	Prealbumin
Alpha-1-acid glycoprotein	CRP (C-Reactive Protein)	RF
Alpha-1-antitrypsin	Cystatin C*	soluble Transferrin receptor
Alpha-2-macroglobulin	Haptoglobin	(sTfR)*
ASO	IgA, IgE, IgG, IgM	Transferrin
Beta-2-microglobulin	Kappa light chains, total* and free	
C3, C4	Lambda light chains, total* and free	

* This parameter is not accredited according to DIN EN ISO/ IEC 17043.

THYROID ANTIBODIES — ANTI-THYR

Program: ANTI-THYR: 4 surveys/year x 2 samples
Material: Samples liquid or lyophilized (minimum 0,5 mL)
Evaluation:Qualitative and quantitative

Analytical parameters:

anti-TG	anti-TPO
TRAb (TSH-Receptor Antibodies)	

TUMOR MARKER — TM

Program: TM12: 12 surveys/year x 1 sample
TM4: 4 surveys/year x 2 samples
Material: Lyophilized samples of human sera with added analytes (minimum 3 mL)
Evaluation: Quantitative

Analytical parameters:

AFP	CA 125	PSA, total
CEA	CA 15-3	PSA, free
CA 19-9	Ferritin	

TUMOR MARKER & HORMONES — TMH

Program: TMH12: 12 surveys/year x 1 sample
TMH4: 4 surveys/year x 2 samples
TMH2: 2 surveys/year x 2 samples
Material: Lyophilized samples of human sera with added analytes (minimum 3 mL)
Evaluation: Quantitative

Analytical parameters:

17-OH-Progesterone	Estradiol	PSA, free
AFP	Ferritin	PSA, total
Aldosterone	Folate	PTH
AMH	FSH	SHBG
Androstenedione CA 125	hCG (qualitative and quantitative)	T3, free
CA 15-3	Homocysteine	T3, total
CA 19-9	Human Growth Hormone	T4, free
Calcitonin	IgE	T4, total
CEA	IGF-1	Testosterone Total
Cortisol	Insulin	Thyroglobulin
C-Peptide	LH (Luteinizing Hormone)	TSH
DHEA-S	Methylmalonic Acid Progesterone	Vitamin B12
	Prolactin	Vitamin D (25-OH)

MICROBIOLOGY PROGRAMS

ADENOVIRUS & ROTAVIRUS STOOL ANTIGEN — ADROTAg

Program:ADROTAg: 2 surveys/yearx 2samples
Material: Liquid or lyophilized material simulating human liquid stool specimens (minimum 0,3 mL)
Evaluation:Qualitative

New Program

Analytical parameters:

Adenovirus Stool Antigen
Rotavirus Stool Antigen

ADENOVIRUS SEROLOGY — ADE

Program:ADE: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for NovaLisa, Virion/Serion and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Adenovirus

*ThequantitativeparametersarenotaccreditedaccordingtoDIN EN ISO/ IEC 17043.

ASPERGILLUS FUMIGATUS SEROLOGY — ASF

Program:ASF: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for Virion/Serion ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG, IgM and total antibodies against Aspergillus fumigatus

* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

ASPERGILLUS GALACTOMANNAN ANTIGEN — ASPAG

Program:ASPAG:2surveys/yearx2 samples
Material: Liquid samples of simulated bronchoalveolar lavage (BAL) fluid or serum (minimum 0,5 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

Aspergillus Antigen (Galactomannan)

*Thequantitativeparametersarenotaccreditedaccording to DIN EN ISO/ IEC 17043.

BACTERIOLOGY — BAC

Program: BAC-CorBAC-E: 4 surveys/year x 4 samples
Material: Lyophilised samples (pure strain and/or mixture of bacteria): 2 for identification and 2 for antibiotic susceptibility testing (AST). AST according to EUCAST or CLSI guidelines.
Evaluation: Qualitative
In this program we simulate different types of specimens: blood, urine, swabs (e.g. surgical/wound site, etc.), sputum/bronchospcopy specimen, paracentesis samples (e.g. ascites), joint/synovial fluid, sonicate fluid of explanted prosthetic joints, and CSF.

Analytical parameters:

Identification (genus and species)
Antibiotic susceptibility testing (according to EUCAST or CLSI guidelines)

BACTERIOLOGY BLOOD CULTURE — BACBC-C, BACBC-E

Program: BACBC-C or BACBC-E: 4 surveys/yearx 4 samples
Material: Lyophilised samples (pure strain and/or mixture of bacteria): 2 for identification and 2 for antibiotic susceptibility testing (AST). AST according to EUCAST or CLSI guidelines.
In this program we simulate blood specimens focusing on blood culture pathogen identification and antimicrobial susceptibility testing.
Evaluation: Qualitative

Analytical parameters:

Identification (genus and species)
Antibiotic susceptibility testing (according to EUCAST or CLSI guidelines)

BACTERIOLOGY URINE CULTURE — BACUC-C, BACUC-E

Program: BACUC-Cor BACUC-E: 4 surveys/yearx 2 samples
Material: Lyophilised samples (pure strain and/or mixture of bacteria): 1 for identification and 1 for antibiotic susceptibility testing (AST). AST according to EUCAST or CLSI guidelines. In this program we simulate urine specimens focusing on urine culture pathogen isolation, identification, and antimicrobial susceptibility testing.
Evaluation: Qualitative

Analytical parameters:

Identification (genus and species)
Antibiotic susceptibility testing (according to EUCAST or CLSI guidelines)

BORDETELLA SEROLOGY — BPES

Program:BPES: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

IgA, IgG and IgM antibodies against Bordetella
IgA antibodies against Bordetella Pertussis-Toxin
IgG antibodies against Bordetella Pertussis-Toxin

* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

BORRELIA IgG ANTIBODY INDEX — BOR-G-AI

Program: BOR-G-AI: 2 surveys/year x 2 samples
Material: One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (CSF sample: 0,8 mL; serum sample: 0,3 mL)
Evaluation: Qualitative and quantitative

Analytical parameters:

Borrelia IgG-antibody index (AI), qualitative and quantitative

BORRELIA IgM ANTIBODY INDEX — BOR-M-AI

Program: BOR-M-AI: 2 surveys/year x 2 samples
Material: One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (CSF sample: 0,8 mL; serum sample: 0,3 mL)
Evaluation: Qualitative and quantitative

Analytical parameters:

Borrelia IgM-antibody index (AI), qualitative and quantitative

BORRELIA SEROLOGY — BOR

Program:BOR: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Borrelia burgdorferi

BRUCELLA SEROLOGY BRU

Program:BRU: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

IgA, IgG, IgM and agglutinating antibodies against Brucella

*ThequantitativeparametersarenotaccreditedaccordingtoDINENISO/IEC 17043.

CHAGAS SEROLOGY CHA

Program:CHA: 2 surveys/yearx2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,5 mL
Evaluation:Qualitative and quantitative*

Analytical parameters:

IgG, IgM and total antibodies against Trypanosoma cruzi (qualitative)
IgG and total antibodies against Trypanosoma cruzi (quantitative)

* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

CHIKUNGUNYA VIRUS SEROLOGY CHIKV

Program:CHIKV: 2surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Chikungunya Virus

CHLAMYDIA TRACHOMATIS SEROLOGY CHT

Program:CHT: 2surveys/yearx2samples
Material:Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgA, IgG and IgM antibodies against Chlamydia trachomatis

C. DIFFICILE STOOL ANTIGEN — CDIFFAg

Program: CDIFFAg: 2 surveys/year x2 samples
Material: Swabs simulating human solid stool (on swabs) or lyophilized samples simulating liquid stool specimens (minimum 0,4 mL)
Evaluation: Qualitative

New Program

Analytical parameters:

C. difficile GDH
C. difficile Toxins A/B

COXSACKIEVIRUS SEROLOGY — COX

Program:COX: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for Virion/Serion ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Coxsackievirus

* ThequantitativeparametersarenotaccreditedaccordingtoDINEN ISO/ IEC 17043.

DENGUE VIRUS ANTIBODIES — DENV

Program:DENV: 2surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative

Analytical parameters:

IgG and IgM antibodies against Dengue Virus

DENGUE VIRUS NS1 ANTIGEN — DENVAG

Program: DENVAG: 2 surveys/year x2 samples
Material: Liquid or lyophilized samples. The samples are either serum or plasma samples or simulated samples consisting of an aqueous protein matrix. Dengue virus NS1 antigen positive samples contain recombinant DENV NS1 protein.
Evaluation: Qualitative
This program is intended for immunochromatographic tests (Lateral Flow Rapid tests) and ELISA. Other reagents on request.

Analytical parameters:

Dengue Virus NS1 antigen

ECHO VIRUS SEROLOGY ECH

Program:ECH: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for Virion/Serion ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against ECHO-Virus

*ThequantitativeparametersarenotaccreditedaccordingtoDIN EN ISO/ IEC 17043.

ENTEROVIRUS SEROLOGY ENT

Program:ENT: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Enterovirus

*ThequantitativeparametersarenotaccreditedaccordingtoDIN EN ISO/ IEC 17043.

EPSTEIN-BARR VIRUS SEROLOGY EBV

Program:EBV: 4 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

anti-EBV EBNA-1 IgG + total | anti-EBV VCA IgG + total | anti-EBV VCA IgM

HELICOBACTER PYLORI ANTIBODIES HPYL

Program:HPYL: 2surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative

Analytical parameters:

IgA, IgG and total antibodies against Helicobacter pylori

HELICOBACTER PYLORI ANTIGEN — HPYLAG

Program:HPYLAG: 2 surveys/yearx2 samples
Material: Liquid or lyophilized simulated stool samples (minimum 0,3 mL)
Evaluation:Qualitative

Analytical parameters:

Helicobacter pylori Antigen

HEPATITIS A VIRUS SEROLOGY — HAV

Program:HAV12: 12surveys/year x 1sample
HAV4: 4 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

IgG, IgM and total antibodies against HAV

*Thequantitativeparametersarenotaccreditedaccording to DIN EN ISO/ IEC 17043.

HEPATITIS B VIRUS SEROLOGY — HBV

Program:HBV12: 12surveys/year x 1sample
HBV4: 4 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 1 mL)
Evaluation:Qualitative and quantitative

Analytical parameters:

anti-HBs	anti-HBe*	HBsAg
anti-HBc IgG + total*	anti-HBc IgM*	HBeAg*

*ThequantitativeparametersarenotaccreditedaccordingtoDIN EN ISO/ IEC 17043.

HEPATITIS E VIRUS SEROLOGY — HEV

Program:HEV: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative

Analytical parameters:

IgG, IgM and total antibodies against HEV

HIV ANTIBODIES AND ANTIGEN — HIV

Program: HIV: 4 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
Please note that the HIV survey is designed for assays that detect HIV antibodies and HIV antigen separately. For combo tests (e.g. HIV 4th generation assays) that detect HIV antibodies and HIV antigen simultaneously we recommend the enrollment in the ESfEQA INF program.

Analytical parameters:

anti-HIV 1/2 antibodies	HIV p24 Antigen

*Thequantitativeparametersare not accreditedaccordingtoDINEN ISO/ IEC 17043.

