ESfEQA
European Society for
External Quality Assessment

DAkkS
Deutsche
Akkreditierungsstelle
D-EP-19851-01-00

Quality Assessment Schemes Program

2024

CONTENT - ESFEQA PROGRAMS

BIOCHEMISTRY

IMMUNOLOGIY

MICROBIOLOGY

ESfEQA

CONTENT - ESFEQA PROGRAMS

MICROBIOLOGY

MOLECULAR

Molecular Diagnostics Programs

HEMATOLOGY

Hematology Programs

CONTENT - ESFEQA PROGRAMS

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

ABOUT ESFEQA

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 well-being 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 international standard ISO 17043 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. Thus, ESfEQA will launch in 2024 the following new programs: Glucose and hemoglobin in whole blood, hCG in Urine, Bordetella Serology, Helicobacter Pylori antibodies, Mycoplasma antibodies, Streptococcus-A antigen, Viral antigen detection (Andenovirus, Influenza A/B, RSV, Rotavirus). In addition we will offer in 2024 more programs in a semi-annual format: COA2, OXI2, CSF2, US2, USEDL2, USEDM2.

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. In general, programs should be ordered for an entire calendar year.

Survey Calendar

The dates for begin of result entry and deadline for result entry are published in this catalogue and on the ESfEQA website (www.esfeqa.eu).

The testing periods of the 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 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.

New Programs

Based on the feedback of our participants, ESfEQA extends the EQA portfolio continously. Please contact us for further suggestions on new programs.
Programs that have not been listed on the ESfEQA ISO 17043 accreditation certificate yet are marked in this catalogue as not accredited.

Heidelberg, September 2023

BIOCHEMISTRY PROGRAMS

BILIRUBIN NEONATAL — BILI-N

Program: BILI-N: 4 surveys/year x 2 samples
Material: Lyophilized samples of human Serum (minimum 0,5mL)
Evaluation: Quantitative

Analytical parameters:

Bilirubin direct	Bilirubin total
Bilirubin conjugated	Bilirubin non-conjugated

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:

Calcium	pCO2	Sodium
Chloride	pH	Urea
Glucose	pO2	
Lactate	Potassium	

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

CLINICAL CHEMISTRY CC

Program: CC12: 12 surveys/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	Cholesterol	Lithium
ALP Alkaline phosphatase	Cholinesterase	Magnesium
ALT/GPT	CK Creatinkinase	Phosphate
α-Amylase	Creatinine	Potassium
Amylase pancreatic	Copper	Sodium
AST/GOT	Gamma GT	TIBC Total Iron Binding Capacity
Bilirubin, direct	Glucose	Total protein
Bilirubin, total	HDL Cholesterol	Triglycerides
Bilirubin conjugated	Iron	UIBC Unsaturated Iron Binding Capacity
Bilirubin non-conjugated	Lactate	Urea
Calcium	LDH Lactate Dehydrogenase	Uric acid
Calcium (ionized)	LDL Cholesterol	Zinc
Chloride	Lipase	

COAGULATION COA

Program: COA12: 12 surveys/year x 1 sample
COA4: 4 surveys/year x 2 samples
COA2: 2 surveys/year x 2 samples

New Program COA2

Material: Lyophilized samples of human plasma (1 mL)
Evaluation: Quantitative

Analytical parameters:

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

CO-OXIMETRIE OXI

Program: OXI4: 4 surveys/year x 2 samples
OXI2: 2 surveys/year x 2 samples

New Program OXI2

Material: Lyophilized samples containing bovine hemoglobin (minimum 0,5 mL)
Evaluation: Quantitative

This program is not accredited according to DIN EN ISO/ IEC 17043

Analytical parameters:

Oxyhemoglobin	Carboxyhemoglobin	total Hemoglobin
Desoxyhemoglobin	Methemoglobin	

CSF DIAGNOSTICS — CSF

New Program CSF2

Program: CSF4: 4 surveys/year x 2 samples
CSF2: 2 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	Proteine
Glucose	Lactate	
IgA	LDH	

