

# Quality Assessment Schemes Program

## 2026





## CONTENT - ESFEQA PROGRAMS

Content ESFEQA Programs	3	
Introduction	6	
<b>Biochemistry Programs</b>		
Bilirubin neonatal	7	BIOCHEMISTRY
Blood Gas and Electrolytes	7	
Cardiac Marker	7	
Clinical Chemistry	8	
Coagulation	8	
Co-Oximetry	8	
CSF diagnostics	9	
Drugs of Abuse	9	
Ethanol, Ammonia and Bicarbonate	9	
Fecal Occult Blood	9	
Glucose POC - Whole Blood	10	
Glycated Hemoglobin (HbA1c)	10	
Prothrombin Time (POCT)	10	
Qualitative Urine Analysis (Urine stick)	10	
Therapeutic Drugs	11	
Urine Chemistry	11	
Urine Sediment for light scattering methods	11	
Urine Sediment for microscopic methods	12	
<b>Immunoassay Programs</b>		
hCG in serum	13	IMMUNOASSAYS
Hormones	13	
Procalcitonin	13	
Specific Proteins	14	
Thyroid Antibodies	14	
Tumor Marker	14	
Tumor Marker & Hormones	15	
<b>Microbiology Programs</b>		
Adenovirus Serology	16	MICROBIOLOGY
Aspergillus Fumigatus Serology	16	
Aspergillus Galactomannan Antigen	16	
Bacteriology	16	
Bacteriology Blood Culture	17	
Bacteriology Urine Culture	17	
Bordetella Serology	17	
Borrelia Serology	17	
Borrelia IgG antibody index	18	
Borrelia IgM antibody index	18	
Brucella Serology	18	
Chagas Serology	18	
Chikungunya Virus Serology	19	
Chlamydia Trachomatis Serology	19	
Coxsackievirus Serology	19	
Dengue Virus Antibodies	19	
Dengue Virus NS1 Antigen	20	

## CONTENT - ESFEQA PROGRAMS

### MICROBIOLOGY

ECHO Virus Serology	20
Enterovirus Serology	20
Epstein-Barr Virus Serology	20
Helicobacter Pylori-Antibodies	21
Helicobacter Pylori Antigen	21
Hepatitis A Virus Serology	21
Hepatitis B Virus Serology	21
Hepatitis E Virus Serology	21
HIV Antibodies and Antigen	22
HTLV I/II	22
Infectious Disease Combination Control (HBV, HCV, HIV) Serology	22
Influenza A Virus Serology	22
Influenza B Virus Serology	23
Legionella Pneumophila Antibodies	23
Leptospira Serology	23
Malaria Microscopy	23
Measles Serology	24
Mycoplasma Antibodies	24
Parainfluenza Virus Serology	24
Parvovirus B19 Serology	24
Respiratory Syncytial Virus (RSV) Serology	25
Respiratory Viral Antigen Detection	25
SARS-CoV-2 Antigen	25
SARS-CoV-2 Serology	25
Streptococcus A Antigen	26
Syphilis Serology	26
TBEV IgG antibody index	26
TBEV IgM antibody index	26
ToRCH Serology	27
Varizella Zoster Virus Serology	27
West Nile Virus Serology	27
Zika Virus Serology	27

### MOLECULAR

#### **Molecular Diagnostics Programs**

HBV Molecular	28
HCV Molecular	28
HIV Molecular	28
SARS-CoV-2 Molecular	28

### HEMATOLOGY

#### **Hematology Programs**

Blood grouping	29
Erythrocyte sedimentation rate	29
Erythrocyte sedimentation rate for Alcor iSED analysers	29
Erythrocyte sedimentation rate for Alifax and Mindray analysers	29
Hemogram	30
Hemogram incl. 3-part diff.	30
Hemogram incl. 5-part diff.	30
Immunoematology	31

## CONTENT - ESFEQA PROGRAMS

Educational Programs		EDUCATIONAL PROGRAMS
Clinical Case Study Program	31	
Case Studies in Clinical Laboratory Science	31	
Calendar	32	
General Terms for the Participation	34	

### ESfEQA GmbH

Siemensstraße 38

69123 Heidelberg

GERMANY

phone +49(0)6221-4166-700

fax +49(0)6221-4166-790

info@esfeqa.eu

www.esfeqa.eu

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 wellbeing 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 17043:2023 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.

### Extension of Accreditation Scope

Due to the flexible scope of the ESfEQA ISO 17043 accreditation the number of accredited EQA programs in our portfolio has increased. Non-accredited programs / analytes are highlighted in our catalog as follows: "This program / parameter is not accredited according to DIN EN ISO/ IEC 17043."

### 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. Participants generally sign up for a subscription for an entire calendar year.

### Survey Calendar

The dates when participants can enter results and the deadlines are published in this catalogue and on the ESfEQA website ([www.esfeqa.eu](http://www.esfeqa.eu)).

The testing periods of our proficiency test programs are synchronized in order to make the samples of a year available to participants in as few shipments as possible. Thus, a maximum of 4 shipments per year are required per participant.

Survey samples are sent to the participants in good time, usually at the beginning of the respective testing period. In order to keep the logistical, environmental and financial effort as low as possible, the samples of the first and second quarters of the monthly and quarterly programs are sent together; as well as the samples for the third and fourth quarters. This procedure is chosen for samples with sufficient stability for a period of at least 6 months. Samples

with a shorter shelf life, as well as the samples for the semi-annual programs are sent quarterly.

### Submission of Results, Survey Reports and Certificates

Participants submit their results online via the TEQA web-application. Requests for new method, instrument and reagent codes can be made online. The subscription to any ESfEQA program allows participants to submit up to three results obtained from a single control set using different devices. Reports and certificates are provided online as pdf-files within 3 weeks (within one week for monthly programs) after the deadline of result submission. Report files and certificates can be stored electronically, forwarded and printed.

### Educational Programs

For laboratory medicine we added the CASE and CASE-T programs to our portfolio. Each case study presents a different hypothetical patient case.