HTLV I/II — HTL

Program:HTL: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative

Analytical parameters:

total antibodies against HTLV I/II

INFECTIOUS DISEASE COMBINATION CONTROL SEROLOGY — INF

Program:INF12: 12 surveys/year x 1 sample
INF4: 4 surveys/year x 2 samples
INF4x4: 4 surveys/year x 4 samples
INF2: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 1 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

anti-HIV 1/2 / p24 Ag	anti-HBc
anti-HCV	HBsAg

*Thequantitativeparameters are not accredited accordingtoDIN EN ISO/ IEC 17043.

INFLUENZA A VIRUS SEROLOGY — INA

Program: INA: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for NovaLisa, Virion/Serion and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza A Virus

*ThequantitativeparametersarenotaccreditedaccordingtoDINENISO/ IEC 17043.

INFLUENZA B VIRUS SEROLOGY — INB

Program: INB: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for NovaLisa, Virion/Serion and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza B Virus

*Thequantitativeparametersarenotaccreditedaccordingto DINENISO/ IEC 17043.

LEGIONELLA PNEUMOPHILA ANTIBODIES — LPAB

Program:LPAB: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

IgG, IgM and total antibodies against Legionella pneumophila

* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

LEPTOSPIRA SEROLOGY — LEP

Program:LEP: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

IgG and IgM antibodies against Leptospira

* Thequantitativeparametersarenotaccreditedaccordingto DIN EN ISO/ IEC 17043.

MALARIA MICROSCOPY — MALM

Program: MALM: 4 surveys/year x 2 samples
Material: Slides of stained smears
Evaluation: Qualitative and quantitative
This program is not accredited according to DIN EN ISO/ IEC 17043.

Analytical parameters:

Malaria Parasite Detection	Stage Identification
Species Identification	Quantification of Plasmodium falciparum

MEASLES SEROLOGY — MEA

Program:MEA: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Measles Virus

MYCOPLASMA ANTIBODIES — MYPL

Program:MYPL:2 surveys/yearx2 samples
Material: Samples of human serum (minimum 0,3 mL)
Evaluation:Qualitative

Analytical parameters:

IgA, IgG, IgM and total antibodies against Mycoplasma pneumoniae

NOROVIRUS STOOL ANTIGEN — NOROAg

Program:NOROAg:2surveys/year x2 samples
Material: Swabs simulating human solid stool
Evaluation: Qualitative

New Program

Analytical parameters:

Norovirus GI Antigen
Norovirus GII Antigen

PARAINFLUENZA VIRUS SEROLOGY — PIN

Program:PIN: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for NovaLisa, Virion/Serion and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Parainfluenza Virus

*ThequantitativeparametersarenotaccreditedaccordingtoDINENISO/ IEC 17043.

PARVOVIRUS B19 SEROLOGY — PAR

Program:PAR: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Parvovirus B19

RESPIRATORY SYNCYTIAL VIRUS (RSV) SEROLOGY — RSV

Program: RSV: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative*
The scheme is intended for NovaLisa, Virion/Serion and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgG, IgM and IgA antibodies against Respiratory Syncytial Virus (RSV)

* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

RESPIRATORY VIRAL ANTIGEN DETECTION — RESPAG

Program: RESPAg: 2 surveys/year x 3 samples
Material: Lyophilized samples (minimum 0,3mL) simulating swab specimens (e.g. oropharyngeal, nasal, nasopharyngeal,etc.) or swabs. Antigen positive samples contain inactivated whole virus.
Evaluation: Qualitative

Analytical parameters:

Influenza A Antigen	Influenza B Antigen	RSV Antigen

SARS-CoV-2 ANTIGEN — COVAG

Program: COVAG: 4surveys/year x 3 samples
Material: Liquid or lyophilized samples simulating swab specimens (e.g. oropharyngeal, nasopharyngeal, nasal etc.). SARS-CoV-2 antigen positive samples contain inactivated whole virus (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

SARS-CoV-2 Antigen

SARS-CoV-2 SEROLOGY — COVID

Program: COVID: 2 Surveys/year x 4 samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

IgA, IgG and total antibodies against SARS-CoV-2
SARS-CoV-2 neutralising antibodies

*ThequantitativeparametersarenotaccreditedaccordingtoDINEN ISO/ IEC 17043.

STREPTOCOCCUS A ANTIGEN — STAA

:STAA: 2Surveys/yearx2 samples
Program
Material: Swab, liquid or lyophilized samples (minimum 0,3 mL) simulating swab specimens.
Evaluation: Qualitative

Analytical parameters:

Streptococcus A Antigen

SYPHILIS SEROLOGY — SYP

Program:SYP12: 12surveys/year x 1 sample
SYP4: 4 surveys/year x 2 samples
SYP2: 2 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (1 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

Total antibodies against Treponema pallidum (qualitative, semi-quantitative* and quantitative*)
IgG and IgM antibodies against Treponema pallidum (qualitative*)
Non-treponemal Lipoid antibodies (RPR/VDRL Tests) (qualitative)
Non-treponemal Lipoid antibodies (RPR/VDRL Tests Titers) (semi-quantitative*)

* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

TBEV IgG ANTIBODY INDEX — TBEV-G-AI

Program: TBEV-G-AI: 2 surveys/year x 2samples
Material: CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (CSF sample 0,8 mL; 0,3 mL for the serum sample)
Evaluation: Qualitative and quantitative

Analytical parameters:

TBEV IgG-antibody index (AI), qualitative and quantitative

TBEV IgM ANTIBODY INDEX — TBEV-M-AI

Program:TBEV-M-AI: 2 surveys/year x 2samples
Material: CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (CSF sample 0,8 mL; 0,3 mL for the serum sample)
Evaluation: Qualitative and quantitative

Analytical parameters:

TBEV IgM-antibody index (AI), qualitative and quantitative

ToRCH SEROLOGY — TORCH

Program:TORCH12: 12 surveys/year x 1 sample
TORCH4: 4 surveys/year x 2 samples
Material: Liquid samples of defibrinated human plasma (minimum 1 mL)
Evaluation: Qualitative and quantitative*

Analytical parameters:

anti-CMV IgG	anti-HSV 1 IgG	anti-Rubella IgG
anti-CMV IgM	anti-HSV 2 IgG	anti-Rubella IgM
anti-HSV 1/2 IgG	anti-HSV 1 IgM	anti-Toxoplasmose gondii IgG
anti-HSV 1/2 IgM	anti-HSV 2 IgM	anti-Toxoplasma gondii IgM

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043.