DRUGS OF ABUSE — DAT

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

Analytical parameters:

Acetylmorphine	Cannabinoids	Opiates
Amphetamines	Cocaine and metabolites	Synthetic Cannabinoids (K2/Spice)
Barbiturates	MDMA	Tricyclic Antidepressants
Benzodiazepines	Methadone and metabolites	
Buprenorphine	Metamphetamines	

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

New Program

Program: 4 surveys/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 1 sample
GHB4: 4 surveys/year x 2 samples

Material: Lyophilized samples of hemolysate of human blood (minimum 0,5 mL)
Evaluation: Quantitative

Analytical parameters:

HbA1c	Hemoglobin

PROTHROMBIN TIME (INR)-POCT — INR-POCT

Program: 4 surveys/year x 2 samples
INR-POCT: Registration of 1-3 measuring systems
INR-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

New Program US2

Program: US4: 4 surveys/year x 2 samples
US2: 2 surveys/year x 2 samples

Material: Liquid samples of urine preparation of human origin with added preservatives and stabilizers (minimum 10 mL)
Evaluation: Semi-quantitative

Analytical parameters:

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

THERAPEUTIC DRUGS TDM

Program: DAT: 4 surveys/year x 2 samples

Material: Liquid samples with added compounds (minimum 2 mL)
Evaluation: Quantitative

Analytische Parameter:

Amikacin	Gentamicin	Procainamide
Carbamazepine	Lidocain	Salicylate
Chinidine	NAPA	Theophylline
Chloramphenicol	Paracetamol	Tobramycin
Digoxin	Phenobarbital	Valproic Acid
Disopyramide	Phenytoin	Vancomycin
Ethosuximide	Primidone	

URINE CHEMISTRY UC

Program: UC: 4 surveys/year x 2 samples

Material: Lyophilized samples of human urine (minimum 5 mL)
Evaluation: Quantitative

Analytical parameters:

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

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

URINE SEDIMENT FOR LIGHT SCATTERING METHODS USEDL

Program: USEDL4: 4 surveys/year x 2 samples
USEDL2: 2 surveys/year x 2 samples

New Program USEDL2

Material: Lyophilized 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, Sysmex UN

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

New Program USEDM2

Program: USEDM4: 4 surveys/year x 2 samples
USEDM2: 2 surveys/year x 2 samples
Material: Lyophilized 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

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.

WHOLE BLOOD HEMOGLOBIN — WHGN

New Program

Program: WHGN: 4 surveys/year x 2 samples
Material: Hemoglobin solution (1 mL)
Evaluation: Quantitative

Analytical parameters:

- Hemoglobin

IMMUNOLOGY PROGRAMS

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 qualitativ

HCG IN URINE — HCGU

Program: HCGU: 4 surveys/year x 2 samples

New Program

Material: Liquid samples of synthetic urine (minimum 1 mL)
Evaluation: Qualitative

Analytical parameters:

hCG qualitativ

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:

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

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

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	free
Alpha-1-acid glycoprotein	CRP (C-Reactive Protein)	Prealbumin
Alpha-1-antitrypsin	Cystatin C*	RF
Alpha-2-macroglobulin	Haptoglobin	soluble Transferrin receptor
ASO	IgA, IgE, IgG, IgM	(sTfR)*
Beta-2-microglobulin	Kappa light chains, total* and free	Transferrin
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 (0,5 mL)
Evaluation: Quantitative

Analytical parameters:

anti-TG (qual. and quant.)	anti-TPO (qual. and quant.)
TRAb (TSH-Receptor Antibodies) (qual. and quant.)	

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:

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

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

MICROBIOLOGY PROGRAMS

ADENOVIRUS SEROLOGY — ADE

Program: ADE: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative

The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

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

Analytical parameters:

IgA, IgG and IgM antibodies against Adenovirus

ASPERGILLUS FUMIGATUS SEROLOGY — ASF

Program: ASF: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative

The scheme is intended for Virion/Serion ELISA reagents. Other reagents upon request.

