February 2024

**European External Influenza virus**

**Quality Assessment Programme**

Dear ERLI-Net members,

Herewith you can find all the necessary information about the forthcoming European External Influenza virus Quality Assessment Programme (EEIQAP) panel organized by the [ECDC-funded AURORAE consortium](https://www.rivm.nl/en/international-projects/aurorae) that will be distributed to the EISN ERLI-Net laboratory network, that consists of WHO National Influenza Centres (NICs) and/or reference laboratories for influenza in European Union and European Economic Area (EU/EEA), Western Balkan countries and Türkiye, planned for April 2024. **This 2024 panel is dedicated to molecular detection and subtyping by PCR or other Nucleic Acid Amplification Test (NAAT) and genetic characterization through sequencing of potential zoonotic influenza viruses.**

**Rationale**

During the global outbreak of highly pathogenic H5N1 (clade 2.3.4.4b) type A influenza virus in over a 100 million wild birds and poultry in 2022 and 2023, an expanding range of mammals have been found infected. Since increased activity of clade 2.3.4.4b viruses from mid-2021 also at least 12 confirmed human cases with this clade have been reported to the WHO, most after direct contact with affected poultry. This amplified the concern about the enzootic circulation of H5N1 influenza virus and transmission to humans. There are also concerns about direct transmission of swine influenza viruses to humans and about possible reassortment at mixed poultry and swine farms of swine influenza viruses with avian and/or human seasonal influenza viruses, increasing the risk that viruses develop with enhanced potential for transmission to and between humans. Current external quality assessments (EQA) organized by WHO and other commercial and non-profit EQA providers provide panels for detection of (potentially) zoonotic avian influenza viruses, but not for (potentially) zoonotic swine influenza viruses. Hemagglutinin and neuraminidase subtyping is often optional, if included in the challenge. Sequencing for genetic characterization (clade assignment) and evaluation of markers for enhanced mammalian transmission and virulence and antiviral resistance are not, or only for antiviral reduced susceptibility, included in these programmes. Therefore, it is hardly known from objective EQAs what the capabilities of the National Influenza Centres and National Influenza Reference Laboratories in the EU/EEA, Western Balkan and Türkiye are with respect to detection, subtyping and molecular characterization of zoonotic type A influenza viruses. To fill this gap and to prepare for potential human cases of avian or swine influenza viruses, on the request of ECDC, the National Institute for Public Health and the Environment (RIVM) with partners in [the AURORAE consortium](https://www.rivm.nl/en/international-projects/aurorae) developed an EQA for potentially zoonotic type A influenza viruses.

**Panel objective**

The EEIQAP 2024 will cover two main skills:

* Molecular Detection & Subtyping, detect and H- and N-subtype viruses included in the panel using RT-PCR or other NAAT (results to be reported within 7 working days);
* Molecular Characterization, using sequencing, of the H- and N-subtype, clade designation and identification of the likely host species (results to be reported within 30 working days);

The panel consists of **15** simulated clinical specimens containing heat-inactivated type A influenza viruses (confirmed by virus isolation) relevant for the purpose of this EQA in a range of viral loads or no virus.

Further details regarding processing the samples will be provided with the panel.

**Panel distribution**

Panel distribution will be coordinated by National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands and shipment will be done by Quality Control for Molecular Diagnostics (QCMD), Glasgow, Scotland, the United Kingdom. It is essential that QCMD has the correct contact details and postal address where dry-ice packages can be sent to. This information you provide on the form will be forwarded by RIVM to QCMD.

**Data collection**

Data will be collected by QCMD:

* QCMD will contact you directly with log-in details so you can access your laboratories personal pages for data reporting;
* You will need to report the date and time of panel receipt;
* You will need to report results for the Molecular Detection & Subtyping component of the panel within 7 working days of receipt;
* You will need to report results for the Molecular Characterization component of the panel within 30 working days of receipt.

**Timeline for EQA**

* The panel is planned to be distributed shortly after Western Easter holidays the second week of April 2024;
* Participants have up to 7 working days after receipt to complete the Molecular Detection & Subtyping component of the panel;
* Participants have up to 30 working days to complete the Molecular Characterization component of the panel.

**Reports**

Each participating laboratory of the respective country will receive a report with the expected results after the last participant has completed submission of results. After completion of data analysis each participant will receive an overall EQA report that also will be published on the ECDC website.

**Certificate:**

Each participant will receive a certificate of participation for those components of the panel for which the participants completed data submission to QCMD.

**Intellectual property:**

After completion of the study, the cleaned and analysed EEIQAP data reported to QCMD and RIVM will be transferred to ECDC. Ownership of this data is with ECDC (for EU/EEA and Western Balkan countries and Türkiye). Please answer the question in the Participation Registration Form whether you agree or disagree with ECDC sharing your country EEIQAP results with WHO.

**RESPONSE REQUIRED FROM PARTICIPANT** **before 15 March 2024:**

To register your laboratory’s participation in the EEIQAP 2024 please use our weblink <https://ec.europa.eu/eusurvey/runner/EEIQAP2024Influenza>. Then use the generic password ‘EEIQAPAURORAE2024!’, without quotation marks. If you prefer to use the enclosed paper form, please complete **all** boxes and send it to adam.meijer@rivm.nl and info.aurorae@rivm.nl.

Yours sincerely,

**Adam Meijer (PhD)**

Senior researcher respiratory viruses | Head RIVM location of the Dutch National Influenza Centre | Head of the National Reference Laboratory for Respiratory Viruses

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**T** +31 88 6893595

**M** +31 6 31146442**AURORAE EEIQAP 2024 Participation Registration Form**

|  |  |
| --- | --- |
| Contact person for this EEIQAP: | [Name contact person][Institute][Street & number][City][Post Code][Country][Email address][Telephone number] |
| Laboratory address where dry-ice package containing the EEIQAP panel can be sent to [no PO-Box!]: | [Name shipment contact person][Institute][Street & number][City][Post Code][Country][Email address][Telephone number] |
| Please provide your Economic Operators Registration and Identification (EORI) number: |  |
| Which component(s) of the EISN-2024 panel will your laboratory participate in (strongly recommended to participate in all the components for which you have any test running in your laboratory): |  |
| * Molecular Detection and Subtyping
* Molecular Characterization (through sequencing)
 | * Yes / No
* Yes / No
 |
| Do you agree with ECDC sharing your country EEIQAP results with WHO? | Yes, I agree / No, I don’t agree |

Return by email **before 15 March 2024** using preferably the online registration form or by email to adam.meijer@rivm.nl and info.aurorae@rivm.nl.

**Adam Meijer (PhD)**

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