Survey for antibodies against SARS-CoV-2 (COVID-19)

EQA Provider: ESfEQA GmbH Heidelberg

Survey Coordinator: Dr. D. Groche

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 blood donations used for production were found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV.
The samples should be handled by trained personnel only.

WARNING: Contains methylisothiazolones.
H317 May cause allergic skin reaction.

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 antibodies against SARS-CoV-2:

anti-SARS-CoV-2 IgA
anti-SARS-CoV-2 IgG
anti-SARS-CoV-2 IgM
anti-SARS-CoV-2 antibodies total
anti-SARS-CoV-2 neutralizing antibodies
anti-N IgG
anti-S IgG
anti-RBD IgG
anti-N total antibodies
anti-S total antibodies
anti-RBD total antibodies

We like to encourage all participants, who submit quantitative results, also to report qualitative results. This will enable them to compare their results with all participants independently on the used reagent since quantitative results are frequently reagent-specific.

Please note that, in general, we will not issue a certificate of successful participation for the quantitative determination of anti-SARS-CoV-2 antibodies since the target values are reagent-specific and a bias to the calculated consensus value does not necessarily represent a poor laboratory performance. The statistical evaluation is for information purposes only.

2. Product Description

The samples are based on human blood plasma and are liquid, ready-to-use.

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.

4. Sample Preparation and Analysis

Allow the sample to equilibrate to room temperature for 15 minutes prior to testing. Directly before use, agitate the sample by gently inverting the vial several times.

All samples should be treated the same way as patient samples and analyzed in accordance with the instructions of the instrument and reagent manufacturers.

Quantitative analysis: As a result, please transmit the numerical value of your result, which you have received with a manufacturer-specific unit, with the indication of AU/mL (arbitrary unit/mL) in our web application TEQA.

The conversion of such arbitrary units per mL to BAU/mL (BAU = Binding Antibody Units) in accordance with the WHO international standard is reagent-specific. Therefore, in case you want to report a **result as "BAU/mL"** please select the corresponding analyte in TEQA (e.g. "anti-S IgG, BAU/mL").

Result for SARS-CoV-2 neutralizing antibodies (e.g. from virus neutralization tests or surrogate SARS-CoV-2 neutralization (ELISA) assays) may be reported with a manufacturer specific unit (AU/mL), or as IU/mL in accordance with the WHO international standard. Please select the corresponding analyte in TEQA (e.g. "anti-SARS-CoV-2 neutralizing antibodies, IU/mL").

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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 measure-ment 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 method, instrument and the reagent used 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 instrument and method used for the analysis of the samples.

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.

Please note that, in general, we will not issue a certificate of successful participation for the quantitative deter-mination of anti-SARS-COV-2 antibodies since the target values are reagent-specific and a bias to the calculated consensus value does not necessarily represent a poor laboratory performance. The statistical evaluation is for information purposes only.

The individual laboratory reports and certificates can be retrieved online at https://teqa.esfeqa.eu.

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