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

Analytical parameters:

IgA, IgG, IgM and total antibodies against Aspergillus fumigatus

ASPERGILLUS GALACTOMANNAN ANTIGEN — ASPAG

Program: ASPAG: 2 surveys/year x 2 samples

Material: Liquid samples of simulated bronchoalveolar lavage (BAL) fluid or serum (minimum 0,5 mL)
Evaluation: Qualitative and quantitative

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

Analytical parameters:

Aspergillus Antigen (Galactomannan)

BACTERIOLOGY — BAC-C, BAC-E

Program: BAC-C or BAC-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

Analytical parameters:

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

BORDETELLA SEROLOGY — BPES

New Program

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

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

Analytical parameters:

Bordetella IgA, IgG, IgM	Bordetella Pertussis-Toxin IgA	Bordetella Pertussis-Toxin IgG

BORRELIA SEROLOGY — BOR

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

Analytical parameters:

IgG and IgM antibodies against Borrelia burgdorferi

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

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

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

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

Analytical parameters:

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

BRUCELLA SEROLOGY BRU

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

Analytical parameters:

IgA, IgG and IgM antibodies against Brucella | agglutinating antibodies against Brucella

CHAGAS SEROLOGY CHA

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

Analytical parameters:

IgG antibodies against Trypanosoma cruzi

CHIKUNGUNYA VIRUS SEROLOGY CHIKV

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

Analytical parameters:

IgG and IgM antibodies against Chikungunya Virus

CHLAMYDIA TRACHOMATIS SEROLOGY CHT

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

Analytical parameters:

IgA, IgG and IgM antibodies against Chlamydia trachomatis

COXSACKIEVIRUS SEROLOGY COX

Program: COX: 2 surveys/year x 2 samples
Material: Liquid samples of 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.

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

Analytical parameters:

IgA, IgG and IgM antibodies against Coxsackievirus

DENGUE VIRUS ANTIBODIES — DENV

Program: DENV: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Dengue Virus

DENGUE VIRUS NS1 ANTIGEN — DENVAG

New Program

Program: DENVAG: 2 surveys/year x 2 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 programme is intended for immunochromatographic tests (Lateral Flow Rapid tests) and ELISA. Other reagents on request.

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

Analytical parameters:

Dengue Virus NS1 antigen

ECHO VIRUS SEROLOGY — ECH

Program: ECH: 2 surveys/year x 2 samples

Material: Liquid samples of 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.

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

Analytical parameters:

IgA, IgG and IgM antibodies against ECHO-Virus

ENTEROVIRUS SEROLOGY — ENT

Program: ENT: 2 surveys/year x 2 samples

Material: Liquid samples of 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.

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

Analytical parameters:

IgA, IgG and IgM antibodies against Enterovirus

EPSTEIN-BARR VIRUS SEROLOGY — EBV

Program: EBV: 4 surveys/year x 2 samples
Material: Liquid samples of 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

New Program

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

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

Analytical parameters:

Helicobacter pylori Antibody

HEPATITIS A VIRUS SEROLOGY — HAV

Program: HAV: 4 surveys/year x 2 samples
Material: Liquid samples of human plasma (minimum 1 mL)
Evaluation: Qualitative

Analytical parameters:

anti-HAV IgG + total	anti-HAV IgM

HEPATITIS B VIRUS SEROLOGY — HBV

Program: HBV: 4 surveys/year x 2 samples
Material: Liquid samples of human plasma (minimum 0,5 mL)
Evaluation: Qualitative and quantitative

Analytical parameters:

anti-HBs (qual. and quant.*)	anti-HBe	HBsAg (qual. and quant.*)
anti-HBc IgG + total	anti-HBc IgM	HBeAg