VARIZELLA ZOSTER VIRUS SEROLOGY — VZV

Program:VZV: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation:Qualitative and quantitative*

Analytical parameters:

IgA, IgG, and IgM antibodies against Varizella Zoster Virus (VZV)

*ThequantitativeantibodydeterminationisnotaccreditedaccordingtoDINENISO/IEC 17043.

WEST NILE VIRUS SEROLOGY — WNV

Program:WNV: 2surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against West Nile Virus

ZIKA VIRUS SEROLOGY — ZIKV

Program:ZIKV: 2 surveys/yearx2samples
Material: Liquid samples of defibrinated human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Zika Virus

MOLECULAR DIAGNOSTICS PROGRAMS

HBV MOLECULAR — HBVM

Program: HBVM: 4surveys/year x 3samples
Material: Lyophilized samples of human serum. Virus positive samples contain the whole genome of inactivated HBV (minimum 1 mL)
Evaluation: Qualitative and quantitative*

Analytical parameters:

HBV-DNA

*Thequantitativeparametersarenot accredited according to DIN EN ISO/ IEC 17043.

HCV MOLECULAR — HCVM

Program: HCVM:4surveys/year x 3 samples
Material: Lyophilized samples of human serum. Virus positive samples contain the whole genome of inactivated HCV (minimum 1 mL)
Evaluation: Qualitative and quantitative*

Analytical parameters:

HCV-RNA)

*Thequantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

HIV MOLECULAR — HIVM

Program: HIVM:4surveys/year x 3 samples
Material: Lyophilized samples of human serum. Virus positive samples contain the whole genome of inactivated HIV (minimum 1 mL)
Evaluation: Qualitative and quantitative*

Analytical parameters:

HIV-RNA

*Thequantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

HUMAN PAPILLOMA VIRUS MOLECULAR — HPVM

Program: HPVM: 2 surveys/year x 3 samples
Material: Swab specimens simulating cervical swabs containing inactivated cells that may or may not carry HPV.
Evaluation: Qualitative
This program is suitable for HPV DNA as well as mRNA detection methods.

New Program

Analytical parameters:

HPV detection
High-Risk HPV type detection (types covered are 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)
High-Risk HPV type identification: HPV 16, HPV 18, HPV types without 16/18 grouped

RESPIRATORY PATHOGENS MOLECULAR — RESPM

Program: RESPM: 2 surveys/year x 3 samples
Material: Liquid, lyophilized samples or swabs containing human epithel cells or fibroblasts as control for positive nucleic acid extraction and amplification. Positive samples contain the whole genome of inactivated pathogens, thus covering all possible gene targets used in different NAT/PCR assays (minimum 1 mL).
Evaluation: Qualitative

Analytical parameters:

Adenovirus		Influenza A	*Bordetella parapertussis*
Coronavirus	229E	Influenza B	*Bordetella pertussis*
Coronavirus	HKU1	Human Rhinovirus/Enterovirus	*Chlamydia pneumoniae*
Coronavirus	NL63	Human Metapneumovirus	*Haemophilus influenzae*
Coronavirus	OC43	Parainfluenza virus	*Legionella pneumophila*
SARS-CoV-2 (COVID-19)		RSV	*Streptococcus pneumoniae*
			Mycoplasma pneumoniae

SEXUALLY TRANSMITTED INFECTIONS MOLECULAR STIM

Program: STIM: 2surveys/yearx3samples
Material: Swab specimens simulating genital swabs containing inactivated cells that may or may not carry STI pathogens
Evaluation: Qualitative

Analytical parameters:

New Program

- Chlamydia trachomatis (CT) DNA
- HSV-1 DNA
- HSV-2 DNA
- Mycoplasma genitalium (MG) DNA
- Mycoplasma hominis (MH) DNA
- Neisseria gonorrhoeae (NG) DNA
- Treponema pallidum (TP) DNA
- Trichomonas vaginalis (TV) DNA
- Ureaplasma urealyticum (UU) DNA

HEMATOLOGY PROGRAMS

BLOOD GROUPING — ABO

Program: ABO: 4 surveys/year x 2 samples
Material: Liquid samples of stabilized human red cells suspended in a buffered fluid and preservative. Erythrocyte suspensions contain a red blood cell concentration of 8% minimum (minimum 4 mL).
Evaluation: Qualitative

Analytical parameters:

ABO-Typing	Rhesus (D)-Detection

ERYTHROCYTE SEDIMENTATION RATE — ESR

Program:ESR: 4 surveys/yearx2samples
Material: Liquid samples containing erythrocytes in blood collection tubes (75x13mm) with pierceable caps (3 mL)
Evaluation: Quantitative
The samples are not suitable for testing on Alifax, Alcor iSED and Mindray BC instruments.