The CASE-T program is intended for medical laboratory technicians to strengthen analytical troubleshooting skills. Participants are invited to evaluate a basic patient profile and to answer multiple-choice questions designed to test knowledge of pre- and post-analytical phases of laboratory medicine. A total of six CASE-T cases are offered every year (bimonthly)

The CASE program is intended for clinicians to strengthen diagnostic acumen. A more detailed hypothetical patient profile is provided with anonymized clinical data including age, sex, patient history, laboratory test results (Clinical Chemistry, Hematology, Coagulation etc). The multiple choice questions are designed to invite participants to provide a suspected diagnosis, to recommend tests to support or exclude the diagnosis and to suggest further investigations or therapeutic considerations. A total of twelve CASE cases are offered every year (monthly).

Participants can join the CASE or CASE-T programs at any time of the year (since no sample shipment is required). Please contact your distributor or ESfEQA ([info@esfeqa.eu](mailto:info@esfeqa.eu)) to register. COMPLIMENTARY (free of charge): When you register as a first-time participant you will receive two complimentary CASE-T cases and/or three CASE cases.

### New Programs

Based on the feedback of our participants, ESfEQA extends the EQA portfolio continuously. Please contact us for further suggestions on new programs.

Heidelberg, September 2025

**BILIRUBIN NEONATAL**

**BILI-N**

**Program:** BILI-N: 4 surveys/year x 2 samples

**Material:** Lyophilized samples of human Serum (minimum 0,5mL)

**Evaluation:** Quantitative

**Analytical parameters:**

Bilirubin direct	Bilirubin total
Bilirubin conjugated*	Bilirubin non-conjugated*

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

**BLOOD GAS AND ELECTROLYTES**

**BG**

**Program:** BG12: 12 surveys/year x 1 sample

BG4: 4 surveys/year x 2 samples

**Material:** Liquid buffered aqueous solution or serum-based samples (minimum 2 mL)

**Evaluation:** Quantitative

New:  
Creatinine

**Analytical parameters:**

Bicarbonate (HCO <sub>3</sub> <sup>-</sup> )	Glucose	pH	Urea
Calcium	Lactate	pO <sub>2</sub>	
Chloride	Magnesium	Potassium	
Creatinine	pCO <sub>2</sub>	Sodium	

**CARDIAC MARKER**

**CM**

**Program:** CM12: 12 surveys/year x 1 sample

CM4: 4 surveys/year x 2 samples

CM2: 2 surveys/year x 2 samples

**Material:** Lyophilized samples of human sera with added analytes of human origin (minimum 1 mL)

**Evaluation:** Quantitative

New:  
hsCRP

Analytical devices that are intended for whole blood only are not suitable for these samples.

**Analytical parameters:**

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

**Program:** CC12: 12 surveys/year x 1 sample  
 CC4: 4 surveys/year x 2 samples  
 CC2: 2 surveys/year x 2 samples

**Material:** Lyophilized samples of human sera with added enzymes and proteins of human origin (5 mL)  
**Evaluation:** Quantitative

**Analytical parameters:**

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

**COAGULATION**

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

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

**Analytical parameters:**

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

**CO-OXIMETRY**

**Program:** OXI: 4 surveys/year x 2 samples  
**Material:** Purified bovine hemoglobin solution treated with carbon monoxide (minimum 1,0 mL)  
**Evaluation:** Quantitative  
 This program is not accredited according to DIN EN ISO/ IEC 17043

**Analytical parameters:**

Oxyhemoglobin	Carboxyhemoglobin	Total Hemoglobin
Desoxyhemoglobin	Methemoglobin	

## CSF DIAGNOSTICS

CSF

**Program:** CSF: 4 surveys/year x 2 samples

**Material:** Liquid samples made from human serum and other human and chemical components (minimum 1 mL)

**Evaluation:** Quantitative

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

### Analytical parameters:

Albumin	IgG	Sodium
Chloride	IgM	Proteins
Glucose	Lactate	
IgA	LDH	

BIOCHEMISTRY

## DRUGS OF ABUSE

DAT

**Program:** DAT12: 12 surveys/year x 1 sample

DAT4: 4 surveys/year x 2 samples

**Material:** Liquid or lyophilized samples of filtered human urines with added drugs for qualitative analysis (minimum 2 mL)

**Evaluation:** Qualitative

### Analytical parameters:

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

New:  
Ketamine  
Tramadol

New Program  
DAT12

## ETHANOL, AMMONIA AND BICARBONATE

ETH

**Program:** ETH12: 12 surveys/year x 1 sample

ETH4: 4 surveys/year x 2 samples

**Material:** Liquid samples with added compounds (minimum 1 mL)

**Evaluation:** Quantitative

### Analytical parameters:

Ethanol	Ammonia	Bicarbonate
---------	---------	-------------

## FECAL OCCULT BLOOD

FOB

**Program:** FOB: 2 surveys/year x 2 samples

**Material:** Liquid samples simulating extracted stool samples (minimum 0,5 mL)

**Evaluation:** Qualitative and quantitative

### Analytical parameters:

Human Hemoglobin (qualitative and quantitative)

**GLUCOSE POC - WHOLE BLOOD** **GLUWB**

**Program:** 4 surveys/year x 2 samples  
 GLUWB: Registration of 1-3 measuring systems  
 GLUWB 6 DEVICES: Registration of up to 6 measuring systems  
 GLUWB 9 DEVICES: Registration of up to 9 measuring systems

**Material:** Simulated whole blood (minimum 1 mL)  
**Evaluation:** Quantitative

**Analytical parameters:**

Glucose

**GLYCATED HEMOGLOBIN (HbA1c)** **GHB**

**Program:** GHB12: 12 surveys/year x 1 sample  
 GHB4: 4 surveys/year x 2 samples

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

**Analytical parameters:**

HbA1c

**PROTHROMBIN TIME (INR)-POCT** **INR-POCT**

**Program:** 4 surveys/year x 2 samples  
 INR-POCT: Registration of 1-3 measuring systems  
 INR-POCT 6 DEVICES: Registration of up to 6 measuring systems  
 INR-POCT 9 DEVICES: Registration of up to 9 measuring systems

**Material:** Liquid samples (minimum 0,3 mL)  
**Evaluation:** Quantitative

Suitable for POCT analyzers, e.g. Roche CoaguChek, Siemens Xprecia Stride, Abbott iStat.