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

HEPATITIS E VIRUS SEROLOGY — HEV

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

Analytical parameters:

anti-HEV IgG + total	anti-HEV IgM

HIV ANTIBODIES AND ANTIGEN — HIV

Program: HIV: 4 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

anti-HIV 1/2 antibodies	HIV p24 Antigen*

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

HTLV I/II — HTL

Program: HTL: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

anti-HTLV I/II

INFECTIOUS DISEASE COMBINATION CONTROL SEROLOGY — INF

Program: 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 human plasma (minimum 1 mL)
Evaluation: Qualitative

Analytical parameters:

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

INFLUENZA A VIRUS SEROLOGY — INA

Program: INA: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative

The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

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

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza A Virus

INFLUENZA B VIRUS SEROLOGY — INB

Program: INB: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative

The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

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

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza B Virus

LEGIONELLA PNEUMOPHILA ANTIBODIES — LPAB

Program: LPAB: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative

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

Analytical parameters:

IgG, IgM and total antibodies against Legionella pneumophila

LEPTOSPIRA SEROLOGY — LEP

Program: LEP: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Leptospira	agglutinating antibodies against Leptospira*

* This parameter is not accredited according to 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/year x 2 samples
Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Measles Virus

MYCOPLASMA ANTIBODIES — MYPL

New Program

Program: MYPL: 2 surveys/year x 2 samples
Material: Samples of human serum (minimum 0,5 mL)
Evaluation: Qualitative

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

Analytical parameters:

Mycoplasma Antibody

PARAINFLUENZA VIRUS SEROLOGY — PIN

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

The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

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

Analytical parameters:

IgA, IgG and IgM antibodies against Parainfluenza Virus

PARVOVIRUS B19 SEROLOGY — PAR

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

Analytical parameters:

IgG and IgM antibodies against Parvovirus B19

RSV SEROLOGY — RSV

Program: RSV: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative

The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun IFT reagents. Other reagents upon request.

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

Analytical parameters:

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

SARS-CoV-2 ANTIGEN — COVAG

Program: COVAG: 4 surveys/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 (qualitative)

SARS-CoV-2 SEROLOGY — COVID

Program: COVID: 4 Surveys/year x 4 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative

Analytical parameters:

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

STREPTOCOCCUS A ANTIGEN — STAA

Program: STAA: 2 Surveys/year x 2 samples

New Program

Material: Swab
Evaluation: Qualitative

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

Analytical parameters:

Streptococcus A Antigen

SYPHILIS SEROLOGY — SYP

Program: SYP4: 4 surveys/year x 2 samples
SYP2: 2 surveys/year x 2 samples

Material: Liquid samples of human plasma (1 mL)
Evaluation: Qualitative and quantitative

Analytical parameters:

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

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

TBEV IgG ANTIBODY INDEX — TBEV-G-AI

Program: TBEV-G-AI: 2 surveys/year x 2 samples

Material: CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (Liquorsample: 1 mL), (0,3 mL for the serum sample of the Tick-borne encephalitis virus antibody index survey)
Evaluation: Qualitative and quantitative

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

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 2 samples

Material: CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (Liquorsample: 1 mL), (0,3 mL for the serum sample of the Tick-borne encephalitis virus antibody index survey)
Evaluation: Qualitative and quantitative

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

Analytical parameters:

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

ToRCH SEROLOGY — TORCH

Program: TORCH: 4 surveys/year x 2 samples

Material: Liquid samples of human plasma (minimum 1 mL)
Evaluation: Qualitative and quantitative

Analytical parameters:

anti-CMV IgG (qual. and quant.*)
anti-CMV IgM
anti-HSV 1/2 IgG (qual. and quant.*)
anti-HSV 1/2 IgM
anti-HSV 1 IgG
anti-HSV 2 IgG
anti-HSV 1 IgM
anti-HSV 2 IgM
anti-Rubella IgG (qual. and quant.*)
anti-Rubella IgM
anti-Toxoplasmose gondii IgG (qual. and quant.*)
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/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative and quantitative