Analytical parameters:

Erythrocyte Sedimentation Rate

ERYTHROCYTE SEDIMENTATION RATE FOR ALCOR — ESRAL

Program: ESRAL:2surveys/yearx2samples
Material: Liquid samples of stabilized human red cells suspended in a buffered fluid and preservative (minimum 2 mL)
Evaluation: Quantitative

Analytical parameters:

Erythrocyte Sedimentation Rate

ERYTHROCYTE SEDIMENTATION RATE FOR ALIFAX — ESRAF

Program:ESRAF-G: 2 surveys/year x 3 samples in Greiner tubes
ESRAF-S: 2 surveys/year x 3 samples in Sarstedt tubes
Material: Liquid samples for transmittance measurement related to ESR values in human samples (3 mL)
Evaluation: Quantitative

Analytical parameters:

Erythrocyte Sedimentation Rate

ERYTHROCYTE SEDIMENTATION RATE FOR MINDRAY — ESRMR

Program: ESRMR: 2 surveys/year x 3 samples
Material: Liquid samples for transmittance measurement related to ESR values in human samples (3 mL)
Evaluation: Quantitative
This program is suitable for Mindray ESR analyzers BC-700 and BC-7000 series.

New Program

Analytical parameters:

Erythrocyte Sedimentation Rate

HEMOGRAM — HEM

Program: HEM12: 12 surveys/year x 1 sample
HEM4: 4 surveys/year x 2 samples
HEM2: 2 surveys/year x 2 samples
Material: Plasma like fluid samples that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs (minimum 2 mL)
Evaluation: Quantitative

Analytical parameters:

HCT (hematocrit)	MCV (mean corpuscular volume)	RDW (RBC distribution width)
HGB (hemoglobin)	MPV (mean platelet volume)	WBC (white blood cells)
MCH (mean corpuscular hemoglobin)	PCT (Plateletcrit)	
MCHC (mean cellular hemoglobin concentration)	PDW (Platelet distribution width)	
	PLT (platelets)	
	RBC (red blood cells)	

HEMOGRAM INCL. 3-PART DIFF. — HEM3D

Program: HEM3D: 4 surveys/year x 2 samples
Material: Plasma like fluid samples that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs (minimum 1,5 mL)
Evaluation: Quantitative
This program is dedicated for 3-part WBC/leucocyte differential hematology analyses.

Analytical parameters:

GRAN (granulocytes)*	MCHC (mean cellular hemoglobin concentration)	PCT (plateletcrit)
HCT (hematocrit)	MCV (mean corpuscular volume)	PDW (Platelet distribution width)
HGB (hemoglobin)	MID, MXD (mid-sized leucocytes)	PLT (platelets)
LYMPH (lymphocytes)	MONO (monocytes)	RBC (red blood cells)
MCH (mean corpuscular hemoglobin)	MPV (mean platelet volume)	RDW (RBC distribution width)
		WBC (white blood cells)

*Thequantitativeantibodydetermination isnotaccreditedaccordingtoDINENISO/IEC17043.

HEMOGRAM INCL. 5-PART DIFF. HEM5D

Program: HEM5D12: 12 surveys/year x 1 sample
HEM5D4: 4 surveys/year x 2 samples
Material: Plasma like fluid samples that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs (minimum 1,5 mL)
Evaluation: Quantitative
This program is dedicated for 5-part WBC/leucocyte differential hematology analyses.

Analytical parameters:

BASO (basophiles)*	MCHC (mean cellular hemoglobin concentration)	PDW (platelet distribution width)
EO (eosinophiles)*	MCV (mean corpuscular volume)	PLT (platelets)
HCT (hematocrit)	MONO (monocytes)	RBC (red blood cells)
HGB (hemoglobin)	MPV (mean platelet volume)	RDW (RBC distribution width)
LYMPH (lymphocytes)	NEUT (neutrophiles)	RET (reticulocytes)
MCH (mean corpuscular hemoglobin)	PCT (plateletcrit)	WBC (white blood cells)

*Thequantitativeantibodydeterminationisnotaccreditedaccordingto DIN EN ISO/IEC 17043.

IMMUNOHEMATOLOGY IMHEM

Program: IMHEM4x3: 4 surveys/year x 3 samples
IMHEM2x6: 2 surveys/year x 6 samples
Material: 1(IMHEM4x3) or 2 (IMHEM2x6) tubes of the patient's red blood cell suspension (minimum 4 mL),1(4x3)or 2 (2x6) tubes of the patient's serum (minimum 4 mL) and 1 (4x3) or 2 (2x6) tubes of the donor'sredblood cell suspension (minimum 4 mL). Erythrocyte suspensions contain a red blood cell concentrationof 8% minimum
Evaluation:Qualitative

Analytical parameters:

ABO-Typing	Rh-Typing	Antibody screening
A-Subtypes	Kell-Antigen Detection	Antibody identification
Rhesus (D)-Detection	Direct Coombs test	Cross-matching

CLINICAL CASE STUDY PROGRAM — CASE

12 cases/year.

For new Subscribers: 3 cases free of charge

This program focuses on the interpretation of analytical data and aims to support and strengthen the skills of staff to draw the right conclusions from the analytical results. Participants receive the case description online and submit their interpretation of the clinical data via the ESfEQA web application.

Participants are asked to derive a diagnosis from the laboratory data and to identify the analytes that lead to the diagnosis. A further question addresses additional tests to support the stated diagnosis, and finally, to provide a therapy recommendation.

CASE STUDIES IN CLINICAL LABORATORY SCIENCE — CASE-T

6 cases/year.

For new Subscribers: 2 cases free of charge

The target group of this program is technical personnel as well as laboratory doctors in medical laboratories. It aims to support and to strengthen the skills of the staff for (pre)analytical questions. Participants receive the case description online and submit their interpretation of the clinical data via the ESfEQA web application.

Each study in the Clinical Laboratory Sciences Case Study program provides a case description with analyti cal data for Clinical Chemistry, Hematology, Coagulation, and related areas. Participants in the survey will be asked for their interpretation, explanation and corrective actions (if applicable) for the described case. Possible answers will be offered in dropdown lists. Participants are requested to select one or more responses they consider appropriate.

