ESfEQA
European Society for
External Quality Assessment

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Akkreditierungsstelle
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Quality Assessment Schemes Program

2022

CONTENT - ESFEQA PROGRAMS

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ESfEQA

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 17043:2010 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. Currently, ESfEQA offers more than 90 quantitative and qualitative EQA programs worldwide in the areas of biochemistry, immunology, microbiology, molecular diagnostics and hematology.

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. To ensure a cost-effective shipping process, survey samples are shipped semi-annually as long as this frequency is permitted by sample stability.

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).

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 10 days 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.

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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

BIOCHEMISTRY PROGRAMS

BILIRUBIN NEONATAL — BILI-N

New Program

2 lyohilized samples (minimum 0,5 mL) of human serum.
4 surveys per year.

Analytical parameter:

Bilirubin

BLOOD GAS AND ELECTROLYTES — BG

Liquid buffered aqueous solution or serum-based samples (minimum 2 mL). 4 or 12 surveys per year.
One sample per survey in monthly program (BG12), two samples per survey in quarterly program (BG4).

Analytical parameters:

Calcium	pCO_2	Sodium
Chloride	pH	Urea
Glucose	pO_2	
Lactate	Potassium	

CARDIAC MARKER — CM

Lyophilized samples (minimum 1 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program (CM12), two samples per survey in quarterly program (CM4).
The samples are based on human serum. Analytical devices that are intended for whole blood only are not suitable for these samples.

Analytical parameters:

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

CEREBROSPINAL FLUID — CSF

2 liquid samples (minimum 1 mL) made from human serum and other human and chemical components.
4 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Albumin	IgG	Sodium
Chloride	IgM	Protein
Glucose	Lactate	
IgA	LDH	

CLINICAL CHEMISTRY CC

Lyophilized samples (5 mL) of human sera with added enzymes and proteins of human origin.
2, 4 or 12 surveys per year. One sample per survey in monthly program (CC12), two samples per survey in quarterly and semiannual programs (CC4 and CC2).

Analytical parameters:

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

COAGULATION COA

Lyophilized samples (1 mL) of human plasma.
4 or 12 surveys per year. One sample per survey in monthly program (COA12), two samples per survey in quarterly program (COA4).

Analytical parameters:

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

CO-OXIMETRY OXI

2 liquid or lypholized samples (minimum 0,5 mL) containing bovine hemoglobin.
4 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytische Parameter:

Oxyhemoglobin	Carboxyhemoglobin	total Hemoglobin
Desoxyhemoglobin	Methemoglobin	

DRUGS OF ABUSE DAT

2 liquid or lyophilized samples (minimum 1 mL) of filtered human urines with added drugs for qualitative analysis.
4 surveys per year.

Analytical parameters:

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

ETHANOL, AMMONIA AND BICARBONATE — ETH

Liquid samples (minimum 0.5 mL) with added compounds. 4 or 12 surveys per year. One sample per survey in monthly program (ETH12), two samples per survey in quarterly program (ETH4).

Analytical parameters:

Ethanol	Ammonia	Bicarbonate*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010

FECAL OCCULT BLOOD — FOB

2 liquid samples (minimum 0.5 mL) simulating extracted stool samples. 2 surveys per year.

Analytical parameters:

Human Hemoglobin (qualitative and quantitative)

GLYCATED HEMOGLOBIN — GHB

Lyophilized samples (minimum 0.5 mL) of hemolysate of human blood.
4 surveys or 12 per year. One sample per survey in monthly program (GHB12), two samples per survey in quarterly program (GHB4).

Analytical parameters:

HbA1c	Hemoglobin

PROTHROMBIN TIME (INR)-POCT — INR-POCT

2 liquid samples (minimum 0.3 mL) suitable for POCT analyzers, e.g. Roche Coaguchek, Siemens Xprecia Stride, Abbott iStat.
4 surveys per year.

New Program

Analytical parameters:

Prothrombine time (INR)

QUALITATIVE URINE ANALYSIS (URINE STICK) — US

2 liquid samples (min. 2 mL) of urine preparation of human origin with added preservatives and stabilizers.
4 surveys per year.

Analytical parameters:

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

QUALITATIVE URINE ANALYSIS (URINE STICK) USXL

2 liquid samples (min. 10 mL) of urine preparation of human origin with added preservatives and stabilizers.
4 surveys per year.