**Analytical parameters:**

Prothrombin Time (INR)

**QUALITATIVE URINE ANALYSIS (URINE STICK)** **US**

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

**Material:** Liquid or lyophilized samples of urine preparation of human origin with added preservatives and stabilizers (minimum 10 mL)

**Evaluation:** Semi-quantitative

**Analytical parameters:**

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

## THERAPEUTIC DRUGS

TDM

**Program:** TDM: 4 surveys/year x 2 samples

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

**Evaluation:** Quantitative

### Analytische Parameter:

Amikacin	Gentamicin	Primidone
Carbamazepine	Lidocain	Salicylate
Chinidine	Paracetamol	Theophylline
Digoxin	Phenobarbital	Valproic Acid
Ethosuximide	Phenytoin	Vancomycin

## URINE CHEMISTRY

UC

**Program:** UC: 4 surveys/year x 2 samples

**Material:** Liquid or lyophilized samples of human urine (minimum 5 mL)

**Evaluation:** Quantitative

### Analytical parameters:

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

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

## URINE SEDIMENT FOR LIGHT SCATTERING METHODS

USEDL

**Program:** USED4: 4 surveys/year x 2 samples

USED2: 2 surveys/year x 2 samples

**Material:** Liquid samples of human urine (minimum 5 mL)

**Evaluation:** Qualitative, quantitative and semi-quantitative

This program is suitable for light scattering methods, e.g. Sysmex UF-5000/4000/1500.

### 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.	

**Program:** USED4: 4 surveys/year x 2 samples  
USED2: 2 surveys/year x 2 samples

**Material:** Liquid samples of human urine (minimum 5 mL)

**Evaluation:** Qualitative, quantitative and semi-quantitative

This program is suitable for manual microscopy and automated microscopy, e.g. Siemens Atellica, Beckman Coulter Iris, Roche Cobas u 701, Menarini Sedimax, 77 Elektronika UriSed, Dirui FUS, Analyticon Urilyzer Cell, Mindray EH Series, Mindray EU series.

**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.

## IMMUNOASSAY PROGRAMS

### HCG IN SERUM

HCG

**Program:** HCG: 4 surveys/year x 1 sample

**Material:** Lyophilized or liquid sample of human serum with added analytes of human origin (minimum 1 mL)

**Evaluation:** Qualitative

**Analytical parameters:**

hCG qualitative

### HORMONES

HOR

**Program:** HOR12: 12 surveys/year x 1 sample

HOR4: 4 surveys/year x 2 samples

**Material:** Lyophilized samples of human sera with added analytes (minimum 3 mL)

**Evaluation:** Quantitative

**Analytical parameters:**

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

### PROCALCITONIN

PCT

**Program:** PCT: 4 surveys/year x 2 samples

**Material:** Lyophilized samples of human sera with added analyte (minimum 0,5 mL)

**Evaluation:** Quantitative

**Analytical parameters:**

Procalcitonin

## SPECIFIC PROTEINS

SP

**Program:** SP12: 12 surveys/year x 1 sample  
 SP4: 4 surveys/year x 2 samples

**Material:** Liquid or lyophilized samples of human sera with added analytes of human origin (minimum 1 mL)

**Evaluation:** Quantitative

### Analytical parameters:

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

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

IMMUNOASSAYS

## THYROID ANTIBODIES

ANTI-THYR

**Program:** ANTI-THYR: 4 surveys/year x 2 samples

**Material:** Samples liquid or lyophilized (0,5 mL)

**Evaluation:** Qualitative and quantitative

### Analytical parameters:

anti-TG TRAb (TSH-Receptor Antibodies)	anti-TPO
---	----------

## TUMOR MARKER

TM

**Program:** TM12: 12 surveys/year x 1 sample  
 TM4: 4 surveys/year x 2 samples

**Material:** Lyophilized samples of human sera with added analytes (minimum 3 mL)

**Evaluation:** Quantitative

### Analytical parameters:

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

**Program:** TMH12: 12 surveys/year x 1 sample  
 TMH4: 4 surveys/year x 2 samples  
 TMH2: 2 surveys/year x 2 samples

**Material:** Lyophilized samples of human sera with added analytes (minimum 3 mL)

**Evaluation:** Quantitative

**Analytical parameters:**

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

IMMUNOASSAYS

## MICROBIOLOGY PROGRAMS

### ADENOVIRUS SEROLOGY

ADE

**Program:** ADE: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

#### Analytical parameters:

IgA, IgG and IgM antibodies against Adenovirus

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

### ASPERGILLUS FUMIGATUS SEROLOGY

ASF

**Program:** ASF: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

#### Analytical parameters:

IgA, IgG, IgM and total antibodies against Aspergillus fumigatus

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

### ASPERGILLUS GALACTOMANNAN ANTIGEN

ASPAG

**Program:** ASPAG: 2 surveys/year x 2 samples

**Material:** Liquid samples of simulated bronchoalveolar lavage (BAL) fluid or serum (minimum 0,5 mL)

**Evaluation:** Qualitative and quantitative\*

#### Analytical parameters:

Aspergillus Antigen (Galactomannan)

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## BACTERIOLOGY

BAC-C, BAC-E

**Program:** BAC-C or BAC-E: 4 surveys/year x 4 samples

**Material:** Lyophilised samples (pure strain and/or mixture of bacteria): 2 for identification and 2 for antibiotic susceptibility testing (AST). AST according to EUCAST or CLSI guidelines.

In this program we simulate different types of specimens: blood, urine, swabs (e.g. surgical/wound site, etc.), sputum/bronchoscopy specimen, paracentesis samples (e.g. ascites), joint/synovial fluid, sonicate fluid of explanted prosthetic joints, and CSF.

**Evaluation:** Qualitative

#### Analytical parameters:

Identification (genus and species)

Antibiotic susceptibility testing (according to EUCAST or CLSI guidelines)

## BACTERIOLOGY BLOOD CULTURE

BACBC-C, BACBC-E

**Program:** BACBC-C or BACBC-E: 4 surveys/year x 4 samples

**Material:** Lyophilised samples (pure strain and/or mixture of bacteria): 2 for identification and 2 for antibiotic susceptibility testing (AST). AST according to EUCAST or CLSI guidelines.

