

# ABOUT ESFEQA



ESFEQA is a German company based in Heidelberg and accredited according to DIN EN ISO/IEC 17043:2010 by the German Accreditation Body DAkkS. ESFEQA offers more than 90 External Quality Assessment programs in Biochemistry, Hematology, Immunology, Microbiology, Molecular Diagnostics, and Educational Programs. Please visit our website for more information.

Ask your local distributor or ESFEQA how to get enrolled in the ESFEQA External Quality Assessment Schemes.

## ESFEQA MOLECULAR DIAGNOSTICS PROGRAMS

EXTERNAL QUALITY ASSESSMENT /  
PROFICIENCY TESTING PROGRAMS

ESFEQA GmbH  
European Society for External  
Quality Assessment  
Siemensstr. 38  
69123 Heidelberg  
GERMANY  
Phone +49(0)6221-4166-700  
Fax +49(0)6221-4166-790  
info@esfeqa.eu  
www.esfeqa.eu



## EXTERNAL QUALITY ASSESSMENT

### SCHEMES

#### ESfEQA Molecular Diagnostics Programs

HBV Molecular - HBVM

HCV Molecular - HCVM

HIV Molecular - HIVM

SARS-CoV-2 Molecular - COVM

### Background

Nucleic Acid Testing (NAT) is a powerful tool to detect the presence of viral RNA and DNA and has become an indispensable tool in clinical investigations due to its high sensitivity, specificity and short turn-around times.

The presence of virus is detected by Nucleic Acid Testing (NAT) at an early stage of an infection. Therefore, HBV, HCV and HIV NAT/PCR assays are widely used for blood donation screening.

Molecular detection of SARS-CoV-2 RNA remains the primary method for the confirmation of acute COVID-19 infections.

### Schedule

ESfEQA offers the Molecular Diagnostics EQAs as quarterly programs. In general, the subscription is valid until the end of the calendar year. Participants can enroll in each program at any quarter of the year. All ESfEQA Molecular Diagnostic surveys are suitable for various NAT/PCR methods (real-time PCR, isothermal amplification such as LAMP etc.).

PROGRAM	FREQUENCY	SAMPLES PER SURVEY	PARAMETERS
COVM	Quarterly	3	SARS-CoV-2 RNA qual. and quant.
HBVM	Quarterly	3	HBV DNA qual. and quant.
HCVM	Quarterly	3	HCV DNA qual. and quant.
HIVM	Quarterly	3	HIV RNA qual. and quant.

### Samples & Analytical Methods

Each survey consists of 3 lyophilized samples with a minimum of 1 mL per sample. The samples do not require dry ice shipment but can be delivered under temperature-controlled conditions. The storage temperature is 2-8 °C.

The samples for the HBV, HCV, and HIV Molecular schemes are based on human serum; virus-positive specimens contain inactivated whole virus from human donors. The samples for SARS-CoV-2 Molecular testing contain human epithelial cells or fibroblast serum, and virus-positive specimens contain inactivated whole virus in addition.

After reconstitution, ESfEQA samples reflect patient samples in native matrix allowing the assessment of the entire workflow including nucleic acid extraction and amplification. Virus-positive samples contain the whole genome and can be used by NAT/PCR tests independently from the gene target of the assay.

Participants can report qualitative and quantitative results.

Additional sample sets for replicate measurement (extraction etc.) can be ordered for a reduced fee.

### ESfEQA Reports and Certificates

Reports with a detailed statistical analysis are provided as PDF-files to each participant via the TEQA web application. This includes the assessment of the laboratory performance in comparison to participants that have used the same, but also other analytical devices. Moreover, the reports contain specific comments on the evaluation and conclusions for a better understanding of the survey results.

Certificates are provided as PDF-files for download from the TEQA web application as well.

Reports and certificates are made available within 3 weeks after the closing date for the result submission.

### Benefits of ESfEQA

#### Molecular Diagnostics Programs

- Stable control material allowing safe and efficient shipment cycles and storage at 2-8 °C
- High commutability of control material for use with a wide range of methods, instruments and kits
- Assessment of the entire workflow including nucleic acid extraction and amplification
- Benchmarking with an international participant base
- Customer-oriented service by local ESfEQA distributor and second-level support by ESfEQA, Heidelberg/Germany.
- Fast and simple enrollment in ESfEQA schemes via local distributor. Contact ESfEQA directly if the local distributor is unknown.