ESfEQA EQA-CALENDAR 2027

Version 01

Monthly	Program / Date*
	02/02/2027 - 16/02/2027
	23/02/2027 - 09/03/2027
	23/03/2027 - 06/04/2027
	27/04/2027 - 11/05/2027
	25/05/2027 - 08/06/2027
	22/06/2027 - 06/07/2027
	27/07/2027 - 10/08/2027
	25/08/2027 - 08/09/2027
	21/09/2027 - 05/10/2027
	19/10/2027 - 02/11/2027
	09/11/2027 - 23/11/2027
	30/11/2027 - 14/12/2027
BG12	Blood Gas and Electrolytes
CASE	Clinical Case Study Program
CC12	Clinical Chemistry
CM12	Cardiac Marker
CM-POCT12	Cardiac Marker POCT
COA12	Coagulation
DAT12	Drugs of Abuse
ETH12	Ethanol, Ammonia and Bicarbonate
GHB12	Glycated Hemoglobin (HbA1c)
HAV12	Hepatitis A Virus Serology
HBV12	Hepatitis B Virus Serology
HEM12	Hemogram
HEM5D12	Hemogram incl. 5-part diff.
HOR12	Hormones
INF12	Inf. Disease Combination Control
SP12	Specific Proteins
SYP12	Syphilis Serology
TM12	Tumor Marker
TMH12	Tumor Marker & Hormones
ToRCH12	ToRCH Serology

Bimonthly	Program / Date*
	23/02/2027 - 16/03/2027
	27/04/2027 - 18/05/2027
	22/06/2027 - 13/07/2027
	24/08/2027 - 14/09/2027
	05/10/2027 - 26/10/2027
	16/11/2027 - 07/12/2027
CASE-T	Case Studies in Clinical Laboratory Science

Quarterly	Program / Date*
	16/02/2027 - 09/03/2027
	20/04/2027 - 11/05/2027
	20/07/2027 - 10/08/2027
	12/10/2027 - 02/11/2027
ABO	Blood grouping
ANTI-THYR	Thyroid antibodies
BAC	Bacteriology
BACBC	Bacteriology Blood Culture
BACUC	Bacteriology Urine Culture
BG4	Blood Gas and Electrolytes
CC4	Clinical Chemistry
CM4	Cardiac Marker
CM-POCT4	Cardiac Marker POCT
COA4	Coagulation
COVAg	SARS-CoV-2 Antigen
CSF	CSF diagnostics
DAT4	Drugs of Abuse
EBV	Epstein-Barr Virus Serology
ESR	Erythrocyte sedimentation rate
ETH4	Ethanol, Ammonia and Bicarbonate
GHB4	Glycated Hemoglobin (HbA1c)
GLUWB	Glucose POC - Whole Blood
HAV4	Hepatitis A Virus Serology
HBV4	Hepatitis B Virus Serology
HBVM	HBV Molecular
HCG	hCG in serum
HCVM	HCV Molecular
HEM3D	Hemogram incl. 3-part diff.
HEM4	Hemogram
HEM5D4	Hemogram incl. 5-part diff.
HIV	HIV Antibodies and Antigen
HIVM	HIV Molecular
HOR4	Hormones
INF4	Inf. Disease Combination Control
INF4x4	Inf. Disease Combination Control
IMHEM4x3	Immunohematology
INR-POCT	Prothrombin Time (POCT)
LIPID	Lipids
MALM	Malaria Microscopy
OXI	Co-Oximetry
PCT	Procalcitonin
SP4	Specific Proteins
SYP4	Syphilis Serology
TDM	Therapeutic Drug Monitoring
TM4	Tumor Marker
TMH4	Tumor Marker & Hormones
ToRCH4	ToRCH Serology
UC	Urine Chemistry
US4	Qualitative Urine Analysis (Urine stick)
USEDL4	Urine Sediment Light scattering methods
USEDM4	Urine Sediment Microscopy methods

* Start of the measurement period until closing date

Registration deadline: in each case 3 months before the start of the corresponding measurement period.

Late registrations can still be considered if samples are available.

ESfEQA EQA-CALENDAR 2027

Semi-annual 1 (Q1+Q3)	Program / Date*	Semi-annual 2 (Q2+Q4)	Program / Date*
	16/02/2027 - 09/03/2027		04/05/2027- 25/05/2027
	20/07/2027 - 10/08/2027		26/10/2027 - 16/11/2027
CC2	Clinical Chemistry	ADE	Adenovirus Serology
CM2	Cardiac Marker	ADROTAg	Adenovirus & Rotavirus Stool Antigen
CM-POCT2	Cardiac Marker POCT	ANA	Autoimmunity - ANA
COA2	Coagulation	ASF	Aspergillus Fumigatus Serology
HEM2	Hemogram	ASPAg	Aspergillus Galactomannan Antigen
IMHEM2x6	Immunohematology	BOR	Borrelia Serology
INF2	Inf. Disease Combination Control	BOR-G-AI	Borrelia IgG antibody index
SYP2	Syphilis Serology	BOR-M-AI	Borrelia IgM antibody index
TMH2	Tumor Marker & Hormones	BPES	Bordetella Serology
US2	Qualitative Urine Analysis (Urine stick)	BRU	Brucella Serology
USEDL2	Urine Sediment Light scattering methods	CCP	Cyclic Citrullinated Peptide Antibodies
USEDM2	Urine Sediment Microscopy methods	CDIFFAg	C. difficile Stool Antigen
		CHA	Chagas Serology
		CHIKV	Chikungunya Virus Serology
		CHT	Chlamydia Trachomatis Serology
		COVID	SARS-CoV-2 Serology
		COX	Coxsackievirus Serology
		DENV	Dengue Virus Antibodies
		DENVAg	Dengue Virus NS1 Antigen
		ECH	ECHO Virus Serology
		ENT	Enterovirus Serology
		ESRAF	Erythrocyte sedimentation rate for Alifax analysers
		ESRAL	Erythrocyte sedimentation rate for Alcor iSED analysers
		ESRMR	Erythrocyte sedimentation rate for Mindray analysers
		FOB	Fecal Occult Blood
		HEV	Hepatitis E Virus Serology
		HPVM	HPV Molecular
		HPYL	Helicobacter Pylori Antibodies
		HPYLAg	Helicobacter Pylori Antigen
		HTL	HTLV I/II
		INA	Influenza A Virus Serology
		INB	Influenza B Virus Serology
		LEP	Leptospira Serology
		LPAb	Legionella Pneumophila Antibodies
		MEA	Measles Serology
		MYPL	Mycoplasma Antibodies
		NOROAg	Norovirus Stool Antigen
		PAR	Parvovirus B19 Serology
		PIN	Parainfluenza Virus Serology
		RESPAg	Respiratory Viral Antigen Detection
		RESPM	Respiratory Pathogens Molecular
		RSV	RSV Serology
		STAA	Streptococcus A Antigen
		STIM	Sexually Transmitted Infections Molecular
		TBEV-G-AI	TBEV IgG antibody index
		TBEV-M-AI	TBEV IgM antibody index
		VZV	Varizella Zoster Virus Serology
		WNV	West Nile Virus Serology
		ZIKV	Zika Virus Serology