In this program we simulate blood specimens focusing on blood culture pathogen identification and antimicrobial susceptibility testing.

**Evaluation:** Qualitative

New  
Program

### Analytical parameters:

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

## BACTERIOLOGY URINE CULTURE

BACUC-C, BACUC-E

**Program:** BACUC-C or BACUC-E: 4 surveys/year x 2 samples

**Material:** Lyophilised samples (pure strain and/or mixture of bacteria): 1 for identification and 1 for antibiotic susceptibility testing (AST). AST according to EUCAST or CLSI guidelines.

In this program we simulate urine specimens focusing on urine culture pathogen isolation, identification, and antimicrobial susceptibility testing.

**Evaluation:** Qualitative

New  
Program

### Analytical parameters:

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

## BORDETELLA SEROLOGY

BPES

**Program:** BPES: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

IgA, IgG and IgM antibodies against Bordetella  
IgA antibodies against Bordetella Pertussis-Toxin  
IgG antibodies against Bordetella Pertussis-Toxin

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## BORRELIA SEROLOGY

BOR

**Program:** BOR: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgG and IgM antibodies against Borrelia burgdorferi

## BORRELIA IgG ANTIBODY INDEX

BOR-G-AI

**Program:** BOR-G-AI: 2 surveys/year x 2 samples

**Material:** One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (CSF sample: 0,8 mL; serum sample: 0,3 mL)

**Evaluation:** Qualitative and quantitative

### Analytical parameters:

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

## BORRELIA IgM ANTIBODY INDEX

BOR-M-AI

**Program:** BOR-M-AI: 2 surveys/year x 2 samples

**Material:** One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (CSF sample: 0,8 mL; serum sample: 0,3 mL)

**Evaluation:** Qualitative and quantitative

### Analytical parameters:

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

## BRUCELLA SEROLOGY

BRU

**Program:** BRU: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

IgA, IgG, IgM and agglutinating antibodies against Brucella

## CHAGAS SEROLOGY

CHA

**Program:** CHA: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

IgG, IgM and total antibodies against *Trypanosoma cruzi* (qualitative)  
IgG and total antibodies against *Trypanosoma cruzi* (quantitative)

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## CHIKUNGUNYA VIRUS SEROLOGY

CHIKV

**Program:** CHIKV: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgG and IgM antibodies against Chikungunya Virus

## CHLAMYDIA TRACHOMATIS SEROLOGY

CHT

**Program:** CHT: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgA, IgG and IgM antibodies against Chlamydia trachomatis

## COXSACKIEVIRUS SEROLOGY

COX

**Program:** COX: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

### Analytical parameters:

IgA, IgG and IgM antibodies against Coxsackievirus

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## DENGUE VIRUS ANTIBODIES

DENV

**Program:** DENV: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgG and IgM antibodies against Dengue Virus

## DENGUE VIRUS NS1 ANTIGEN

DENVAG

**Program:** DENVAG: 2 surveys/year x 2 samples

**Material:** Liquid or lyophilized samples. The samples are either serum or plasma samples or simulated samples consisting of an aqueous protein matrix. Dengue virus NS1 antigen positive samples contain recombinant DENV NS1 protein

**Evaluation:** Qualitative

This programme is intended for immunochromatographic tests (Lateral Flow Rapid tests) and ELISA. Other reagents on request.

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

### Analytical parameters:

Dengue Virus NS1 antigen

## ECHO VIRUS SEROLOGY

ECH

**Program:** ECH: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

### Analytical parameters:

IgA, IgG and IgM antibodies against ECHO-Virus

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## ENTEROVIRUS SEROLOGY

ENT

**Program:** ENT: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

### Analytical parameters:

IgA, IgG and IgM antibodies against Enterovirus

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## EPSTEIN-BARR VIRUS SEROLOGY

EBV

**Program:** EBV: 4 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

anti-EBV EBNA-1 IgG + total

anti-EBV VCA IgG + total

anti-EBV VCA IgM

## HELICOBACTER PYLORI ANTIBODIES

HPYL

**Program:** HPYL: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

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

### Analytical parameters:

IgA, IgG, IgM and total antibodies against Helicobacter pylori

## HELICOBACTER PYLORI ANTIGEN

HPYLAG

**Program:** HPYLAG: 2 surveys/year x 2 samples

**Material:** Liquid or simulated stool samples (minimum 0,3 mL)

**Evaluation:** Qualitative

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

### Analytical parameters:

Helicobacter pylori Antigen

New Program

## HEPATITIS A VIRUS SEROLOGY

HAV

**Program:** HAV12: 12 surveys/year x 1 sample  
HAV4: 4 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

IgG, IgM and total antibodies against HAV

New Program  
HAV12

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## HEPATITIS B VIRUS SEROLOGY

HBV

**Program:** HBV12: 12 surveys/year x 1 sample  
HBV4: 4 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 1 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

anti-HBs	anti-HBe	HBsAg
anti-HBc IgG + total	anti-HBc IgM	HBeAg

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

New Program  
HBV12

## HEPATITIS E VIRUS SEROLOGY

HEV

**Program:** HEV: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgG, IgM and total antibodies against HEV

MICROBIOLOGY

## HIV ANTIBODIES AND ANTIGEN

HIV

**Program:** HIV: 4 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

Please note that the HIV survey is designed for assays that detect HIV antibodies and HIV antigen separately. For combo tests (e.g. HIV 4th generation assays) that detect HIV antibodies and HIV antigen simultaneously we recommend the enrollment in the ESfEQA INF survey.

