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.

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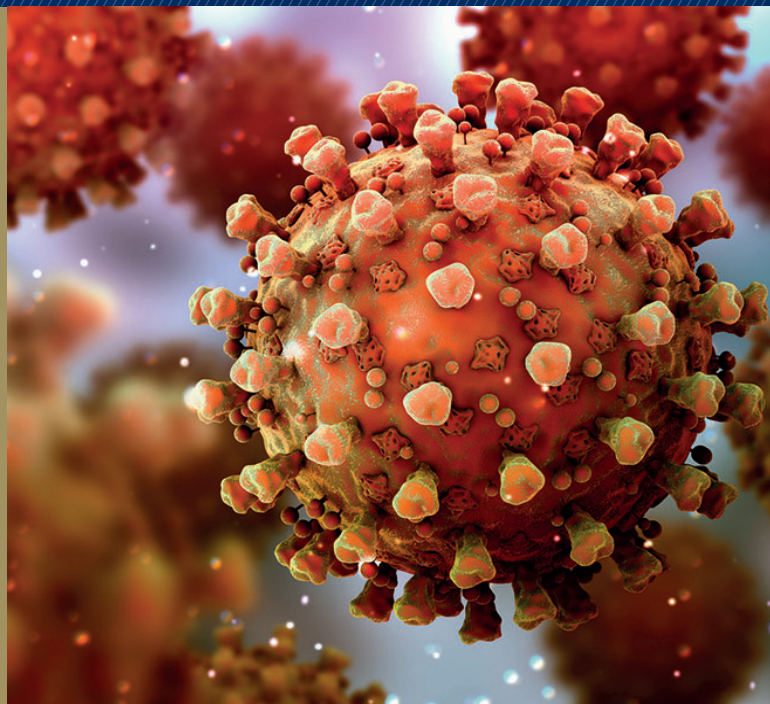
ESfEQA
European Society for External Quality Assessment

SARS-COV-2 / COVID-19

EXTERNAL QUALITY ASSESSMENT / PROFICIENCY TESTING PROGRAMS



EXTERNAL QUALITY ASSESSMENT SCHEMES

SARS-CoV-2 / COVID-19

SARS-CoV-2 Antigen

SARS-CoV-2 antigen

SARS-CoV-2 Antibodies

SARS-CoV-2 IgA
SARS-CoV-2 IgG
SARS-CoV-2 IgM
SARS-CoV-2 total antibodies
SARS-CoV-2 neutralizing antibodies

with determination of antibodies against specific antigens
anti-N IgG
anti-RBD IgG
anti-S IgG
anti-N total antibodies
anti-RBD total antibodies
anti-S total antibodies

Reporting of quantitative results in BAU/mL

SARS-CoV-2 Molecular

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

Background

Diagnostic testing for the detection of the SARS-CoV-2 pathogen is an important tool for the response to the COVID-19 pandemic. Molecular detection of SARS-CoV-2 RNA remains the primary method for the confirmation of acute COVID-19 infections due to superior sensitivity of NAT/PCR methods while rapid testing for SARS-CoV-2 antigen has become an important tool to limit the spread of infection by providing results in the range of minutes.

Serological testing for COVID-19 is an important supplement to direct detection of the pathogen. Testing for antibodies can provide valuable information whether persons had already been exposed to the virus, which usually results in an immune response with subsequent presence of corresponding antibodies in a patient's bloodstream.

Moreover, with vaccines having become available serological testing is a powerful tool to assess the levels and neutralizing ability of antibodies from vaccinated individuals. This is particularly relevant for persons belonging to a risk group, for personnel in critical areas (hospitals, nursing, medical practices, schools etc.), and for deciding the optimal timing for booster shots.

Programs and Schedule

ESfEQA now offers a complete suite of ISO 17043 accredited EQA/PT programs for testing related to SARS-CoV-2, whether molecular or antigen testing for virus detection or serological testing for determination of antibodies against the virus. Participants can enroll in a program at any quarter of the year. In general, the subscription is valid until the end of the calender year.

PROGRAM	FREQUENCY	SAMPLES PER SURVEY	PARAMETERS
COVAG	Quarterly	3	Antigen
COVM	Quarterly	3	Molecular
COVID	Quarterly	4	Antibodies

Samples & Analytical Methods

COVAG: Each survey consists of 3 samples simulating swab specimens (e.g. nasal, nasopharyngeal, etc.). SARS-CoV-2 antigen positive samples contain inactivated (non-infectious) whole virus, thus covering all possible antigen targets used in different antigen detection assays (Immunochromatography/Lateral Flow assays (Rapid tests), ELISA, CLIA).

COVM: Each survey consists of 3 samples, with a minimum of 1 mL per sample. The samples contain the whole genome of SARS-CoV-2, thus covering all possible gene targets used in different NAT/PCR assays (RT-real-time PCR, isothermal amplification such as LAMP etc.). All samples contain human epithelial cells or fibroblasts as positive control to assess the entire workflow including nucleic acid extraction and amplification.

COVID: Each survey consists of 4 liquid stable (2-8°C) samples, in general from single donors, with a minimum of 0.3 mL per sample. The samples are of 100% human origin, and thus highly commutable for use on different platform such as ELISA including surrogate Virus Neutralization Tests, Lateral-flow (Rapid) tests, CLIA, ECLIA, etc. Antibody positive samples are from donors that were once tested PCR-positive or from vaccinated individuals. Comprehensive clinical data of the patient and information on the samples will be provided with the report.

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 the target values and to the results of 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 SARS-COV- 2 EQAs

- Complete suite of SARS-CoV-2 testing parameters
- Well characterized specimens
- Stable control material allowing efficient shipment cycles and storage at 2-8 °C
- High commutability of control material for use with a wide range of methods and instruments
- Benchmarking with international participant base