

Quality Assessment Schemes Program

2021



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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 70 quantitative and qualitative EQA programs worldwide in the areas of biochemistry, immunology, microbiology and hematology. In 2021, ESfEQA will launch its first molecular diagnostics EQA for the detection of SARS-CoV-2 RNA.

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.

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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 shortly before the first testing period 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 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.

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	

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 program (CC4 and CC2).

Analytical parameters:

BIOCHEMISTRY

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)	

DRUGS OF ABUSE

DAT

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

Analytical parameters:

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

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

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*
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* 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
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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
Alpha-1-antitrypsin	CRP (C-Reactive Protein)	Lambda light chains
Alpha-2-macroglobulin	Haptoglobin	Prealbumin
ASO	IgA	RF
Beta-2-microglobulin	IgE	Transferrin
C3	IgG	

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)	Thyroglobulin
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 guide-lines)

BORRELIA

BOR

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

2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Borrelia

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 antibodies total against Brucella*

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

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 *Chlamydomphila 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

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

antibodies total against Leptospira

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
Species Identification

Stage 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

MOSQUITO TRANSMITTED DISEASES

MTD

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

Analytical parameters:

anti-Chikungunya Virus IgG/IgM
anti-Dengue Virus IgG/IgM

anti-West Nile Virus IgG/IgM

anti-Zika Virus IgG/IgM

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

New Program

Analytical parameters:

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

SARS-CoV-2 ANTIGEN

COVAG

3 liquid or lyophilized samples (minimum 0,3 mL) simulating swab specimens (e.g. oropharyngeal or nasopharyngeal). 4 surveys per year. SARS-CoV-2 antigen positive samples contain inactivated whole virus. This program is not accredited according to DIN EN ISO/IEC 17043:2010.

New Program

Analytical parameters:

SARS-CoV-2 Antigen (qualitative)

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

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

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.

** This parameter 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)

* This parameter 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

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

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
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New Program

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.

New Program

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.

New Program

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)
IG (immature granulocytes)*
LYMPH (lymphocytes)
MCH (mean corpuscular hemoglobin)

MCHC (mean cellular hemoglobin concentration)
MCV (mean corpuscular volume)
MONO (monocytes)
MPV (mean platelet volume)
NEUT (neutrophiles)
NRBC (nucleated red blood cells)*
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.