### Analytical parameters:

anti-HIV 1/2 antibodies                      HIV p24 Antigen

## HTLV I/II

HTL

**Program:** HTL: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

total antibodies against HTLV I/II

## INFECTIOUS DISEASE COMBINATION CONTROL SEROLOGY

INF

**Program:** INF12: 12 surveys/year x 1 sample  
INF4: 4 surveys/year x 2 samples  
INF4x4: 4 surveys/year x 4 samples  
INF2: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 1 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

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

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## INFLUENZA A VIRUS SEROLOGY

INA

**Program:** INA: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

### Analytical parameters:

IgA, IgG and IgM antibodies against Influenza A Virus

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## INFLUENZA B VIRUS SEROLOGY

INB

**Program:** INB: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

### Analytical parameters:

IgA, IgG and IgM antibodies against Influenza B Virus

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## LEGIONELLA PNEUMOPHILA ANTIBODIES

LPAB

**Program:** LPAB: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

IgG, IgM and total antibodies against Legionella pneumophila

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## LEPTOSPIRA SEROLOGY

LEP

**Program:** LEP: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

IgG and IgM antibodies against Leptospira

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## MALARIA MICROSCOPY

MALM

**Program:** MALM: 4 surveys/year x 2 samples

**Material:** Slides of stained smears

**Evaluation:** Qualitative and quantitative

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

### Analytical parameters:

Malaria Parasite Detection  
Species Identification

Stage Identification  
Quantification of Plasmodium falciparum

## MEASLES SEROLOGY

MEA

**Program:** MEA: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgG and IgM antibodies against Measles Virus

## MYCOPLASMA ANTIBODIES

MYPL

**Program:** MYPL: 2 surveys/year x 2 samples

**Material:** Samples of human serum (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgA, IgG, IgM and total antibodies against Mycoplasma pneumoniae

## PARAINFLUENZA VIRUS SEROLOGY

PIN

**Program:** PIN: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

### Analytical parameters:

IgA, IgG and IgM antibodies against Parainfluenza Virus

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## PARVOVIRUS B19 SEROLOGY

PAR

**Program:** PAR: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgG and IgM antibodies against Parvovirus B19

## RESPIRATORY SYNCYTIAL VIRUS (RSV) SEROLOGY

RSV

**Program:** RSV: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

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

### Analytical parameters:

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

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## RESPIRATORY VIRAL ANTIGEN DETECTION

RESPAG

**Program:** RESPAG: 2 surveys/year x 3 samples

**Material:** Lyophilized samples (minimum 0,3mL) simulating swab specimens (e.g. oropharyngeal, nasopharyngeal, nasal etc.) or swabs. Antigen positive samples contain inactivated whole virus.

**Evaluation:** Qualitative

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

### Analytical parameters:

Influenza A Antigen

Influenza B Antigen

RSV Antigen

## SARS-CoV-2 ANTIGEN

COVAG

**Program:** COVAG: 4 surveys/year x 3 samples

**Material:** Liquid or lyophilized samples simulating swab specimens (e.g. oropharyngeal, nasopharyngeal, nasal etc.). SARS-CoV-2 antigen positive samples contain inactivated whole virus (minimum 0,3 mL).

**Evaluation:** Qualitative

### Analytical parameters:

SARS-CoV-2 Antigen (qualitative)

## SARS-CoV-2 SEROLOGY

COVID

**Program:** COVID: 2 Surveys/year x 4 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

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

SARS-CoV-2 neutralising antibodies

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## STREPTOCOCCUS A ANTIGEN

STAA

**Program:** STAA: 2 Surveys/year x 2 samples

**Material:** Swab, liquid or lyophilized samples (minimum 0,3 mL) simulating swab specimens.

**Evaluation:** Qualitative

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

### Analytical parameters:

Streptococcus A Antigen

## SYPHILIS SEROLOGY

SYP

**Program:** SYP12: 12 surveys/year x 1 sample

SYP4: 4 surveys/year x 2 samples

SYP2: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (1 mL)

**Evaluation:** Qualitative and quantitative

### Analytical parameters:

Total antibodies against *Treponema pallidum* (qualitative, semi-quantitative\* and quantitative\*)

IgG and IgM antibodies against *Treponema pallidum* (qualitative\*)

Non-treponemal Lipoid antibodies (RPR/VDRL Tests) (qualitative)

Non-treponemal Lipoid antibodies (RPR/VDRL Tests Titers) (semi-quantitative\*)

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

## TBEV IgG ANTIBODY INDEX

TBEV-G-AI

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

**Material:** CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (CSF sample 0,8 mL; 0,3 mL for the serum sample)

**Evaluation:** Qualitative and quantitative

### Analytical parameters:

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

## TBEV IgM ANTIBODY INDEX

TBEV-M-AI

**Program:** TBEV-M-AI: 2 surveys/year x 2 samples

**Material:** CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant (CSF sample 0,8 mL; 0,3 mL for the serum sample)

**Evaluation:** Qualitative and quantitative

### Analytical parameters:

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

## ToRCH SEROLOGY

TORCH

**Program:** TORCH12: 12 surveys/year x 1 sample  
TORCH4: 4 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 1 mL)

**Evaluation:** Qualitative and quantitative\*

New Program  
ToRCH12

### Analytical parameters:

anti-CMV IgG  
anti-CMV IgM  
anti-HSV 1/2 IgG  
anti-HSV 1/2 IgM

anti-HSV 1 IgG  
anti-HSV 2 IgG  
anti-HSV 1 IgM  
anti-HSV 2 IgM

anti-Rubella IgG  
anti-Rubella IgM  
anti-Toxoplasma gondii IgG  
anti-Toxoplasma gondii IgM

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

## VARIZELLA ZOSTER VIRUS SEROLOGY

VZV

**Program:** VZV: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative and quantitative\*

### Analytical parameters:

IgA, IgG, and IgM antibodies against Varizella Zoster Virus (VZV)

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

## WEST NILE VIRUS SEROLOGY

WNV

**Program:** WNV: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgG and IgM antibodies against West Nile Virus

## ZIKA VIRUS SEROLOGY

ZIKV

**Program:** ZIKV: 2 surveys/year x 2 samples

**Material:** Liquid samples of defibrinated human plasma (minimum 0,3 mL)

**Evaluation:** Qualitative

### Analytical parameters:

IgG and IgM antibodies against Zika Virus

## MOLECULAR DIAGNOSTICS PROGRAMS

### HBV MOLECULAR

HBVM

**Program:** HBVM: 4 surveys/year x 3 samples

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

**Evaluation:** Qualitative and quantitative

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

**Analytical parameters:**

HBV-DNA (qualitative and quantitative)

### HCV MOLECULAR

HCVM

**Program:** HCVM: 4 surveys/year x 3 samples

**Material:** Lyophilized samples of human serum. Virus positive samples contain the whole genome of inactivated HCV (minimum 1 mL)

**Evaluation:** Qualitative and quantitative

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

**Analytical parameters:**

HCV-RNA (qualitative and quantitative)

### HIV MOLECULAR

HIVM

**Program:** HIVM: 4 surveys/year x 3 samples

**Material:** Lyophilized samples of human serum. Virus positive samples contain the whole genome of inactivated HIV (minimum 1 mL)

**Evaluation:** Qualitative and quantitative

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

**Analytical parameters:**

HIV-RNA (qualitative and quantitative)

### SARS-COV-2 MOLECULAR

COVM

**Program:** COVM: 4 surveys/year x 3 samples

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

**Evaluation:** Qualitativ and quantitative\*

**Analytical parameters:**

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

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

\* The quantitative parameters are not accredited according to DIN EN ISO/ IEC 17043.

