

Survey for SARS-CoV-2 (COVID-19) Antigen Testing (COVAg)

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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.



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.esfega.eu.

1. Intended Use

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

SARS-CoV-2/COVID-19 Antigen qualitative
SARS-CoV-2/COVID-19 Antigen (semi-)quantitative

2. Product Description

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

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. After reconstitution, 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) or tap the lyophilisate to the bottom of the tube before opening. Reconstitute each sample by adding 0.3 to 1.0 mL of test/extraction buffer included in your test kit. Allow the control to reconstitute for 10-15 minutes, gently swirl and invert the closed tube to ensure homogeneity.

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

For antigen tests using saliva as specimen and without extraction buffer in the test kit: Please reconstitute each sample by adding 1.0 mL of H₂O into each vial. Allow the control to reconstitute for 10-15 minutes, gently swirl and invert the closed tube to ensure homogeneity. After

reconstitution of the samples, they should be handled/treated like patient saliva, and testing should be conducted in accordance with the instructions of the instrument and reagent manufacturers.

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 and method used - indication of the instrument is optional - and submit your results electronically to ESfEQA at www.esfega.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 method used for the analysis of the samples - indication of the instrument is optional.

In TEQA, All entries are confirmed by clicking the "Save changes" button. Successful submission of the results is indicated by the message: "Success: Lab results records processed successfully."

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-labv2.esfega.eu>.