

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:

| | | |
|--------------------------|---------------------------|--|
| 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 |

BIOCHEMISTRY

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 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 | | |

* 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* |
|---------|---------|--------------|

* 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 |
|-------|------------|

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

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 agglutinating antibodies 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

agglutinating antibodies 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.

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, nasopharyngeal, nasal etc.). 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

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), 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.

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 |
|--|--|

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.

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) | 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.

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) | | | | | |

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 2021
Hemogram

| Program (Program Code) Monthly Program | Sample | Begin of Result Entry - Closing Date | Program (Program Code) Quarterly Program | Sample Name | Begin of Result Entry - Closing Date |
|---|-------------|--------------------------------------|--|-------------|--------------------------------------|
| Hemogram (HEM12) | 2021_01_a | 25/01/2021 - 08/02/2021 | 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 | |
| | 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 | |
| | 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 | |
| | 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 | |
| | 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 | | | |
| Program (Program Code) Quarterly Program | Sample Name | Begin of Result Entry - Closing Date | Program (Program Code) Semiannual Program | Sample Name | Begin of Result Entry - Closing Date |
| Hemogram (HEM4) | 2021_01_a | 09/02/2021 - 22/02/2021 | Hemogram (HEM2) | 2021_01_a | 09/02/2021 - 22/02/2021 |
| | 2021_01_b | | | 2021_01_b | |
| | 2021_02_a | 03/05/2021 - 17/05/2021 | | 2021_02_a | 12/07/2021 - 16/08/2021 |
| | 2021_02_b | | | 2021_02_b | |
| | 2021_03_a | 12/07/2021 - 16/08/2021 | | | |
| | 2021_03_b | | | | |
| | 2021_04_a | 01/11/2021 - 15/11/2021 | | | |
| | 2021_04_b | | | | |

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, ESRAF, 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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