

Quality Assessment Schemes Program

2023



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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, hematology and one educational program aimed at analytical result interpretation.

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 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 continuously. 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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BILIRUBIN NEONATAL

BILI-N

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

Analytical parameter:

Bilirubin direct	Bilirubin total
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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 lyophilized 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.

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.

Analytical parameters:

Prothrombin 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

Glucose

hCG

Hemoglobin

Ketone bodies

Leucocytes

Nitrite

pH

Specific Gravity

Total Protein

Urobilinogen

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.
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 FOR LIGHT SCATTERING METHODS

USEDL

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. 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 SEDIMENTS FOR MICROSCOPIC METHODS

USEDM

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. 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.

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).

New Analyte
Cystatin C

Analytical parameters:

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

Analytische Parameter:

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

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 simulated bronchoalveolar lavage (BAL) fluid or serum.

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

ASPERGILLUS GALACTOMANNAN ANTIGEN

ASPAG

2 liquid samples (minimum 0,5 mL) of simulated bronchoalveolar lavage (BAL) fluid or serum.

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

Analytical parameters:

Aspergillus Antigen (Galactomannan)

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 burgdorferi

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.

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 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.

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

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-HBc IgG + total

anti-HBe
HBsAg (qual. and quant.)

HBeAg
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-HCV

anti-HBc

HBsAg

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

LEGIONELLA PNEUMOPHILA ANTIBODIES**LPAB**

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

Analytical parameters:

IgG, IgM and total antibodies against Legionella pneumophila

New
Program

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 (qual. and quant.)
neutralizing antibodies against SARS-CoV-2 (qual. and quant.)
anti-N IgG (qual. and quant.)
anti-S IgG (qual. and quant.)
anti-RBD IgG (qual. and quant.)
anti-N total antibodies (qual. and quant.)
anti-S total antibodies (qual. and quant.)
anti-RBD total antibodies (qual. and quant.)

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-annual 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 (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 17043:2010.

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 of the Tick-borne encephalitis virus antibody index survey.

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

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 of the Tick-borne encephalitis virus antibody index survey.

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

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

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

Analytical parameters:

IgG and IgM antibodies against Zika Virus

MOLECULAR DIAGNOSTICS PROGRAMS

HBV MOLECULAR

HBVM

3 lyophilized samples (minimum 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.

New Program

Analytische Parameter:

HBV-DNA (qualitative and quantitative)

HCV MOLECULAR

HCVM

3 lyophilized samples (minimum 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.

New Program

Analytische Parameter:

HCV-RNA (qualitative and quantitative)

HIV MOLECULAR

HIVM

3 lyophilized samples (minimum 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.

New Program

Analytische Parameter:

HIV-RNA (qualitative and quantitative)

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.

One sample per survey in monthly program (COVM12), three samples per survey in quarterly program (COVM4).

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

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

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

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

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.

Parameters:

Suspected diagnosis

Other tests to confirm the diagnosis

Parameters supporting the suspected diagnosis

Therapy suggestions

ESFEQA INTERNATIONAL EQA SCHEMES SURVEY SAMPLE SCHEDULE 2023 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 ANTI-THYR - Thyroid Antibodies BAC-C, BAC-E - Bacteriology BG4 - Blood Gas & Electrolytes BIU-N - Bilirubin Neonatal CC4 - Clinical Chemistry CMA - Cardiac Marker COA4 - Coagulation COVAg - SARS-CoV-2 (COVID-19) antigen COVID - SARS-CoV-2 (COVID-19) antibodies COVM - SARS-CoV-2 (COVID-19) molecular CSF - Cerebrospinal Fluid DAT - Drugs of Abuse EBV - Epstein-Barr Virus ESR - Erythrocyte Sedimentation Rate ETH4 - Ethanol, Ammonia, Bicarbonate GHB4 - Glycated Hemoglobin HAV - Hepatitis A HBV - Hepatitis B HBVM - HBV Molecular HCG - hCG HCV - HCV Molecular HEM3D - Hemogram including 3-part Differential HEM5D - Hemogram including 5-part Differential HEM4 - Hemogram HEV - Hepatitis E HIV - HIV Antibodies and Antigen HIVM - HIV Molecular HOR4 - Hormones INF4, INF4x4 - Infectious Disease Control INR-POCT - Prothrombin time (POCT) MALM - Malaria Microscopy PCT - Procalcitonin 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 USEDL - Urine Sediments Light Scattering Methods US, USXL - Qualitative Urine Analysis	2023_01_a 2023_01_b 2023_02_a 2023_02_b 2023_03_a 2023_03_b 2023_04_a 2023_04_b	13/02/2023 - 06/03/2023 10/04/2023 - 02/05/2023 10/07/2023 - 31/07/2023 16/10/2023 - 07/11/2023	ADE - Adenovirus ASF - Aspergillus fumigatus ASPAG - Aspergillus Galactomannan Ag BOR - Borrelia BOR-M-AI - Borrelia IgG-Antibody Index BRU - Brucella CHA - Chagas CHIKV - Chikungunya Virus CHT - Chlamydia Trachomatis COX - Coxsackievirus DENV - Dengue Virus ECH - Echovirus ENT - Enterovirus ESRAF-G, ESRAF-S - ESR on Alifax analyzers ESRAL - ESR on Alcor analyzers FOB - Fecal Occult Blood HTL - HTLV I/II IMHEM - Immunohematology INA - Influenza A INB - Influenza B LEP - Leptospira LPAB - Legionella Antibodies MEA - Measles PAR - Parvovirus B19 PIN - Parainfluenza Virus RSV - Respiratory Syncytial Virus TBEV-G-AI - TBEV IgG-Antibody Index TBEV-M-AI - TBEV IgM-Antibody Index VZV - Varicella Zoster Virus WNV - West-Nile Virus ZIKV - Zika Virus	2023_01_a 2023_01_b 2023_02_a 2023_02_b	24/04/2023 - 15/05/2023 30/10/2023 - 20/11/2023

