



SCOPE OF ACCREDITATION TO ISO/IEC 17043:2010

ESFEQA GMBH
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Heidelberg, GERMANY
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PROFICIENCY TESTING PROVIDER

Valid To: September 30, 2027

Certificate Number: 4839.06

In recognition of the successful completion of the A2LA evaluation process, this proficiency testing provider has been found to meet the ISO/IEC 17043:2010, "Conformity assessment - General Requirements for Proficiency Testing". Accreditation is granted to this provider to provide proficiency testing samples in the following programs:

<u>PROGRAM NAME</u>	<u>SUB-DISCIPLINE</u>	<u>ANALYTES MEASURED¹</u>
Chemistry EQA	Quantitative: Serum Chemistry/Immunoassay* (Includes alcohol, basic chemistry, lipids, cardiac markers, endocrinology analytes, tumor markers, therapeutic drugs, and specific proteins) Basic Glycated Hemoglobin Blood Gas/Electrolytes Body Fluid Chemistry Cerebrospinal Fluid Chemistry Co-oximetry GFR Monitoring* Immunosuppressants Occult Blood (Fecal and Gastric) Serum Protein Electrophoresis Sweat Testing Trace Elements – Blood, Serum, and Urine Urinalysis Urine Chemistry Urine Drugs of Abuse Whole Blood Glucose and Hemoglobin Procalcitonin Bilirubin Neonatal Urine sediment Cardiac markers basic Cardiac markers extended Ethanol, ammonia, bicarbonate Hormones	Quantitative Analysis = Assigned values determined either by consensus values from participants, or reference values as determined by a reference laboratory (*)

<u>PROGRAM NAME</u>	<u>SUB-DISCIPLINE</u>	<u>ANALYTES MEASURED¹</u>
Clinical Serology EQA	<p>Quantitative: EBV Serology SARS-Cov-2-Antigen Adenovirus serology Aspergillus fumigatus serology Borrelia serology Bordetella serology Brucella serology Chagas serology Chikungunya serology Chlamydia trachomatis serology Coxsackievirus serology Dengue virus NS1 antigen Dengue virus serology Echovirus serology Enterovirus serology Infection disease combination control – serology Multimarker comprehensive serology ToRCH serology</p> <p>Qualitative: Viral Antigen Detection EBV Serology <i>Helicobacter pylori</i> Antibody Herpes Simplex Lyme Disease Infectious Mononucleosis Mycoplasma Antibody SARs-CoV-2 Antibodies Aspergillus galactomannan antigen Hepatitis A virus serology Hepatitis B virus serology Hepatitis E virus serology Influenza A virus serology Influenza B virus serology Leptospira serology Legionella pneumophila serology Measles serology Parvovirus B19 serology Parainfluenza virus serology RVS serology Syphilis serology Varizella Zoster virus serology Zikavirus serology</p>	<p>Quantitative Analysis = Consensus values from participants</p> <p>Qualitative Analysis = Reference values as determined by analysis PLUS matching Consensus values from participants</p>

<u>PROGRAM NAME</u>	<u>SUB-DISCIPLINE</u>	<u>ANALYTES MEASURED</u>
Andrology EQA	Quantitative: Sperm Analysis (count, morphology, viability) Sperm Mobility (Total Motility; Progressive Motility; Non-Progressive Motility; Immotility) Qualitative: Sperm Screen	Quantitative Analysis = Consensus values from participants Qualitative Analysis = Reference values as determined by analysis PLUS matching Consensus values from participants
Bacteriology EQA	Qualitative: Urine Colony Count Qualitative: Bacterial Identification and Culture <i>Clostridium difficile</i> Antigen Methicillin Resistant <i>Staphylococcus aureus</i> <i>Neisseria Gonorrhoeae</i> Culture <i>Streptococcus A</i> Antigen and Culture Vancomycin Resistant Enterococcus Virtual Gram Stain Virtual Bacterial Vaginosis Carbapenem Resistant Enterobacteriaceae (Carbapenem Resistance Detection) Group B Streptococcus	Qualitative = Reference values as determined by analysis PLUS matching Consensus values from participants Qualitative = Reference values as determined by analysis PLUS matching Consensus values from participants
Mycobacteriology EQA	Qualitative: Mycobacterium Acid Fast Stain Mycobacterium Species Culture	Reference values as determined by analysis PLUS matching Consensus values from participants
Mycology EQA	Qualitative: Cryptococcus Antigen Dermatophyte KOH slides Mold / Yeast Culture	Reference values as determined by analysis PLUS matching Consensus values from participants
Parasitology EQA	Qualitative: Blood Parasites Malaria PVA Smear Wet Mount Virtual Blood Parasites Virtual Malaria Virtual Stool Parasite	Qualitative = Reference values as determined by analysis PLUS matching Consensus values from participants

<u>PROGRAM NAME</u>	<u>SUB-DISCIPLINE</u>	<u>ANALYTES MEASURED¹</u>
SARS-CoV-2 Molecular	Qualitative: Molecular Diagnostics	SARS-CoV-2
CFS diagnostic EQA	Quantitative: Borrelia IgG-Antibody Index TBEV IgG-Antibody Index TBEV IgM-Antibody Index	Quantitative Analysis = Consensus values from participants
Molecular Diagnostic	Quantitative: HBV molecular HCV molecular Transplant transmitted infections molecular Qualitative: HIV	Quantitative Analysis = Consensus values from participants Qualitative = Reference values as determined by analysis PLUS matching Consensus values from participants

¹Analytes/parameters in each program are targeted per defined specifications. Assigned values and associated uncertainties are known values with results determined by finished product testing of proficiency program.



Accredited Proficiency Testing Provider

A2LA has accredited

ESFEQA GMBH

Heidelberg, GERMANY

This accreditation covers the specific proficiency testing schemes listed on the agreed upon Scope of Accreditation.

This provider is accredited in accordance with the recognized International Standard ISO/IEC 17043: 2010 *Conformity assessment - General requirements for proficiency testing*. This accreditation demonstrates technical competence for a defined scope and the operation of a quality management system.



Presented this 5th day of September 2023.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 4839.06
Valid to September 30, 2027

For the proficiency testing schemes to which this accreditation applies, please refer to the provider's Scope of Accreditation.