ESfEQA
European Society for External Quality Assessment

Survey for *Bordetella* Serology

EQA Provider:	ESfEQA GmbH Heidelberg
ESfEQA Head of Operations:	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 applied 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, the provider of proficiency testing (ESfEQA) takes full responsibility for all subcontracted work performed.

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 following analytes:

Anti-*Bordetella* IgA
Anti-*Bordetella* IgG
Anti-*Bordetella* IgM
Anti-*Bordetella* Pertussis-Toxin IgA
Anti-*Bordetella* Pertussis-Toxin IgG

2. Product Description

Sample 1: BPES_2024_01_a
Sample 2: BPES_2024_01_b

The samples 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.

Qualitative analysis:
In general, please interpret the results according to the reagent manufacturer's instructions. For the analytes 'Anti-*Bordetella* Pertussis-Toxin IgA, qualitative' and 'Anti-*Bordetella* Pertussis-Toxin IgG, qualitative', please use the following decision limits for reporting qualitative results as 'positive', 'borderline' or 'negative':

Anti-*Bordetella* Pertussis-Toxin IgA: cut-off 12 IU/mL
Anti-*Bordetella* Pertussis-Toxin IgG: cut-off 40 IU/mL

Quantitative analysis:
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 Period for Sample 1 and 2: 23/04/24 - 14/05/24

For the evaluation of survey results, please indicate the method and the reagent used. The indication of the instrument is optional.

The complete lists are available at www.esfeqa.de or can be requested at info@esfeqa.de and +49 6221 4166-700.

5.1. Submission of Results by use of the Web-Application TEQA

Please submit your results electronically to ESfEQA at https://teqa.esfeqa.eu while indicating the method and the reagent used. The indication of the instrument used is optional. To change the configuration please refer to the TEQA LAB Instructions at http://www.esfeqa.eu/en/eqa-programs/instructions-for-participants/

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance for the registration, configuration and result submission in TEQA

ESfEQA GmbH
Siemensstr. 38
69123 Heidelberg
Germany

Phone: + 49 6221 4166-700
Fax: + 49 6221 4166-790
info@esfeqa.eu
www.esfeqa.eu

5.2. Submission of Results by use of Result Sheets

As an alternative to the result submission via our web-application TEQA, use the editable result sheet (“Fax Data Entry Form”) provided on the ESfEQA website.
Please transmit the completed result sheet including the method and the reagent used, for each parameter via email (info@esfeqa.eu) or fax (+49 6221 4166-790) to ESfEQA.

6. Deadline for Data Submission

Deadline for data submission (time zone GMT +1):

Sample 1 and 2: 14/05/24

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 determination of the analytes ‘Anti-*Bordetella* IgA‘, ‘Anti-*Bordetella* IgG‘, and ‘Anti-*Bordetella* IgM‘, 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. The reports and certificates will be available within 3 weeks after the deadline of data submission.

ESfEQA GmbH
Siemensstr. 38
69123 Heidelberg
Germany

Phone: + 49 6221 4166-700
Fax: + 49 6221 4166-790
info@esfeqa.eu
www.esfeqa.eu