## BLOOD GROUPING

ABO

**Program:** ABO: 4 surveys/year x 2 samples

**Material:** Liquid samples of stabilized human red cells suspended in a buffered fluid and preservative. Erythrocyte suspensions contain a red blood cell concentration of 8% minimum (minimum 4 mL).

**Evaluation:** Qualitative

**Analytical parameters:**

ABO-Typing

Rhesus (D)-Detection

## ERYTHROCYTE SEDIMENTATION RATE

ESR

**Program:** ESR: 4 surveys/year x 2 samples

**Material:** Liquid samples containing erythrocytes in blood collection tubes (75x13mm) with pierceable caps (3 mL)

**Evaluation:** Quantitative

The samples are not suitable for testing on Alifax and Alcor iSED instruments.

**Analytical parameters:**

Erythrocyte Sedimentation Rate

## ERYTHROCYTE SEDIMENTATION RATE FOR ALCOR

ESRAL

**Program:** ESRAL: 2 surveys/year x 2 samples

**Material:** Liquid samples of stabilized human red cells suspended in a buffered fluid and preservative (minimum 2 mL)

**Evaluation:** Quantitative

**Analytical parameters:**

Erythrocyte Sedimentation Rate

## ERYTHROCYTE SEDIMENTATION RATE FOR ALIFAX AND MINDRAY

ESRAF

**Program:** ESRAF-G: 2 surveys/year x 3 samples in Greiner tubes  
ESRAF-S: 2 surveys/year x 3 samples in Sarstedt tubes

**Material:** Liquid samples for transmittance measurement related to ESR values in human samples (3 mL)

**Evaluation:** Quantitative

**Analytical parameters:**

Erythrocyte Sedimentation Rate

## HEMOGRAM

HEM

**Program:** HEM12: 12 surveys/year x 1 sample  
 HEM4: 4 surveys/year x 2 samples  
 HEM2: 2 surveys/year x 2 samples

**Material:** Plasma like fluid samples that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs (minimum 2 mL)

**Evaluation:** Quantitative

### Analytical parameters:

HCT (hematocrit)	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)
MCHC (mean cellular hemoglobin)	PCT (Plateletcrit)	WBC (white blood cells)
	PDW (Platelet distribution width)	

## HEMOGRAM INCL. 3-PART DIFF.

HEM3D

**Program:** HEM3D: 4 surveys/year x 2 samples

**Material:** Plasma like fluid samples that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs (minimum 1,5 mL)

**Evaluation:** Qualitative

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

### Analytical parameters:

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

## HEMOGRAM INCL. 5-PART DIFF.

HEM5D

**Program:** HEM5D12: 12 surveys/year x 1 sample  
 HEM5D4: 4 surveys/year x 2 samples

**Material:** Plasma like fluid samples that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs (minimum 1,5 mL)

**Evaluation:** Quantitative

This program is dedicated for 5-part WBC/leucocyte differential hematology analyses

### Analytical parameters:

BASO (basophiles)*	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.

**Program:** IMHEM4x3: 4 surveys/year x 3 samples  
 IMHEM2x6: 2 surveys/year x 6 samples

**Material:** 1 (IMHEM4x3) or 2 (IMHEM2x6) tubes of the patient's red blood cell suspension (minimum 4 mL), 1 (4x3) or 2 (2x6) tubes of the patient's serum (minimum 4 mL) and 1 (4x3) or 2 (2x6) tubes of the donor's red blood cell suspension (minimum 4 mL). Erythrocyte suspensions contain a red blood cell concentration of 8% minimum

**Evaluation:** Qualitative

New Program  
 IMHEM 4x3

**Analytical parameters:**

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

EDUCATIONAL PROGRAMS

CLINICAL CASE STUDY PROGRAM

CASE

12 cases/year

This program 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.

For new  
 Subscribers:  
 3 cases free  
 of charge

**Parameter:**

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

CASE STUDIES IN CLINICAL LABORATORY SCIENCE

CASE-T

6 cases/year

The target group of this program is technical personnel as well as laboratory doctors in medical laboratories. It aims to support and to strengthen the skills of the staff for (pre)analytical questions. Participants receive the case description online and submit their interpretation of the clinical data via the ESfEQA web application.

For new  
 Subscribers:  
 2 cases free  
 of charge

Each study in the Clinical Laboratory Sciences Case Study program provides a case description with analytical data for Clinical Chemistry, Hematology, Coagulation, and related areas. Participants in the survey will be asked for their interpretation, explanation and corrective actions (if applicable) for the described case. Possible answers will be offered in dropdown lists. Participants are requested to select one or more responses they consider appropriate.