Analytical parameters:

IgA, IgG, and IgM antibodies against Varizella Zoster Virus (VZV), qual. and quant.*

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

VIRAL ANTIGEN DETECTION — AVIR

Program: AVIR: 2 surveys/year x 2 samples

Material: Inactivated Solution (1 mL)
Evaluation: Qualitative

New Program

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

Analytical parameters:

Adenovirus Antigen	Influenza B Antigen	Rotavirus Antigen
Influenza A Antigen	Respiratory Syncytial Virus Antigen	

WEST NILE VIRUS SEROLOGY — WNV

Program: WNV: 2 surveys/year x 2 samples

Material: Liquid samples of 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/year x 2 samples

Material: Liquid samples of human plasma (minimum 0,3 mL)
Evaluation: Qualitative

Analytical parameters:

IgG and IgM antibodies against Zika Virus

HBV MOLECULAR — HBVM

Program: HBVM: 4 surveys/year x 3 samples

Material: Lyophilized samples of human serum. Virus positive samples contain the whole genome of inactivated HBV (minimum 1 mL)
Evaluation: Qualitative and quantitative

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

Analytical parameters:

HBV-DNA (qualitative and quantitative)

HCV MOLECULAR — HCVM

Program: HCVM: 4 surveys/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

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

Analytical parameters:

HCV-RNA (qualitative and quantitative)

HIV MOLECULAR — HIVM

Program: HIVM: 4 surveys/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

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

Analytical parameters:

HIV-RNA (qualitative and quantitative)

SARS-COV-2 MOLECULAR — COVM

Program: COVM: 4 surveys/year x 3 samples

Material: Liquid or lyophilized samples containing human epithel cells or fibroblasts as control for positive nucleic acid extraction and amplification. Virus-positive samples contain the whole genome of inactivated SARS-CoV-2, thus covering all possible gene targets used in different NAT/PCR assays (minimum 1 mL).
Evaluation: Quantitative

Analytical parameters:

SARS-CoV-2 RNA (qualitative) General detection as well as reporting per gene target	SARS-CoV-2 RNA (quantitative) General indication as well as reporting of quantitative value per gene target

HEMATOLOGY PROGRAMS

BLOOD GROUPING — ABO

Program: AB0: 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

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

Analytical parameters:

ABO-Typing	Rhesus (D)-Detection

ERYTHROCYTE SEDIMENTATION RATE — ESR

Program: ESR: 4 surveys/year x 2 samples

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 and Alcor iSED instruments.

Analytical parameters:

Erythrocyte Sedimentation Rate

ERYTHROCYTE SEDIMENTATION RATE FOR ALCOR — ESRAL

Program: ESRAL: 2 surveys/year x 2 samples

Material: Liquid samples of stabilized human red cells suspended in a buffered fluid and preservative (4 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

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

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

This program is dedicated for 3-part WBC/leucocyte differential hematology analyses

Analytical parameters:

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

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

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

IMMUNOHEMATOLOGY — IMHEM

Program: IMHEM: 2 surveys/year x 6 samples

Material: 2 Erythrocyte suspension (patient; min. 4 mL), 2 serum sample (patient; min. 4 mL) and 2 erythrocyte suspensions (donor; min. 4 mL). Erythrocyte suspensions contain a red blood cell concentration of 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

EDUCATIONAL PROGRAMS

CLINICAL CASE STUDY PROGRAM — CASE

12 cases/year

This programme 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.