Analytical parameters:

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

THERAPEUTIC DRUGS TDM

2 liquid samples (minimum 2 mL) with added compounds.
4 surveys per year.

Analytical parameters:

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

URINE CHEMISTRY UC

2 lyophilized samples (minimum 5 mL) of urine of human origin with added preservatives and stabilizers.
4 surveys per year.

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 17043:2010.

URINE SEDIMENTS USED

2 liquid samples (minimum 5 mL) of urine of human origin. 4 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

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.	

IMMUNOLOGY PROGRAMS

HCG — HCG

1 lyophilized sample (minimum 1 mL) of human serum with added analytes of human origin.
4 surveys per year.

Analytical parameters:

hCG qualitative

HORMONES — HOR

Liquid or lyophilized samples (minimum 2 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program (HOR12), two samples per survey in quarterly program (HOR4).

Analytical parameters:

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

PROCALCITONIN — PCT

2 lyophilized samples (minimum 0.5 mL) of human sera with added analyte.
4 surveys per year.

Analytical parameters:

Procalcitonin

SPECIFIC PROTEINS — SP

Liquid (minimum 1 mL) or lyophilized samples (1 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program (SP12), two samples per survey in quarterly program (SP4).

Analytical parameters:

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

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

THYROID ANTIBODIES — ANTI-THYR

2 samples (minimum 0,5 mL) .
4 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytische Parameter:

anti-TG	anti-TPO

TUMOR MARKER — TM

Liquid or lyophilized samples (minimum 2 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program (TM12), two samples per survey in quarterly program (TM4).

Analytical parameters:

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

TUMOR MARKER & HORMONES — TMH

Lyophilized sample (minimum 3 mL) of human sera with added analytes.
4 or 12 surveys per year. One sample per survey in monthly program (TMH12), two samples per survey in quarterly program (TMH4).

Analytical parameters:

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

MICROBIOLOGY PROGRAMS

ADENOVIRUS — ADE

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Adenovirus

ASPERGILLUS FUMIGATUS — ASF

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG, IgM and total antibodies against Aspergillus fumigatus

BACTERIOLOGY — BAC-C, BAC-E

4 lyophilized samples (pure strains and/or mixture of bacteria): 2 for identification and 2 for antibiotic susceptibility testing (AST). AST according to EUCAST guidelines (BAC-E) or according to CLSI guidelines (BAC-C)
4 surveys per year. (Simulated) clinical information about the sample type is provided.

Analytical parameters:

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

BORRELIA — BOR

2 liquid samples (minimum 0.3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Borrelia

BORRELIA IgG-ANTIBODY INDEX (AI) — BOR-G-AI

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytical parameters:

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

BORRELIA IgM-ANTIBODY INDEX (AI) — BOR-M-AI

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the anti-body index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytical parameters:

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

BRUCELLA — BRU

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

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

CHAGAS — CHA

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG antibodies against Trypanosoma cruzi

CHIKUNGUNYA VIRUS — CHIKV

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Chikungunya Virus

CHLAMYDOPHILA PNEUMONIAE — CHP

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG, IgM, and IgA antibodies against Chlamydophila pneumoniae

CHLAMYDIA TRACHOMATIS — CHT

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG, IgM, and IgA antibodies against Chlamydia trachomatis

COXSACKIEVIRUS — COX

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. 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

DENGUE VIRUS — DENV

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Dengue Virus

ECHO-VIRUS — ECH

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against ECHO-Virus

ENTEROVIRUS — ENT

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. 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

EPSTEIN-BARR VIRUS — EBV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

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

HEPATITIS A VIRUS — HAV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-HAV IgG + total	anti-HAV IgM

HEPATITIS B VIRUS — HBV

2 liquid samples (minimum 1 mL) of human plasma. 4 surveys per year.

Analytical parameters:

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

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

HEPATITIS E VIRUS — HEV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-HEV IgG + total	anti-HEV IgM

HIV ANTIBODIES AND ANTIGEN — HIV

2 liquid samples (minimum 0,3 mL) of human plasma.
4 surveys per year.

