January 2024

**European SARS-CoV-2 and influenza virus Bioinformatics External**

**Quality Assessment (ESIB-EQA 2024)**

Dear colleagues,

Herewith you can find all the necessary information about the forthcoming European SARS-CoV-2 and influenza virus Bioinformatics External Quality Assessment (ESIB-EQA) planned for the beginning of March 2024.

**Rationale**

It is essential that the reliability and robustness of technologies for SARS-CoV-2 and influenza virus sequencing data analysis are assessed through effective Quality Control (QC) within all National Influenza Centers and national reference laboratories for SARS-CoV-2. An integral part of QC is external quality assessment ([EQA](https://ecdc.europa.eu/en/about-us/networks/disease-and-laboratory-networks/erlinet-influenza-lab-quality-control)). Regular participation in EQA programmes will provide confidence in the techniques performed at a national level and therefore in the results reported. This ESIB-EQA, now in its second iteration, is dedicated to sequence analyses primarily conducted through bioinformatic workflows. The influenza virus part of the EQA is held together with the regular European External Influenza virus Quality Assessment Programme (EEIQAP). This year, the EEIQAP and ESIB-EQA will focus specifically on influenza viruses of zoonotic origin. The SARS-CoV-2 part on the other hand will focus as before on mainly currently circulating viruses.

As data from NICs/national reference laboratories are reported to The European Surveillance System (TESSy) and analysed and published weekly at a European level, this EQA also helps ensure the quality and validity of the results. Furthermore, EQA studies provide useful information for targeting capacity building measures to participating laboratories, Member States, and ECDC but also to other stakeholders including the European Commission and the World Health Organization (WHO). Over time, results from this EQA can be used to monitor the impact of training and support and determine priorities for future training and support for the network. Therefore, participation in this EQA is strongly recommended.

The major objective of the ESIB-EQA 2024 is to examine the ability of laboratories to generate full-length consensus genome sequences from raw sequence reads, perform clustering and classification of full-length genomes as well as mutational analysis for both SARS-CoV-2 and influenza viruses. In the case of influenza, it also includes prediction of the antiviral susceptibility profile, as well as host adaptation mutations.

**Objectives**

The ESIB-EQA 2024 will consist of eight different components, described in Table 1. Laboratories can choose which EQA components they want to participate in. The four components for SARS-CoV-2 will be organised by RIVM in the Netherlands, and the four components for influenza by Institut Pasteur in France.

Each EQA component assesses a different type of analysis and, in the case of SARS-CoV-2, is designed to be entirely independent from any of the other components, so that specifically the performance on the type of analysis in question can be assessed. A separate dataset will consequently be made available for each component for SARS-CoV-2, and the date that this is made available will be used as the start time for measuring processing time as an additional performance metric.

Table 1: EQA components that laboratories can participate in.

|  |  |  |  |
| --- | --- | --- | --- |
| Id | Organism | Samples | Objective |
| SARS1 | SARS-CoV-2 | 20 | Consensus sequence generation from complete amplicons based on Nanopore reads. |
| SARS2 | SARS-CoV-2 | 20 | Consensus sequence generation from fragmented amplicons based on Illumina reads. |
| SARS3 | SARS-CoV-2 | 20 | Clustering and classification of full-length genomes. |
| SARS4 | SARS-CoV-2 | 10 | Detection of particular amino-acid substitutions. |
| INFL1, INFL3, INFL4 (linked) | Influenza (zoonotic, in human) | 10 | Consensus sequence generation from complete amplicons or metagenomic sequencing based on Nanopore reads (INFL1).  Clustering and classification of full-length genomes (INFL3).  Prediction of reduced susceptibility to antivirals and/or host adaptation mutations (major and minor variants) (INFL4). |
| INFL2, INFL3, INFL4  (linked) | Influenza (zoonotic, in human) | 10 | Consensus sequence generation from fragmented amplicons or metagenomic sequencing based on Illumina reads (INFL2).  Clustering and classification of full-length genomes (INFL3).  Prediction of reduced susceptibility to antivirals and/or host adaptation mutations (major and minor variants) (INFL4). |

Further details regarding performing each EQA component will be provided upon confirmation of participation.

**Distribution of the datasets**

The dataset for each EQA component will be made available for download to each participant. The datasets will be encrypted, and each participating laboratory will be provided with the password the moment they indicate they are ready to start the EQA for that component.

**Data collection**

Data will be collected by means of a filled-in reporting template sent by email. The receipt of this email will count as the end time of the EQA component in question.

**Timeline for EQA**

* Laboratories must confirm their participation for selected EQA components by 14 February 2024.
* The EQA is expected to be open between 1 March and 1 April 2024.
* During this period, participants need to complete each EQA component that they chose to participate in.

**Reports**

Each participating laboratory will receive a report with the expected results after the last participant has completed submission of results including details on their own performance in the EQA. After completion of data analysis all participants will receive an overall EQA report that will also be published on the ECDC website including pseudonymized or aggregated data.

**Certificate**

Each laboratory will receive a certificate of participation for those EQA components that they completed data submission for.

**Intellectual property**

After completion of the study, the cleaned and analysed ESIB-EQA data reported to RIVM and Institut Pasteur will be transferred to ECDC. Ownership of these data is with ECDC.

**RESPONSE REQUIRED FROM PARTICIPANT**

Please complete all boxes of the ESIB-EQA 2024 Participation Registration Formto register your laboratories participation in the ESIB-EQA 2024 exercise **before 14 February 2024**.

Link: [https://ec.europa.eu/eusurvey/runner/BioinformaticsEQA202](https://ec.europa.eu/eusurvey/runner/BioinformaticsEQA2024)4. In case of technical problems, please use the form on the next page and return the completed form to [esib\_bioinformatics\_eqa@rivm.nl](mailto:esib_bioinformatics_eqa@rivm.nl).

Yours sincerely,

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**ESIB-EQA 2024 Participation Registration Form**

|  |  |
| --- | --- |
| Contact person for this ESIB-EQA: | [Name contact person]  [Institute]  [Street & number]  [City]  [Post Code]  [Country]  [Email address]  [Telephone number] |
| Which EQA components will your laboratory participate in (strongly recommended to participate in all the components for which you perform the corresponding analyses in your laboratory): | |  |  | | --- | --- | | SARS1 (Nanopore reads) | Yes / No | | SARS2 (Illumina reads) | Yes / No | | SARS3 (clustering, classification) | Yes / No | | SARS4 (mutation detection) | Yes / No | | INFL1+INFL3+INFL4 (Nanopore reads) | Yes / No | | INFL2+INFL3+INFL4 (Illumina reads) | Yes / No | |
| In case you have particular points for us to keep in mind about your participation, please add them here |  |

Return by email **before 14 February 2024** to: [esib\_bioinformatics\_eqa@rivm.nl](mailto:esib_bioinformatics_eqa@rivm.nl)