Parameter:

Suspected diagnosis	Parameters supporting the suspected diagnosis
Other tests to confirm the diagnosis	Therapy suggestions

Monthly	Program / Date*	Quarterly	Program / Date*
30/01/2024 - 13/02/2024		13/02/2024 - 05/03/2024	
20/02/2024 - 05/03/2024		09/04/2024 - 30/04/2024	
19/03/2024 - 02/04/2024		09/07/2024 - 30/07/2024	
16/04/2024 - 30/04/2024		15/10/2024 - 05/11/2024	
14/05/2024 - 28/05/2024		AB0	Blood grouping
11/06/2024 - 25/06/2024		ANTI-THYR	Thyroid antibodies
16/07/2024 - 30/07/2024		BAC	Bacteriology
13/08/2024 - 27/08/2024		BG4	Blood Gas and Electrolytes
10/09/2024 - 24/09/2024		BILI-N	Bilirubin neonatal
22/10/2024 - 05/11/2024		CC4	Clinical Chemistry
12/11/2024 - 26/11/2024		CM4	Cardiac Marker
03/12/2024 - 17/12/2024		COA4	Coagulation
BG12	Blood Gas and Electrolytes	COVAG	SARS-CoV-2 Antigen
CASE	Clinical Case Study Program	COVID	SARS-CoV-2 Serology
CC12	Clinical Chemistry	COVM	SARS-CoV-2 Molekular
CM12	Cardiac Marker	CSF4	CSF diagnostics
COA12	Coagulation	DAT	Drugs of Abuse
ETH12	Ethanol, Ammonia and Bicarbonate	EBV	Epstein-Barr Virus Serology
GHB12	Glycated Hemoglobin (HbA1c)	ESR	Erythrocyte sedimentation rate
HEM12	Hemogram	ETH4	Ethanol, Ammonia and Bicarbonate
HEM5D12	Hemogram incl. 5-part diff.	GHB4	Glycated Hemoglobin (HbA1c)
HOR12	Hormones	GLUWB	Glucose POC - Whole Blood
SP12	Specific Proteins	HAV	Hepatitis A Virus Serology
TM12	Tumor Marker	HBV	Hepatitis B Virus Serology
TMH12	Tumor Marker & Hormones	HBVM	HBV Molecular
		HCG	hCG in serum
		HCGU	hCG in urine
		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
		INR-POCT	Prothrombin Time (POCT)
		MALM	Malaria Microscopy
		OXI4	Co-Oximetry
		PCT	Procalcitonin
		SP4	Specific Proteins
		SYP4	Syphilis Serology
		TM4	Tumor Marker
		TMH4	Tumor Marker & Hormones
		TORCH	ToRCH Serology
		UC	Urine Chemistry
		US4	Qualitative Urine Analysis (Urine stick)
		USEDL4	Urine Sediment for light scattering methods
		USEDM4	Urine Sediment for microscopic methods
		WHGN	Whole blood hemoglobin

* 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.

Semi-annual 1 (Q1+Q3)	Program / Date*	Semi-annual 2 (Q2+Q4)	Program / Date*
	13/02/2024 - 05/03/2024		23/04/2024 - 14/05/2024
	09/07/2024 - 30/07/2024		29/10/2024 - 19/11/2024
CC2	Clinical Chemistry	ADE	Adenovirus Serology
CM2	Cardiac Marker	ASF	Aspergillus Fumigatus Serology
COA2	Coagulation	ASPAG	Aspergillus Galactomannan Antigen
CSF2	CSF diagnostics	AVIR	Viral Antigen Detection
HEM2	Hemogram	BOR	Borrelia Serology
IMHEM	Immunohematology	BOR-G-AI	Borrelia IgG antibody index
INF2	Inf. Disease Combination Control	BOR-M-AI	Borrelia IgM antibody index
OXI2	Co-Oximetry	BPES	Bordetella Serology
SYP2	Syphilis Serology	BRU	Brucella Serology
TMH2	Tumor Marker & Hormones	CHA	Chagas Serology
US2	Qualitative Urine Analysis (Urine stick)	CHIKV	Chikungunya Virus Serology
USEDM2	Urine Sediment for microscopic methods	CHT	Chlamydia Trachomatis 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
		FOB	Fecal Occult Blood
		HEV	Hepatitis E Virus Serology
		HPYL	Helicobacter Pylori-Antibodies
		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 Antibody
		PAR	Parvovirus B19 Serology
		PIN	Parainfluenza Virus Serology
		RSV	RSV Serology
		STAA	Streptococcus A Antigen
		TBEV-G-AI	TBEV IgG antibody index
		TBEV-M-AI	TBEV IgM antibody index
		USEDL2	Urine Sediment for light scattering methods
		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 August 2023