Analytical parameters:

anti-HIV 1/2 antibodies	HIV p24 Antigen*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

HTLV I/II — HTL

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

anti-HTLV I/II

INFECTIOUS DISEASE COMBINATION CONTROL — INF

2 liquid samples (minimum 0,5 mL) of human plasma. 4 surveys per year (INF4).
4 liquid samples (minimum 0,5 mL) of human plasma. 4 surveys per year (INF4x4).
2 liquid samples (minimum 0,5 mL) of human plasma. 2 surveys per year (INF2).

Analytical parameters:

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

INFLUENZA A VIRUS — INA

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza A Virus

INFLUENZA B VIRUS — INB

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza B Virus

LEPTOSPIRA — LEP

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Leptospira — agglutinating antibodies against Leptospira*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

MALARIA MICROSCOPY — MALM

2 slides of stained smears.
4 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Malaria Parasite Detection	Stage Identification
Species Identification	Quantification of Plasmodium falciparum

MEASLES — MEA

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Measles Virus

PARAINFLUENZA VIRUS — PIN

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Parainfluenza Virus

PARVOVIRUS B19 — PAR

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Parvovirus B19

RESPIRATORY SYNCYTIAL VIRUS — RSV

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

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

SARS-CoV-2 ANTIBODIES — COVID

4 liquid samples (minimum 0,3 mL) of human plasma.
4 surveys per year.

Analytical parameters:

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

SARS-CoV-2 ANTIGEN — COVAG

3 liquid or lyophilized samples (minimum 0,3 mL) simulating swab specimens (e.g. oropharyngeal, nasopharyngeal, nasal etc.).
4 surveys per year. SARS-CoV-2 antigen positive samples contain inactivated whole virus.

Analytical parameters:

SARS-CoV-2 Antigen qualitative and quantitative

SYPHILIS — SYP

2 liquid samples (1 mL) of human plasma. 4 surveys per year (SYP4) in quarterly program, 2 surveys per year (SYP2) in semi-anual program.

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 (qualitative)
Non-treponemal Lipoid antibodies (semi-quantitative)*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

TBEV IgG-ANTIBODY INDEX (AI) — TBEV-G-AI

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytical parameters:

TBEV IgG-antibody index (AI)

TBEV IgM-ANTIBODY INDEX (AI) — TBEV-M-AI

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytical parameters:

TBEV IgM-antibody index (AI)

ToRCH TORCH

2 liquid samples (minimum 1 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-CMV IgG (qual. and quant.*)	anti-HSV 1 IgG	anti-Rubella IgM
anti-CMV IgM	anti-HSV 2 IgG	anti-Toxoplasma gondii IgG (qual. and quant.*)
anti-HSV 1/2 IgG (qual. and quant.*)	anti-HSV 1 IgM	anti-Toxoplasma gondii IgM
anti-HSV 1/2 IgM	anti-HSV 2 IgM	
	anti-Rubella IgG (qual. and quant.*)	

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

VARICELLA ZOSTER VIRUS VZV

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

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

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

WEST NILE VIRUS WNV

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against West Nile Virus

ZIKA VIRUS ZIKV

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Zika Virus

HBV MOLECULAR — HBVM

2 lyophilized samples (minimum 1,1 mL) of human serum. Virus positive samples contain the whole genome of inactivated HBV.
4 surveys per year. This program is not accredited according to DIN EN ISO/IEC 17043:2010.
Launch 2nd quarter 2022.

New Program

Analytische Parameter:

HBV-DNA

HCV MOLECULAR — HCVM

2 lyophilized samples (minimum 1,1 mL) of human serum. Virus positive samples contain the whole genome of inactivated HCV.
4 surveys per year. This program is not accredited according to DIN EN ISO/IEC 17043:2010.
Launch 2nd quarter 2022.

New Program

Analytische Parameter:

HCV-RNA

HIV MOLECULAR — HIVM

2 lyophilized samples (minimum 1,1 mL) of human serum. Virus positive samples contain the whole genome of inactivated HIV.
4 surveys per year. This program is not accredited according to DIN EN ISO/IEC 17043:2010.
Launch 2nd quarter 2022.

New Program

Analytische Parameter:

HIV-RNA

SARS-COV-2 MOLECULAR — COVM

3 liquid or lyophilized samples (minimum 1 mL) 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.
4 surveys per year.