* Start of the measurement period until closing date

Registration deadline: in each case 3 months before the start of the corresponding measurement period.

Late registrations can still be considered if samples are available.

GENERAL TERMS FOR THE PARTICIPATION IN EXTERNAL QUALITY ASSESSMENT SURVEYS OF ESFEQA

Status September 2026

1. Participation
Participation in ESfEQA external quality assessment (EQA) surveys is open to anyone who performs laboratory tests in their own practice or in a managed medical laboratory. The following conditions for participation apply.

2. Consent to conditions of participation
By registering with ESfEQA GmbH, the participant agrees to these general terms and conditions of participation.

3. Assignment of services
IIndividual elements of EQA schemes (e.g. pretesting of values, packaging and shipping) may be assigned to subcontractors. ESfEQA is responsible for the work of the subcontractors.

4. ESfEQA catalogue
The ESfEQA portfolio of EQA schemes and analytes contained in individual programs are described in the ESfEQA catalogue. Depending on the availability of samples and number of participants, ESfEQA reserves the right not to offer the entire spectrum of analytes for each EQA survey or sample.

5. Schedule
The schedule, published in the ESfEQA catalogue, contains deadlines for ordering and result submission, as well as the testing periods. Once the deadline for ordering has passed, acceptance of late orders is at ESfEQA's discretion. Results must be submitted to ESfEQA electronically, or using a result entry form, on or before the closing date. All deadlines and calendar dates are given in UTC.

6. Cancellation of EQA surveys
ESfEQA reserves the right to cancel or postpone EQA surveys. This information will be provided to participants before the original sample shipping date and ESfEQA will endeavour to offer an alternative date in a timely manner.

7. Registration
For participation in ESfEQA EQA surveys registration is required. This can be done online, or by sending the necessary information to ESfEQA by email to info@esfeqa.eu. The following information is required: laboratory name, name of the organization/hospital, name of participant, number of analytical devices, and e-mail address.

8. Ordering of samples
Distribution of ESfEQA EQA surveys is usually carried out by international distributors. If there is no distributor available in the participant's region, sales can be carried out directly by ESfEQA. The ordering process between participants and distributors is the responsibility of the parties involved. As a rule, an EQA program is ordered for a full calendar year. Orders placed during the year generally include the survey samples up to the end of the current calendar year.

9. Homogeneity and stability of EQA samples
The EQA survey samples selected by ESfEQA were examined and evaluated with regard to homo¬geneity and stability.

10. Designation of EQA samples
The EQA samples can be distinguished by their identifier, which has the following format: program acronym_survey year_survey number_sample number. For example, the sample CM4_2027_01_a belongs to the quarterly program Cardiac Marker (CM4) in the year 2027 and is sample "a" of the first survey. Samples with the same designation are not necessarily identical, i.e. different results can be obtained despite the same designation. ESfEQA correctly allocates samples to the original batch and thus to the target values.

11. Shipping of EQA samples
EQA samples are shipped by postal or parcel service. Due to governmental restrictions, or insufficient sample stability, shipping of individual EQA programs to specific countries may be excluded.

12. Instructions for use
Instructions for Use (IFU) for each EQA survey are available on the ESfEQA website (www.esfeqa.eu) and on the TEQA 2.0 LAB platform (https://teqa-labv2.esfeqa.eu). Each IFU includes instructions for sample preparation and stability.

13. Use of EQA samples
Usually, EQA samples should be treated exactly like patient samples and measured in the same way as routine samples according to the manufacturer's instructions for the instrument and reagent. They may only be used for the purpose of participating in an EQA survey and may not be used in a laboratory procedure for testing potentially hazardous and potentially infectious samples also applies to EQA samples.

14. Submission of survey results
Where applicable, submission of results includes the actual measured value as well as instrument, reagent and method used. The input mask in TEQA 2.0 LAB (ESfEQA's evaluation software application, https://teqa-labv2.esfeqa.eu) displays the required information for each EQA program. A drop-down list of instruments, reagents and analyte-specific methods is provided in the configuration section. In instances where an instrument, reagent or method is not listed in TEQA 2.0, participants may utilize the designated "coding request" functionality to add the missing information. They can select their specific instrument, reagent and method to create a new configuration prior to entering their test results. The selection of instrument, reagent and method as well as the submission of results, must be performed using the TEQA 2.0 LAB web application. Participants receive their login data (username and password) from ESfEQA, which is required to enter results. The password consists of at least 8 characters, including an uppercase letter, a number, and a special character. Username and password are to be treated confidentially by the participant. An alternative to result submission via the TEQA 2.0 LAB web application, is the result form, which can be sent to ESfEQA either by e-mail (surveys@esfeqa.eu) or fax (+49 6221 4166 790). Result forms specific for each EQA program are provided on the ESfEQA website. ESfEQA encourages all participants to submit their results online via the secure TEQA 2.0 LAB web application, for the sake of data security and convenience.