1. Participation
The participation in the external quality assessment (EQA) surveys of ESfEQA is open to any¬one who performs laboratory tests in their own practice or in a managed medical laboratory. The follow-ing 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
Individual parts of EQA schemes (e.g. pretesting of values, packaging and shipping) may be as-signed to subcontractors. ESfEQA is responsible for the work of the subcontractors.

4. ESfEQA catalog
The ESfEQA portfolio of offered EQA schemes and the analytes contained in the individual programs are described in the ESfEQA catalog. Depending on the availability of samples and the 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 is published in the catalog and on the ESfEQA website. It contains the deadlines for ordering, the testing period, and the deadline for result submission. After the deadline for ordering there is no entitlement for the acceptance of orders. Results have to be submitted to ESfEQA elec-tronically or by fax-form until the closing date. The calendar date refers to the time zone at the place of business of ESfEQA in Heidelberg, Germany (GMT +1).

6. Cancelation of EQA surveys
ESfEQA reserves the right to cancel or postpone EQA surveys. This information will be provided to participants before the originally planned shipping date of the samples. In this case, ESfEQA tries to offer an alternative date in a timely manner.

7. Registration
For the participation in ESfEQA EQA surveys a registration is required. This can be done online, or the necessary information can be provided to ESfEQA in written form. The following infor¬mation is required: laboratory name, name of the organization/hospital, name of participant, number of analyti-cal devices, and e-mail address.

8. Ordering of samples
The 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 programme is ordered for a full calendar year. Orders placed during the year gener¬ally 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. The identifier consists of the short name of the program, the year of the survey, the survey number and an index, when several samples are pro¬vided in a single survey. Thus, the sample with the labeling CM4_2024_01_a belongs to the quarterly program Cardiac Marker (CM4) in the year 2024 and is sample “a” of the first survey. Samples with the same designation are not necessarily identical, i. e. different results can be measured de-spite the same designation. ESfEQA makes the correct allocation to the original batch and thus to the target values.

11. Shipping of EQA samples
Shipping of the EQA samples takes place by postal or parcel service. Due to governmental re-strictions, or insufficient stability, sample shipping of individual EQA programs to specific countries may be excluded.

12. Instructions for Use
Instructions for Use are provided to the participants for each EQA survey on the ESfEQA website (www.esfeqa.eu). A printout of the Instructions for Use is usually enclosed with the sample package. The Instructions for Use include instructions for the preparation of the samples, sample stability and the deadline for submission of results.

13. Use of EQA samples
Usually, EQA samples are to be handled like patient samples and measured in the same way as rou-tine samples according to the instructions of the instrument and reagent manufacturers. They may only be used for the purpose of participating in an EQA survey and may not be used in a misappro-priated manner. Generally, the usual precautions in the laboratory for potentially hazardous and po-tentially infectious samples apply to EQA samples.

14. Submission of survey results
Where applicable the submission of the results includes, in addition to the actual measured value, the indication of the method used, the instrument used and the reagent used. The input mask in the evaluation software application TEQA used by ESfEQA predetermines the required information for each EQA program. A list of methods, instruments and reagents is provided in the configuration section.
If the method, instrument or reagent used for the measurement by the participant is not included in this selection list, participants may add their method, instrument or reagent to this list through the in-put mask “coding request”. They can then select their added method, instrument and reagent to complete their configuration prior to entering their test results.
The selection of method, instrument and reagent as well as the submission of results are to be trans¬mitted through the web-application TEQA. Participants receive the login data required for the entry of results from ESfEQA. The password consists of at least 8 characters, of which at least 2 are special characters. Username and password are to be treated confidentially by the participant.
As alternative to the result submission via the web-application TEQA, results can be submitted using forms, that can be sent to ESfEQA either by E-Mail (info@esfeqa.eu) or Fax (+49 6221 894669-90). The corresponding forms that are specific for each EQA program and survey are provided on the ESfEQA website. ESfEQA encourages the participants to submit their results online via the secured TEQA web application for the sake of data security and convenience.

