Survey for SARS-CoV-2 (COVID-19) Molecular Testing (COVM)

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Instructions for Use

Notes:

The samples should be considered as potentially infectious. The usual precautions in the laboratory for potential hazardous samples apply for these samples.
The samples should be handled by trained personnel only.

WARNING: The reagent contains irritants, avoid ingestion and contact with mucous membranes.

This product contains human source material and should be considered as potentially infectious.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at www.esfeqa.eu.

1. Intended Use

The samples are intended for use as qualitative and quantitative control material for External Quality Assessment (EQA) in medical laboratories for the following parameters:

SARS-CoV-2 RNA qualitative

SARS-CoV-2 RNA quantitative

It is recommended that participants using devices or methods, which provide quantitative values, **also submit values for** the corresponding **qualitative parameters**. Moreover, we like to encourage all participants, who submit results only for specific genes targeted by their NAT/PCR reagent, **also** to **report their interpretation for "SARS-CoV-2 RNA, general" qualitative and quantitative**. This will enable the participants to compare their results with all laboratories.

2. Product Description

The lyophilized samples are prepared from human material with additives for formulation and stabilization. The samples are simulated swab specimens (e.g. from nasopharyngeal or oropharyngeal swabs) and contain human cells. Positive samples contain inactivated whole virus.

For test systems employing conventional nucleic acid extraction, a corresponding tube with diluent is provided for each tube with lyophilized sample material (Diluent: 3 tubes with a minimum of 1.0 mL diluent each for the reconstitution of the lyophilized samples).

Do Not Use the provided "COVM Diluent" from ESfEQA for the reconstitution of the lyophilized survey samples, if you employ a test system using sample material from virus transport medium for direct PCR analysis without prior nucleic acid extraction (e.g. DIAGNOVITAL® HS SARS-CoV-2 Real-Time PCR Kit v2.0 with DIAGNOTransfer Tube). For further instructions refer to chapter 4.2 of this IFU.

3. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated below. Once the lyophilized survey samples are reconstituted (with the provided diluent), the analytical components will be stable for 2 days when stored tightly capped at 2-8°C. After reconstitution (with the provided diluent), the samples can be stored frozen (-20°C) for one month.

4. Sample Preparation and Analysis

In order to ensure that all lyophilized sample material is at the bottom of the tube, briefly spin the tube with the lyophilized control (e.g., 30 seconds at 14.000 rpm) before opening.

4.1. For test systems employing conventional nucleic acid extraction

Reconstitute each lyophilized survey sample by pipetting 1.0 mL of diluent included in the sample kit. Allow the control to reconstitute for 10-15 minutes, gently swirl and invert the closed tubes to ensure homogeneity.

After reconstitution of the samples, they should be handled/treated like patient samples (swab in transport medium), and nucleic acid extraction and testing should be conducted in accordance with the instructions of the instrument and reagent manufacturers.

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4.2. For test systems using sample from virus transport medium for direct PCR analysis without prior nucleic acid extraction:

Do Not Use the provided "COVM Diluent" from ESfEQA for the reconstitution of the lyophilized survey samples!

Reconstitute each lyophilized survey sample by pipetting 1.0 mL from the dedicated virus transport/lysis medium tubes intended for your test system (e.g., liquid from DIAGNOTransfer Tube). Allow the control to reconstitute for 10-15 minutes, gently swirl and invert the closed tubes to ensure homogeneity. Transfer each reconstituted lyophilized sample (approximately 1 mL each) into the remaining liquid of the corresponding virus transport/lysis medium tube. After transfer, the samples should be handled/treated like patient samples (swab in dedicated transport/lysis medium), and direct PCR testing should be conducted in accordance with the instructions of the instrument and reagent manufacturers.

Quantitative analysis: As a result, please transmit the numerical value of your result either as "Ct" value (Cp/Cq/CN are equivalent instrument-specific units) or as "copies/mL" value in our web application TEQA.

Ct values: In case of a **negative result** (e.g. Ct value "> 45") please **transmit the numerical value "0"** for the corresponding sample in TEQA.

Copies/mL: For measurement results below/above the measuring range of the instrument, the lower/ upper measuring limit should be reported as a quantitative value. Please do not further dilute the sample in case of obtaining measurement results above the measuring range.

5. Dates and Submission of Test Results

Testing Periods: Please refer to the sample labels. Results can be submitted anytime within the testing period indicated on the sample labels.

For the evaluation of survey results, please indicate the reagent (used for NAT/PCR) and instrument (e.g. thermal cycler, real-time PCR detection system) - indication of the method is optional - and submit your results electronically to ESfEQA at www.esfeqa.eu.

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance for the registration, configuration and result submission in TEQA. Alternatively, though not preferred, use the result form provided on the ESfEQA website. In both cases indicate the reagent and instrument used for the analysis of the samples - indication of the method is optional.

All entries are confirmed by pressing the button "confirm". The successful transmission of the results is indicated by "data saved".

6. Deadline for Data Submission

The deadlines for submitting results are indicated on the sample labels (time zone GMT +1).

7. Reports and Certificates

The data will be evaluated by ESfEQA. The individual laboratory reports and certificates can be retrieved online at https://teqa.esfeqa.eu.

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