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

2 liquid samples (minimum 4 mL) of stabilized human red cells suspended in a buffered fluid and preservative. Erythrocyte suspensions contain a red blood cell concentration of 8% minimum. 4 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

ABO-Typing	Rhesus (D)-Detection

IMMUNOHEMATOLOGY IMHEM

2 erythrocyte suspensions (patient; min. 4 mL), 2 serum samples (patient; min. 4 mL) and 2 erythrocyte suspensions (donor; min. 4 mL). Erythrocyte suspensions contain a red blood cell concentration of 8% minimum. 2 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

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

ERYTHROCYTE SEDIMENT. RATE ON ALCOR ISED ANALYZERS ESRAL

2 liquid samples (about 4 mL) of stabilized human red cells suspended in a buffered fluid and preservative. 2 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Erythrocyte Sedimentation Rate

ERYTHROCYTE SEDIMENTATION RATE ON ALIFAX ANALYZERS ESRAF

3 liquid samples (about 3 mL) for transmittance measurement related to ESR values in human samples presented in Greiner tubes (ESRAF-G) or in Sarstedt tubes (ESRAF-S). 2 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Erythrocyte Sedimentation Rate

ERYTHROCYTE SEDIMENTATION RATE — ESR

2 liquid samples (3 mL) containing erythrocytes in blood collection tubes (75x13mm) with pierceable caps. 4 surveys per year. The samples are not suitable for testing on Alifax and Alcor iSED instruments.

Analytical parameters:

Erythrocyte Sedimentation Rate

HEMOGRAM — HEM

Plasma like fluid samples (minimum 2 mL) that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs. 2, 4 or 12 surveys per year. One sample per survey in monthly program (HEM12), two samples per survey in quarterly and semiannual program (HEM4 and HEM2). This program is suitable for hematology analyzers with and without leucocyte-differentiation.

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

2 plasma like fluid samples (minimum 1,5 mL) that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs. 4 surveys per year.
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

2 plasma like fluid samples (minimum 1,5 mL) that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs. 4 surveys per year.

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 17043:2010.

CASE STUDY PROGRAM CASE

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.
12 surveys per year.

New Program

Parameters:

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

ESfEQA INTERNATIONAL EQA SCHEMES SURVEY SAMPLE SCHEDULE 2022
Quarterly Programs and Semi-annual Programs 1

Program (Program Code) Quarterly Programs	Sample	Begin of Result Entry - Closing Date	Program (Program Code) Semi-annual Programs 1	Sample	Begin of Result Entry - Closing Date
ABO - Blood Grouping			ADE - Adenovirus		
ANTI-THYR - Thyroid Antibodies			ASF - Aspergillus fumigatus		
BAC-C, BAC-E - Bacteriology	2022_01_a	14/02/2022 - 07/03/2022	BOR - Borrelia	2022_01_a	25/04/2022 - 16/05/2022
BG4 - Blood Gas & Electrolytes	2022_01_b		BOR-G-AI - Borrelia IgG-Antibody Index	2022_01_b	
BILI-N - Bilirubin Neonatal			BOR-M-AI - Borrelia IgM-Antibody Index		
CC4 - Clinical Chemistry	2022_02_a	11/04/2022 - 02/05/2022	BRU - Brucella		
CM4 - Cardiac Marker	2022_02_b		CHA - Chagas		
COA4 - Coagulation			CHIKV - Chikungunya Virus	2022_02_a	31/10/2022 - 21/11/2022
CSF - Cerebrospinal Fluid			CHP - Chlamydophila Pneumoniae	2022_02_b	
DAT - Drugs of Abuse	2022_03_a	11/07/2022 - 01/08/2022	CHT - Chlamydia Trachomatis		
EBV - Epstein-Barr Virus	2022_03_b		COX - Coxsackievirus		
ESR - Erythrocyte Sedimentation Rate			DENV - Dengue Virus		
ETH4 - Ethanol	2022_04_a	17/10/2022 - 07/11/2022	ECH - Echovirus		
GHB4 - Glycated Hemoglobin	2022_04_b		ENT - Enterovirus		
HAV - Hepatitis A			ESRAF-G, ESRAF-S - ESR on Alifax analyzers		
HBV - Hepatitis B			ESRAL - ESR on Alcor analyzers		
HBVM - HBV Molecular			FOB - Fecal Occult Blood		
HCG - hCG			HTL - HTLV I/II		
HCVM - HCV Molecular			IMHEM - Immunohematology		
HEV - Hepatitis E			INA - Influenza A		
HIV - HIV Antibodies and Antigen			INB - Influenza B		
HIVM - HIV Molecular			LEP - Leptospira		
HOR4 - Hormones			MEA - Measles		
INF4, INF4x4 - Infectious Disease Control			PAR - Parvovirus B19		
INR-POCT - Prothrombine time (POCT)			PIN - Parainfluenza Virus		
MALM - Malaria Microscopy			RSV - Respiratory Syncytial Virus		
PCT - Procalcitonin			TBEV-G-AI - TBEV IgG-Antibody Index		
COVID - SARS-CoV-2 (COVID-19) antibodies			TBEV-M-AI - TBEV IgM-Antibody Index		
COVAg - SARS-CoV-2 (COVID-19) antigen			VZV - Varicella Zoster Virus		
COVM - SARS-CoV-2 (COVID-19) molecular			WNV - West-Nile Virus		
HEM3D - Hemogram including 3-part Differential			ZIKV - Zika Virus		
HEM5D - Hemogram including 5-part Differential					
HEM4 - Hemogram					
OXI - CO-Oximetry					
SP4 - Specific Proteins					
SYP4 - Syphilis					
TDM -Therapeutic Drugs					
TM4 - Tumor Marker					
TMH4 - Tumor Marker/Hormones					
ToRCH - Torch Parameters					
UC - Urine Chemistry					
USED - Urine Sediments					
US, USXL - Qualitative Urine Analysis					