ESfEQA evaluates all survey results that are submitted by the participants in due time. For loss or late arrival of their data the participant bears the risk. There is no claim for data assessment of test results arrived late.
Quantitative results are generally reported with a value and a unit. The participant determines the number of digits for reporting. In general, result should be reported as measured, however, results specified "< test range' (e.g. "< 10") and "> test range" (e.g. ">2000") are not valid. If the analyzer system displays such results, they shall be interpreted as follows: for results below the test range, the lower test range limit should be reported (e.g. "10"). For samples that have analyte concentra-tions 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 reported as the result. Several units are usually availa-ble 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
Once the results have been submitted via the web-application TEQA and the participant realizes any need for changing the results, the participant can submit a change request via the TEQA web appli-cation. This option exists until the deadline of result submission of the particular survey. ESfEQA may change the participant results after checking and accepting the change request. A change re-quest for results submitted by participants via the fax form can be sent to ESfEQA by e-mail or fax until the deadline or result submission. Participants who have submitted their results via the TEQA web application have to use the change request function in TEQA for any change request.

17. Evaluation of EQA results
For each analyte of ESfEQA EQA surveys, the type of target value determination and the ac-ceptance criterion are predefined in advance. For quantitative parameters, the target value is usually the consensus value of the participant results. This value is calculated according to ISO 13528:2022-08' 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 where appropriate and possible. The statistical evaluation is carried out accordingly. The broadest possible distinction according to the method, device and/or reagent used is made available to the participants (M, I, R group). The minimum number of results of an evaluation group is 5 values. If this number is not reached in the survey, the individual result has to be compared to the robust mean of the next larger 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.
The maximum permissible ranges of the target value of quantitatively determined analytes are defined in advance . 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 be provided with reports electronically via the TEQA web-application within 10 days for monthly programs and within three weeks for quarterly and semi-annual programs after the deadline for submission of the results. The reports include the results submitted by the par-ticipant and their assessment compared to the target values. The data is displayed both in tabular and illustrated form (e. g. Histogram, Shewart chart, Youden plot). The reports are intended for exter¬nal 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 the participation are set and communicated to the participants by the responsible distrib¬utor of ESfEQA programs in their geographical area/country.

20. Certificates
Participants receive a certificate of participation for each EQA program they participate in.
In addition, the participants receive a certificate for the parameters for which they have met the spec¬ified performance criteria in the respective EQA survey. Both certificates are made available to the participants via the TEQA web-application. The certificates are issued simultaneously with the re-ports.

21. Loss and damage of EQA test material
In the event of loss of or damage to the sample material, ESfEQA shall, if possible and to the extent that an immediate complaint has been made, replace the sample material by sending replacement samples without acknowledging any claims. However, the contract is fulfilled on the date of dispatch of the original sample material.

22. Complaints and Objections
After receipt of an EQA survey report, a complaint or objection can be made within a period of 4 weeks. After expiry of this period, any claims by the participant on the basis of a complaint and objection are excluded. In the event of a justified complaint/objection, there is a claim for reimbursement of the amount paid for the EQA survey or for the conduction of a substitute EQA survey. It is for ESfEQA to decide on one of these two options. 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, regard¬less 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 dis-tributor and ESfEQA employees. ESfEQA collects, processes and uses personal data of the partici¬pant 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 sub¬scriber 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
Internet:	www.esfeqa.eu

ESf-brosch-2024-4_EN_27102023