

(10)(2a)



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Safety and testing instructions

1. Safety instructions

The EQA panel is composed of 12 samples containing inactivated, lyophilized viral material. Although the material is inactivated it should be regarded as potentially hazardous to health according to common good laboratory practice for handling of diagnostic specimens. All samples should be used, stored and discarded according to your own laboratory's safety procedures. Safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. It is advised to reconstitute and handle the panel until lysis in a class 2 biosafety cabinet.

2. Privacy declaration

Hereby we assure that all data and information provided will be handled confidentially. Data will be published in the public domain in anonymized and aggregated form exclusively and only upon approval of the participating laboratories. Moreover, you will get a personalized feedback regarding your individual EQA results. All participating laboratories will be offered co-authorship upon publication of the EQA results.

3. Supplied EQA material

Please make sure that the EQA material you received is complete before you start reconstitution and testing of the samples. The EQA panel is composed of 12 screw cap tubes containing lyophilized material labelled with "Sample 1" – "Sample 12".

4. Storage

Do not expose the EQA material to direct sunshine or heat. The original material should be stored at room temperature (acceptable range -20°C to 25°C). Once the samples are reconstituted please store at RT until extraction. Extraction of nucleic acids should be performed within 6 hours. If you intend to keep remaining resuspended material, we recommend storing it at or below -20°C.

5. Reconstitution of the samples

All samples must be reconstituted as indicated below. Avoid cross-contamination by good laboratory practice including the usage of filter tips. Although the panel has been inactivated it is advised to take the precautionary measure to reconstitute and lyse the panel in a class 2 biosafety cabinet according to standard lab procedures.

- 1) Equilibrate lyophilized samples to ambient temperature for about 15 minutes.
- 2) Add 200 µL of sterile nuclease-free water to each lyophilized sample.
- 3) Let the samples incubate for 3 minutes.
- 4) Vortex the samples for about 10 seconds to resuspend the material properly.

- 5) Centrifugate the samples to spin down the reconstituted materials to avoid contamination.
- 6) Extract nucleic acids according to your routine diagnostic protocols within 6 hours.

If your RNA extraction protocol requires larger volumes than those obtained during reconstitution of the samples, add additional diluent according to your routine protocol for clinical specimen (e.g. sterile nuclease-free water or PBS). Handle all reconstituted EQA samples as you handle clinical specimens. Conduct RNA extraction and SARS-CoV-2 detection exactly according to the laboratory's standard protocol.

6. Submission of results.

Please submit your results at (10)(2g)

Unfortunately, it is not possible to save the submission form in between. Therefore results need to be submitted in one session. You will need the following information to submit your results:

- contact information of the laboratory
- Date receipt EQA panel and date analysis panel (if multiple days, date of RNA extraction)
- Storage conditions of the samples and condition of the panel (upon arrival)
- Detailed information on nucleic extraction process (incl. automated or manual process, exact name of the extraction system and/or the extraction kit)
- Reconstitution volume for samples of the panel, input volume used for RNA extraction, elution volume used for extraction volume
- Detailed information on PCR method and targets used for molecular detection
- Ct values for all samples, for which you detected SARS-CoV-2 RNA

7. Contact

Please refer for additional information to the technical document provided with the panel or contact (10)(2e)

(10)(2e), Ph.D (10)(2e) @rivm.nl).