ESfEQA
European Society for
External Quality Assessment

IFU_RESPM, Ver004

Survey for Respiratory Pathogens Molecular (RESPM)

EQA Provider: ESfEQA GmbH Heidelberg

Survey Coordinator: Dr. H. Depner

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. They 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.esfeqa.eu

1. Intended Use

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

Viral pathogens	Bacterial pathogens
Adenovirus	*Bordetella parapertussis*
Coronavirus 229E	*Bordetella pertussis*
Coronavirus HKU1	*Chlamydia pneumoniae*
Coronavirus NL63	*Haemophilus influenzae*
Coronavirus OC43	*Legionella pneumophila*
SARS-CoV-2 (COVID 19)	*Mycoplasma pneumoniae*
Human Metapneumovirus	*Streptococcus pneumoniae*
Human Rhinovirus/Enterovirus	
Influenza A virus	
Influenza B virus	
Parainfluenza virus	
RSV	

2. Product Description

The lyophilized samples simulate human specimens (e.g. oropharyngeal and nasopharyngeal swabs or saliva). Positive samples contain inactivated pathogens.

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

4.1. Procedure for sample tube/vials

In order to ensure that all lyophilized sample material is at the bottom of the tube/vial, 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 **the exact volume** of transport medium or extraction buffer from your test kit, **as indicated on the sample label**. Allow the control to reconstitute for 5-10 minutes, gently swirl and invert the closed tube to ensure homogeneity.

After reconstitution of the samples, they should be handled/treated like patient samples, and nucleic acid extraction and testing should be conducted in accordance to the instructions of the instrument and reagent manufacturers.

4.2. Procedure for swabs

Handle swab specimens according to the instructions of the instrument and reagent manufacturers.

4.3. Additional Information

For test systems not employing human RNAse P gene as sample adequacy/extraction/internal control, report the results for the pathogens analyzed as measured independent from the internal control result:

- report samples as “positive” that were found “positive” for the pathogens, independently from the finding in the internal control channel
- report samples as “negative” that were found “negative” for the pathogens, independently from the finding in the internal control channel.

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 https://teqa-labv2.esfeqa.eu.

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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 fax 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 pressing the button "confirm". The successful transmission of the results is indicated by “data saved”.

6. Deadline for Data Submission

The deadline for submitting results is 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.esfeqa.eu.

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