Monthly	Program / Date*	Quarterly	Program / Date*
	03/02/2026 - 17/02/2026		17/02/2026 - 10/03/2026
	24/02/2026 - 10/03/2026		21/04/2026 - 12/05/2026
	25/03/2026 - 07/04/2026		21/07/2026 - 11/08/2026
	28/04/2026 - 12/05/2026		13/10/2026 - 03/11/2026
	26/05/2026 - 09/06/2026	ABO	Blood grouping
	23/06/2026 - 07/07/2026	ANTI-THYR	Thyroid antibodies
	28/07/2026 - 11/08/2026	BAC	Bacteriology
	25/08/2026 - 08/09/2026	BACBC	Bacteriology Blood Culture
	22/09/2026 - 06/10/2026	BACUC	Bacteriology Urine Culture
	20/10/2026 - 03/11/2026	BG4	Blood Gas and Electrolytes
	10/11/2026 - 24/11/2026	BILI-N	Bilirubin neonatal
	01/12/2026 - 15/12/2026	CC4	Clinical Chemistry
BG12	Blood Gas and Electrolytes	CM4	Cardiac Marker
CASE	Clinical Case Study Program	COA4	Coagulation
CC12	Clinical Chemistry	COVAg	SARS-CoV-2 Antigen
CM12	Cardiac Marker	COVM	SARS-CoV-2 Molekular
COA12	Coagulation	CSF	CSF diagnostics
DAT12	Drugs of Abuse	DAT4	Drugs of Abuse
ETH12	Ethanol, Ammonia and Bicarbonate	EBV	Epstein-Barr Virus Serology
GHB12	Glycated Hemoglobin (HbA1c)	ESR	Erythrocyte sedimentation rate
HAV12	Hepatitis A Virus Serology	ETH4	Ethanol, Ammonia and Bicarbonate
HBV12	Hepatitis B Virus Serology	GHB4	Glycated Hemoglobin (HbA1c)
HEM12	Hemogram	GLUWB	Glucose POC - Whole Blood
HEM5D12	Hemogram incl. 5-part diff.	HAV4	Hepatitis A Virus Serology
HOR12	Hormones	HBV4	Hepatitis B Virus Serology
INF12	Inf. Disease Combination Control	HBVM	HBV Molecular
SP12	Specific Proteins	HCG	hCG in serum
SYP12	Syphilis Serology	HCVM	HCV Molecular
TM12	Tumor Marker	HEM3D	Hemogram incl. 3-part diff.
TMH12	Tumor Marker & Hormones	HEM4	Hemogram
ToRCH12	ToRCH Serology	HEM5D4	Hemogram incl. 5-part diff.
		HIV	HIV Antibodies and Antigen
		HIVM	HIV Molecular
		HOR4	Hormones
		INF4	Inf. Disease Combination Control
		INF4x4	Inf. Disease Combination Control
		IMHEM4x3	Immunohematology
		INR-POCT	Prothrombin Time (POCT)
		MALM	Malaria Microscopy
		OXI	Co-Oximetry
		PCT	Procalcitonin
		SP4	Specific Proteins
		SYP4	Syphilis Serology
		TDM	Therapeutic Drug Monitoring
		TM4	Tumor Marker
		TMH4	Tumor Marker & Hormones
		ToRCH4	ToRCH Serology
		UC	Urine Chemistry
		US4	Qualitative Urine Analysis (Urine stick)
		USEDL4	Urine Sediment Light scattering methods
		USEDM4	Urine Sediment Microscopy methods
<b>Bimonthly</b>	<b>Program / Date*</b>		
	24/02/2026 - 17/03/2026		
	28/04/2026 - 19/05/2026		
	23/06/2026 - 14/07/2026		
	25/08/2026 - 15/09/2026		
	06/10/2026 - 27/10/2026		
	17/11/2026 - 08/12/2026		
CASE-T	Case Studies in Clinical Laboratory Science		

\* Start of the measurement period until closing date

Registration deadline: in each case 3 months before the start of the corresponding measurement period.

Late registrations can still be considered if samples are available.

Semi-annual 1 (Q1+Q3)	Program / Date*	Semi-annual 2 (Q2+Q4)	Program / Date*
	17/02/2026 - 10/03/2026		05/05/2026 - 26/05/2026
	21/07/2026 - 11/08/2026		27/10/2026 - 17/11/2026
CC2	Clinical Chemistry	ADE	Adenovirus Serology
CM2	Cardiac Marker	ASF	Aspergillus Fumigatus Serology
COA2	Coagulation	ASPAg	Aspergillus Galactomannan Antigen
HEM2	Hemogram	BOR	Borrelia Serology
IMHEM2x6	Immunochemistry	BOR-G-AI	Borrelia IgG antibody index
INF2	Inf. Disease Combination Control	BOR-M-AI	Borrelia IgM antibody index
SYP2	Syphilis Serology	BPES	Bordetella Serology
TMH2	Tumor Marker & Hormones	BRU	Brucella Serology
US2	Qualitative Urine Analysis (Urine stick)	CHA	Chagas Serology
USEDL2	Urine Sediment Light scattering methods	CHIKV	Chikungunya Virus Serology
USEDM2	Urine Sediment Microscopy methods	CHT	Chlamydia Trachomatis Serology
		COVID	SARS-CoV-2 Serology
		COX	Coxsackievirus Serology
		DENV	Dengue Virus Antibodies
		DENVAg	Dengue Virus NS1 Antigen
		ECH	ECHO Virus Serology
		ENT	Enterovirus Serology
		ESRAF	Erythrocyte sedimentation rate for Alifax and Mindray analysers
		ESRAL	Erythrocyte sedimentation rate for Alcor iSED analysers
		FOB	Fecal Occult Blood
		HEV	Hepatitis E Virus Serology
		HPYL	Helicobacter Pylori Antibodies
		HPYLAg	Helicobacter Pylori Antigen
		HTL	HTLV I/II
		INA	Influenza A Virus Serology
		INB	Influenza B Virus Serology
		LEP	Leptospira Serology
		LPAb	Legionella Pneumophila Antibodies
		MEA	Measles Serology
		MYPL	Mycoplasma Antibodies
		PAR	Parvovirus B19 Serology
		PIN	Parainfluenza Virus Serology
		RESPAg	Respiratory Viral Antigen Detection
		RSV	RSV Serology
		STAA	Streptococcus A Antigen
		TBEV-G-AI	TBEV IgG antibody index
		TBEV-M-AI	TBEV IgM antibody index
		VZV	Varizella Zoster Virus Serology
		WNV	West Nile Virus Serology
		ZIKV	Zika Virus Serology

\* Start of the measurement period until closing date

Registration deadline: in each case 3 months before the start of the corresponding measurement period.

Late registrations can still be considered if samples are available.