New Program

ESfEQA INTERNATIONAL EQA SCHEMES SURVEY SAMPLE SCHEDULE 2021

General

Program (Program Code) Monthly Programs	Sample	Begin of Result Entry - Closing Date	Program (Program Code) Semi-annual Programs 1	Sample	Begin of Result Entry - Closing Date
Blood Gas and Electrolytes (BG12)	2021_01_a	18/01/2021 - 08/02/2021	Clinical Chemistry (CC2) Syphilis (SYP2) Infectious Disease Control (INF2)	2021_01_a	15/02/2021 - 08/03/2021
Clinical Chemistry (CC12)	2021_02_a	15/02/2021 - 08/03/2021		2021_01_b	
Cardiac Marker (CM12)	2021_03_a	15/03/2021 - 06/04/2021			
Coagulation (COA12)	2021_04_a	12/04/2021 - 03/05/2021			
Ethanol (ETH12)	2021_05_a	10/05/2021 - 31/05/2021		2021_02_a	12/07/2021 - 02/08/2021
Glycated Hemoglobin (GHB12)	2021_06_a	07/06/2021 - 28/06/2021		2021_02_b	
Hormones (HOR12)	2021_07_a	12/07/2021 - 02/08/2021			
Specific Proteins (SP12)	2021_08_a	09/08/2021 - 30/08/2021			
Tumor Marker (TM12)	2021_09_a	06/09/2021 - 27/09/2021			
Tumor Marker/Hormones (TMH12)	2021_10_a	11/10/2021 - 02/11/2021			
	2021_11_a	08/11/2021 - 29/11/2021			
	2021_12_a	01/12/2021 - 20/12/2021			
Program (Program Code) Quarterly Programs	Sample	Begin of Result Entry - Closing Date	Program (Program Code) Semi-annual Programs 2	Sample	Begin of Result Entry - Closing Date
Blood Grouping (ABO)	2021_01_a	15/02/2021 - 08/03/2021	Adenovirus (ADE)	2021_01_a	19/04/2021 - 10/05/2021
Bacteriology (BAC-C and BAC-E)	2021_01_b		Aspergillus fumigatus (ASF)	2021_01_b	
Blood Gas & Electrolytes (BG4)			Borrelia (BOR)		
Clinical Chemistry (CC4)	2021_02_a	12/04/2021 - 03/05/2021	Brucella (BRU)	2021_02_a	18/10/2021 - 08/11/2021
Cardiac Marker (CM4)	2021_02_b		Chagas (CHA)	2021_02_b	
Coagulation (COA4)			Chikungunya Virus (CHIKV)		
Cerebrospinal Fluid (CSF)	2021_03_a	12/07/2021 - 02/08/2021	Chlamydia Pneumoniae (CHP)		
Drugs of Abuse (DAT)	2021_03_b		Chlamydia Trachomatis (CHT)		
Epstein-Barr Virus (EBV)			Coxsackievirus (COX)		
Erythrocyte Sedimentation Rate (ESR)			Dengue Virus (DENV)		
Ethanol (ETH4)	2021_04_a	11/10/2021 - 02/11/2021	Echovirus (ECH)		
Glycated Hemoglobin (GHB4)	2021_04_b		Enterovirus (ENT)		
Hepatitis A (HAV)			ESR on Alifax analyzers (ESRAF-G, ESRAF-S)		
Hepatitis B (HBV)			ESR on Alcor analyzers (ESRAL)		
Hepatitis E (HEV)			Fecal Occult Blood (FOB)		
hCG (HCG)			HTLV 1/II (HTL)		
Hormones (HOR4)			Immunohematology (IMHEM)		
Infectious Disease Control (INF4, INF4x4)			Influenza A (INA)		
Malaria Microscopy (MALM)			Influenza B (INB)		
Procalcitonin (PCT)			Leptospira (LEP)		
SARS-CoV-2 (COVID-19) antibodies (COVID)			Measles (MEA)		
SARS-CoV-2 (COVID-19) antigen (COVAG)			Mosquito Transmitted Diseases (MTD)		
SARS-CoV-2 (COVID-19) molecular (COVM)			Parvovirus B19 (PAR)		
Specific Proteins (SP4)			Parainfluenza Virus (PIN)		
Syphilis (SYP4)			Respiratory Syncytial Virus (RSV)		
Therapeutic Drugs (TDM)			Varicella Zoster Virus (VZV)		
Tumor Marker (TM4)			West-Nile Virus (WNV)		
Tumor Marker/Hormones (TMH4)			Zika Virus (ZIKV)		
Torch (ToRCH)					
Urine Chemistry (UC)					
Urine Sediments (USED)					
Qualitative Urine Analysis (US and USXL)					