ESfEQA evaluates all survey results submitted by participants by the deadline. In the event of loss or late arrival of their data, the participant bears the risk. ESfEQA is not obliged to evaluate results submitted after the submission deadline.
Quantitative results are generally reported with a value and unit. The participant determines the number of digits for reporting. In general, results should be reported as measured. However, results submitted as "< test range' (e.g. "< 10") or "> test range" (e.g. ">2000") are not valid.
For results below the test range, the lower test range limit should be reported (e.g. "10").
For samples with analyte concentrations above the test range, the sample can be diluted (if recommended for particular applications) or the upper test range limit (e.g. "2000") can be submitted as the result. Several units are usually available for entering quantitative results. The units are converted into the standard unit used by ESfEQA.
Laboratories are obliged to treat their results confidentially and not to pass them on to third parties until the EQA survey report has been received. If ESfEQA becomes aware of the passing on or falsi-fication of results or the collusion between participants, ESfEQA reserves the right to exclude those concerned from further participation in EQA surveys conducted by ESfEQA as well as to exclude the issuance of reports.

15. Number of results per participant
For each EQA sample and analyte, up to 3 values per participant can be submitted. The values have to be determined by different analytical devices that are independent from each other.

16. Correction of transmitted results
Participants can edit their results in their laboratory account on the TEQA 2.0 LAB platform up until the deadline for result submission of the EQA survey.

17. Evaluation of EQA results
For each analyte in ESfEQA EQA surveys, the type of target value determination and acceptance criterion are predefined. For quantitative parameters, the target value is usually the consensus value of participants results. This value is calculated according to ISO 13528:2022 'Statistical methods for use in proficiency testing by interlaboratory comparison' using robust statistics.
Samples provided for testing of qualitative parameters are thoroughly tested with different analytical systems before being used as control material, thereby setting the target value. System-specific differences are taken into account, if appropriate and feasible, with a corresponding statistical evaluation. The broadest possible distinction according to method, device and/or reagent used is made available to participants (M-, I-, R-group). The minimum number of results of an evaluation group is 5. If this number is not reached in the survey, the individual result has to be compared to the robust mean of the next largest group that can be evaluated. Usually, this is the group consisting of participants using the same method (M group), or the general group containing the results of all participants. The definition of the evaluation group is documented in the survey report.

For quantitatively determined analytes, the maximum permissible ranges of the target value are predefined. The permissible range for each analyte is derived from its medical relevance as well as the reference interval. In the report display, the upper limit of the permissible range corresponds to a z-value of 3 and the lower limit to a z-value of -3.

18. Survey reports
In general, the participants will receive reports electronically via the TEQA 2.0 LAB web application within 10 days (for monthly programs), or three weeks (for quarterly and semi-annual programs) after the deadline for submission of the results. The reports include the results submitted by the participant evaluated in comparison to target values. The data is displayed both in tabular and illustrated form
(e. g., Histogram and Shewhart chart). The reports are intended for external quality assurance of laboratories. They may not be published, passed on or used for purposes other than quality assurance without the written consent of ESfEQA.

19. Fees
The fees for participation are set and communicated to the participants by the responsible distrib¬utor of ESfEQA programs in their geographical area/country. Due to the high variability of shipping, handling and customs costs, the prices may vary between various countries. Please contact your local distributor for the participation fee.

20. Certificates
For each EQA program participants receive a certificate of participation. In addition, participants receive a certificate for those parameters which met the specified performance criteria in the respective EQA survey. Both certificates are made available to participants via the TEQA 2.0 LAB web application. The certificates are issued simultaneously with the reports.

21. Loss and damage of EQA test material
In the event of sample loss or damage, ESfEQA should be notified immediately. If possible, ESfEQA will send replacement samples without acknowledging any claims. However, the contract is fulfilled on the date of dispatch of the original sample material.

22. Complaints and appeals
After receipt of an EQA survey report, a complaint/appeal can be made within a period of 4 weeks. After expiry of this period, any claims by the participant based on a complaint /appeal are excluded. In the event of a justified complaint/appeal, ESfEQA will decide whether to reimburse the amount paid for the EQA survey, or to provide a substitute EQA survey. ESfEQA GmbH does not reimburse any costs incurred for reagents, time expenditure etc. unless ESfEQA GmbH is liable in accordance with paragraph 23 of these General Terms and Conditions for Participation.

23. Warranty
ESfEQA shall only be liable for damages of any kind in the case of intent and gross negligence, if the other prerequisites for claims are met. In all other respects, liability for damages of any kind, regardless of the basis of the claim, including liability for culpa in contrahendo, is excluded.

24. Confidentiality
Individual EQA data is kept confidential. It is only known to the corresponding participant, their distributor and ESfEQA employees. ESfEQA collects, processes and uses personal data of the participant only to the extent necessary for the performance of EQA surveys, the preparation of the reports and for the purpose of quality assurance. This includes the forwarding of the data identifiable by subscriber and device number for quality assurance measures to the respective manufacturer of the analytical systems (device and reagent).

COMPANY INFORMATION

ESfEQA GmbH

CEO: Oliver Bošnjak

Head of Operations: Dr. Dieter Groche

Address: Siemensstraße 38
69123 Heidelberg
Germany

Phone: +49(0)6221-4166-700

Fax: +49(0)6221-4166-790

E-mail: info@esfeqa.eu

Website: www.esfeqa.eu

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