The suffix _a and/or _b of the sample identifcation are subject to change to other letters e.g. _c and/or _d

Place your order at least 2 months prior to the begin of the corresponding testing period (3 months for ABO, ESR, ESRAF, ESRAL, HEM4, HEM12, HEM3D, HEM5D and IMHEM).

ESfEQA INTERNATIONAL EQA SCHEMES SURVEY SAMPLE SCHEDULE 2022
Monthly Programs and Semi-annual Programs 2

Program (Program Code)	Sample	Begin of Result Entry - Closing Date	Program (Program Code)	Sample	Begin of Result Entry - Closing Date
Monthly Programs			Semi-annual Programs 2		
BG12 - Blood Gas and Electrolytes	2022_01_a	31/01/2022 - 14/02/2022	CC2 - Clinical Chemistry	2022_01_a	14/02/2022 - 07/03/2022
CASE - Case Study Program (CASE)	2022_02_a	21/02/2022 - 07/03/2022	HEM2 - Hemogram	2022_01_b	
CC12 - Clinical Chemistry	2022_03_a	21/03/2022 - 04/04/2022	SYP2 - Syphilis		
CM12 - Cardiac Marker	2022_04_a	18/04/2022 - 02/05/2022	INF2 - Infectious Disease Control		
COA12 - Coagulation	2022_05_a	16/05/2022 - 30/05/2022		2022_02_a	11/07/2022 - 01/08/2022
ETH12 - Ethanol	2022_06_a	13/06/2022 - 27/06/2022		2022_02_b	
GHB12 - Glycated Hemoglobin	2022_07_a	18/07/2022 - 01/08/2022			
HEM12 - Hemogram	2022_08_a	15/08/2022 - 29/08/2022			
HOR12 - Hormones	2022_09_a	12/09/2022 - 26/09/2022			
SP12 - Specific Proteins	2022_10_a	17/10/2022 - 07/11/2022			
TM12 - Tumor Marker	2022_11_a	14/11/2022 - 28/11/2022			
TMH12 - Tumor Marker/Hormones	2022_12_a	05/12/2022 - 19/12/2022			

The suffix _a and/or _b of the sample identifcation are subject to change to other letters e.g. _c and/or _d

Place your order at least 2 months prior to the begin of the corresponding testing period (3 months for ABO, ESR, ESRAF, ESRAL, HEM4, HEM12, HEM3D, HEM5D and IMHEM).

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

Status September 2021

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_2022_01_a belongs to the quar-terly program Cardiac Marker (CM4) in the year 2022 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/IEC 13528:2020-09' Statistical methods for use in proficiency testing by interlaboratory comparisons' 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 broadest possible distinction is made according to the method, instrument and reagent used (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 and can be retrieved from the ESfEQA website. 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
After receipt of an EQA survey report, a complaint 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 are excluded. In the event of a justified complaint, 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

SCIENTIFIC ADVISORS