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 2021
Hemogram

Program (Program Code)	Sample	Begin of Result Entry - Closing Date	Program (Program Code)	Sample Name	Begin of Result Entry - Closing Date
Monthly Program Hemogram (HEM12)	2021_01_a	25/01/2021 - 08/02/2021	Quarterly Program Hemogram including 3-part Differential (HEM3D) Hemogram including 5-part Differential (HEM5D)	2021_01_a	09/02/2021 - 22/02/2021
	2021_02_a	09/02/2021 - 22/02/2021		2021_01_b	09/02/2021 - 22/02/2021
	2021_03_a	23/02/2021 - 08/03/2021		2021_02_a	03/05/2021 - 17/05/2021
	2021_04_a	12/04/2021 - 26/04/2021		2021_02_b	03/05/2021 - 17/05/2021
	2021_05_a	03/05/2021 - 17/05/2021		2021_03_a	12/07/2021 - 16/08/2021
	2021_06_a	24/05/2021 - 07/06/2021		2021_03_b	12/07/2021 - 16/08/2021
	2021_07_a	12/07/2021 - 26/07/2021		2021_04_a	01/11/2021 - 15/11/2021
	2021_08_a	02/08/2021 - 16/08/2021		2021_04_b	01/11/2021 - 15/11/2021
	2021_09_a	23/08/2021 - 06/09/2021			
	2021_10_a	11/10/2021 - 25/10/2021			
	2021_11_a	01/11/2021 - 15/11/2021			
	2021_12_a	22/11/2021 - 06/12/2021			
Quarterly Program Hemogram (HEM4)	2021_01_a 2021_01_b 2021_02_a 2021_02_b 2021_03_a 2021_03_b 2021_04_a 2021_04_b	09/02/2021 - 22/02/2021 03/05/2021 - 17/05/2021 12/07/2021 - 16/08/2021 01/11/2021 - 15/11/2021	Semiannual Program Hemogram (HEM2)	2021_01_a 2021_01_b 2021_02_a 2021_02_b	09/02/2021 - 22/02/2021 12/07/2021 - 16/08/2021

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 binding 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_2018_01_a belongs to the quarterly program Cardiac Marker (CM4) in the year 2018 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 until the dates published in the catalog. 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

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 potential hazardous samples apply for the EQA samples. In general, the usual precautionary measures in the laboratory for potentially infectious samples apply to EQA samples.

14. Submission of survey results

Where applicable the submission of the measured values by the participant includes, in addition to the actual measured value, 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 area.

If the method, instrument or reagent used for the measurement by the participant is not included in this selection list, participants communicate this to ESfEQA through the input mask and uses his/her own method, instrument and reagent. He or she can use these specifications directly to enter his or her 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. User name and password are to be treated confidentially by the participant.

As alternative to the result submission via the web-applica-

tion 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 evaluates all survey results that are submitted by the participants in due time. For loss or late arrival of his/her data the participant bears the risk. There is no claim for data assessment of test results arrived late. The participant bears the risk of loss of or delayed arrival of his or her data upon sending. There is no entitlement to an evaluation of late examination results.

Quantitative values are generally indicated with a value and a unit. The choice of the number of indicated decimal places is up to the participant. Specifications such as < measuring range or < 100 are not valid. If the analyzer system displays such values, they must be interpreted by the participant, e. g. as 0 or as an indication of the value of the lower measuring range. For results above and beyond the measuring range, the sample can be diluted (if recommended for individual applications) or reported as upper measuring range. Several units are usually available for entering quantitative results. The units are converted into the standard unit used by ESfEQA. This standard unit is also used for creating reports. 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 survey 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, it is no longer possible for the participant to make any changes. If faulty values are detected by the participant, he/she can inform ESfEQA in written form until the deadline of result submission by specifying the reason. ESfEQA may change the information after checking and accepting the change request. The same applies to results sent by e-mail or fax.

17. Evaluation of EQA results

For each analyte of ESfEQA EQA surveys, the type of target value determination and the acceptance criterion are determined in advance. For quantitative parameters, the target value is usually the consensus value. This value is calculated according to ISO/IEC 13528:201505' Statistical methods for use in proficiency testing by interlaboratory comparisons' using robust statistics.

Qualitative samples 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 docume

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 three weeks 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 form and as a graphic (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. 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.

20. 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.

21. Complaints

After receipt of an EQA survey report, a complaint can be made within a period of 4 weeks. After expiry of this period, the participant's claims on the basis of a reclamation 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 deciding on one of the two options. ESfEQA GmbH does not reimburse any costs incurred for reagents, time expenditure etc. unless ESfEQA GmbH is liable in accordance with paragraph 2 of these General Terms and Conditions for Participation.

22. 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 claim, including liability for culpa in contrahendo, is excluded.

23. Confidentiality

Individual EQA data is kept confidential. It is only known to the corresponding participant, his/her 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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