## 1. Participation

Participation in ESfEQA external quality assessment (EQA) surveys 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 elements 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 EQA schemes and analytes contained in individual programs are described in the ESfEQA catalog. Depending on the availability of samples and 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, published in the ESfEQA catalog, contains deadlines for ordering and result submission, as well as the testing periods. Once the deadline for ordering has passed, acceptance of late orders is at ESfEQA's discretion. Results must be submitted to ESfEQA electronically, or using a result entry form, on or before the closing date. All deadlines and calendar dates are in the same time zone as ESfEQA's place of business in Heidelberg, Germany (i.e. 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 original sample shipping date and ESfEQA will endeavor to offer an alternative date in a timely manner.

## 7. Registration

For participation in ESfEQA EQA surveys registration is required. This can be done online, or by sending the necessary information to ESfEQA by email to: [surveys@esfeqa.eu](mailto:surveys@esfeqa.eu). 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

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 program 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.

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.

## 10. Designation of EQA samples

The EQA samples can be distinguished by their identifier, which has the following format: program acronym\_survey year\_survey number\_sample number. For example, the sample CM4\_2025\_01\_a belongs to the quarterly program Cardiac Marker (CM4) in the year 2025 and is sample "a" of the first survey. Samples with the same designation are not necessarily identical, i.e. different results can be obtained despite the same designation. ESfEQA correctly allocates samples to the original batch and thus to the target values.

## 11. Shipping of EQA samples

EQA samples are shipped by postal or parcel service. Due to governmental restrictions, or insufficient sample stability, shipping of individual EQA programs to specific countries may be excluded.

## 12. Instructions for Use

Instructions for Use (IFU) for each EQA survey are available on the ESfEQA website ([www.esfeqa.eu](http://www.esfeqa.eu)). A printout of the IFU is usually enclosed with the sample package. Each IFU includes instructions for sample preparation and stability.

## 13. Use of EQA samples

Usually, EQA samples should be treated exactly like patient samples, measured in the same way as routine samples according to manufacturer's instructions for instruments and reagents. They may only be used for the purpose of participating in an EQA survey and may not be used in a misappropriated manner. Generally normal laboratory procedure for testing potentially hazardous and potentially infectious samples also applies to EQA samples.

## 14. Submission of survey results

Where applicable, submission of results includes the actual measured value as well as method, instrument and reagent used. The input mask in TEQA (ESfEQA's evaluation software application) displays the required information for each EQA program. A drop-down list of methods, instruments and reagents is provided in the configuration section.

If a participant's method, instrument or reagent is not listed in TEQA, participants can add this information using the input mask "coding request". They can select their specific method, instrument and reagent to create a new configuration prior to entering their test results.

The selection of method, instrument and reagent, as well as submission of results, must be performed using the TEQA web-application. Participants receive their login data (username and password) from ESfEQA, which is required to enter results. The password consists of at least 8 characters, including at least 2 special characters. Username and password are to be treated confidentially by the participant.

An alternative to result submission via the TEQA web-application, is the result form, that can be sent to ESfEQA either by E-Mail ([info@esfeqa.eu](mailto:info@esfeqa.eu)) or Fax (+49 6221 894669-90). Result forms specific for each EQA program are provided on the ESfEQA website. ESfEQA encourages all 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 submitted by participants by the deadline. In the event of loss or late arrival of their data the participant bears the risk. ESfEQA are not obliged to evaluate results submitted after the

submission deadline.

Quantitative results are generally reported with a value and a unit. The participant determines the number of digits for reporting. In general, results should be reported as measured. However, results submitted as “< test range” (e.g. “< 10”) or “> test range” (e.g. “>2000”) are not valid.

For results below the test range, the lower test range limit should be reported (e.g. “10”).

For samples with 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 submitted 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**

Participants can edit their results, using a change request via the TEQA web-application, up until the deadline for result submission of the EQA survey. ESfEQA must check and accept change requests before results are edited accordingly. A change request can also be submitted by participants via e-mail or fax to ESfEQA, up until the deadline for result submission. Participants who submitted their results via the TEQA web-application can only use a change request via the TEQA web application.

#### **17. Evaluation of EQA results**

For each analyte in ESfEQA EQA surveys, the type of target value determination and acceptance criterion are predefined. For quantitative parameters, the target value is usually the consensus value of participants results. This value is calculated according to ISO 13528:2022-08 'Statistical methods for use in proficiency testing by interlaboratory comparison' using robust statistics.

Samples provided for testing of qualitative parameters are thoroughly tested with different analytical systems before being used as control material, thereby setting the target value.

System-specific differences are taken into account, if appropriate and feasible, with a corresponding statistical evaluation. The broadest possible distinction according to method, device and/or reagent used, is made available to participants (M-, I-, R-group). The minimum number of results of an evaluation group is 5. If this number is not reached in the survey, the individual result has to be compared to the robust mean of the next largest 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.

For quantitatively determined analytes, the maximum permissible ranges of the target value are predefined. 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 receive reports electronically

via the TEQA web-application within 10 days (for monthly programs), or 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 evaluated in comparison to target values. The data is displayed both in tabular and illustrated form (e. g., Histogram, Stewart 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. Due to the high variability of shipping, handling and customs costs, the prices may vary between various countries. Please contact your distributor for the participation fee.

#### **20. Certificates**

For each EQA program participants receive a certificate of participation. In addition, participants receive a certificate for those parameters which met the specified performance criteria in the respective EQA survey. Both certificates are made available to 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 sample loss or damage, ESfEQA should be notified immediately. If possible, ESfEQA will send replacement samples without acknowledging any claims. However, the contract is fulfilled on the date of dispatch of the original sample material.

#### **22. Complaints and appeals**

After receipt of an EQA survey report, a complaint/appeal can be made within a period of 4 weeks. After expiry of this period, any claims by the participant based on a complaint/appeal are excluded. In the event of a justified complaint/appeal, ESfEQA will decide whether to reimburse the amount paid for the EQA survey, or to provide a substitute EQA survey. 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

### ESfEQA GmbH

CEO: Oliver Bošnjak  
Head of Operations: Dr. Dieter Groche  
Address: Siemensstraße 38  
69123 Heidelberg  
Germany  
Phone: +49(0)6221-4166-700  
Fax: +49(0)6221-4166-790  
E-mail: [info@esfeqa.eu](mailto:info@esfeqa.eu)  
Internet: [www.esfeqa.eu](http://www.esfeqa.eu)