The suffix _a and/or _b of the sample identification 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 2023
Monthly Programs and Semi-annual Programs 2

Program (Program Code) Monthly Programs	Sample	Begin of Result Entry - Closing Date	Program (Program Code) Semi-annual Programs 2	Sample	Begin of Result Entry - Closing Date
BG12 - Blood Gas and Electrolytes CASE - Case Study Program CC12 - Clinical Chemistry CM12 - Cardiac Marker COA12 - Coagulation ETH12 - Ethanol GHB12 - Glycated Hemoglobin HEM12 - Hemogram HOR12 - Hormones SP12 - Specific Proteins TM12 - Tumor Marker TMH12 - Tumor Marker/Hormones	2023_01_a 2023_02_a 2023_03_a 2023_04_a 2023_05_a 2023_06_a 2023_07_a 2023_08_a 2023_09_a 2023_10_a 2023_11_a 2023_12_a	30/01/2023 - 13/02/2023 20/02/2023 - 06/03/2023 20/03/2023 - 03/04/2023 17/04/2023 - 02/05/2023 15/05/2023 - 30/05/2023 12/06/2023 - 26/06/2023 17/07/2023 - 31/07/2023 14/08/2023 - 28/08/2023 11/09/2023 - 25/09/2023 23/10/2023 - 06/11/2023 13/11/2023 - 27/11/2023 04/12/2023 - 18/12/2023	CC2 - Clinical Chemistry HEM2 - Hemogram INF2 - Infectious Disease Control SYP2 - Syphilis	2023_01_a 2023_01_b 2023_02_a 2023_02_b	13/02/2023 - 06/03/2023 10/07/2023 - 31/07/2023

The suffix _a and/or _b of the sample identification 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).

1. Participation

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

2. Consent to conditions of participation

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

3. Assignment of services

Individual parts of EQA schemes (e.g. pretesting of values, packaging and shipping) may be assigned to subcontractors. ESfEQA is responsible for the work of the subcontractors.

4. ESfEQA 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 electronically 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. Cancellation 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 information is required: laboratory name, name of the organization/hospital, name of participant, number of analytical devices, and e-mail address.

8. Ordering of samples

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 generally include the survey samples up to the end of the current calendar year.

9. Homogeneity and stability of EQA samples

The EQA survey samples selected by ESfEQA were examined and evaluated with regard to homogeneity 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 provided in a single survey. Thus, the sample with the labeling CM4_2022_01_a belongs to the quarterly 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 despite 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 restrictions, 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 routine 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 misappropriated manner. Generally, the usual precautions in the laboratory for potentially hazardous and potentially 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 input 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 transmitted 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 concentrations above the test range, the sample can be diluted (if recommended for particular applications) or the upper test range limit (e.g. "2000") can be reported as the result. Several units are usually available for entering quantitative results. The units are converted into the standard unit used by ESfEQA.

Laboratories are obliged to treat their results confidentially and not to pass them on to third parties until the EQA survey report has been received. If ESfEQA becomes aware of the passing on or falsification 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 application. 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 request for results submitted by participants via the fax form can be sent to ESfEQA by e-mail or fax until the deadline of 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 acceptance 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 participant 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 external quality assurance of laboratories. They may not be published, passed on or used for purposes other than quality assurance without the written consent of ESfEQA.

19. Fees

The fees for the participation are set and communicated to the participants by the responsible distributor 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 specified 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 reports.

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, regardless of the basis of the claim, including liability for culpa in contrahendo, is excluded.

24. Confidentiality

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

COMPANY INFORMATION

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