ECDC Procurement Version 2019 1.

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National Institute for Public Health and
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Stockholm, Date:16/07/2020

Our ref: 5.1.2f

Dear Mr. 5.1.2e,

Re: Request for services for specific contract 4 within framework contract ECDC/2017/002 "Support of surveillance activities of human influenza in Europe 2017-2021 – External quality assessment (EQA)" – ID RS/2020/DPR/12287

For the implementation of the above mentioned framework contract, and according to its Article I.4.3 – Implementation of single FWC, ECDC would like to request an estimate of the resources to be allocated for the execution of the following services.

The Contractor is asked to provide expert surge capacity for the development and execution of the following **serology SARS-CoV-2 external quality assessment (EQA)** covering the emergent respiratory virus; the provision of deliverables with increased timeliness and different time lines is requested due to the public health emergency, as stated in the framework contract. The services will be provided within the scope of the FWC.

1. **Description of the services**

Task 1. Coordination and communication

- Provide the technical expertise and capacity to perform the serology EQA scheme for ERLI-Net, ECOVID-LabNet and EVD-LabNet laboratories participating in the laboratory and response activities for COVID-19/SARS-CoV-2.

  Draft a letter to be approved by ECDC and contact the potential EQA participants on the basis of the list and contact information of the persons (name, address, telephone number, email, etc.) provided by ECDC. The contact letter should indicate the rationale and objective of the EQA, the reporting requirements and timelines, including the minimum requirements for obtaining an EQA participation certificate, the provisions for intellectual property, data ownership and sharing, and planned post-EQA activities such as reports, feedback to the individual laboratories and publications. The letter should also indicate any participation requirements in EQA participation or data submission, e.g. for the participating laboratories to be involved in the SARS-CoV detection and response at national level.

- The final participants will be agreed with ECDC. A copy of the final participants list shall be shared with ECDC.

- ECDC shall be copied in all communications of the leader/partners (and sub-contractor where applicable) with relevant stakeholders, including network members and participating laboratories.

Task 2. EQA preparation and material distribution

- In collaboration with ECDC, select the set of sera suitable for the EQA scheme to be included in the EQAs. The pool of sera used for the EQA should reflect the need for assessing the different antibody titres used by the laboratories and representing different severity scales of COVID-19 infection (asymptomatic, mild and severe), with the different methods (ELISA, CLIA, neutralisation assays). EQA panels for the following topic should be prepared:
    - SARS-CoV-2 antibody detection to assess the sensitivity and specificity of the methods.

- Provide for ECDC approval the protocols and the methods to be used in the EQAs, including the performance indicators.

- Prepare selected serum panels, perform quality control and organise confirmatory testing, including prior testing of the panel in minimum 2 laboratories.

- Prepare the protocols and safety instructions on how to handle and store the EQA samples. The final protocols and safety instructions should be shared with ECDC for information before sending the EQA specimens.

- Prepare all EQA sera for each panel in one package per laboratory. Each package should contain the EQA sera, the protocols and safety, storage instructions and detailed information about routines for reporting the results, information on the methods and material used.

- Send the packages in a secure manner with the safety instructions on how to handle the EQA sera to the participating laboratories according to international biosafety regulations for shipment.

Task 3. Data analysis and feedback/support to the participants

- Collect, compile the data and analyse the results by producing and distributing:

    - Individual feedback on the results to each participating laboratory. If needed, assist the laboratories not able to achieve acceptable level of performance in the EQA exercise by providing troubleshooting services and advice. The report should contain recommendations for improvements, troubleshooting advice. A copy of the individual report should be provided to ECDC. A country report should be sent to each contact point in the respective country. The report should include the individual results from the participating laboratories in the country and include a conclusion on the performance and capacity of the participating laboratories. A copy of the national reports should also be provided to ECDC.
    - Make a database with raw data available to ECDC and summarise activities in an interim report, that will include which method(s) was used by each laboratory (ELISA, CLIA, neutralisation assay (pseudotype or culture methodology).

- After the participants have received the individual feedback reports, distribute a link to a feedback survey based on ECDC template to the EQA participants.

Task 4. Certification, reporting and communicating to ECDC

- Prepare and distribute ECDC certificates of participation to the participating laboratories, using the ECDC template (provided by ECDC). Upon approval of ECDC, a certificate of participation could be issued if the laboratory has returned all results within the given timeframe meeting the minimum criteria. The minimum criteria should be decided upon together with the ECDC project manager.

  Draft a comprehensive EQA report per scheme, including the results of all participating laboratories per EQA scheme to be sent to ECDC either using ECDC's template (provided by ECDC) for an ECDC report to be published as technical report on the ECDC's website or in the format of a draft manuscript (to be agreed with ECDC project manager). In the report, recommendations for troubleshooting and training needs should be stated. In addition, the results should be made available and presented to the network at the ECDC organised relevant network meetings and consultations as well as international conferences as appropriate.

2. Description of the deliverables

ECDC expects that 80 laboratories participate and asks to deliver the following services:

DL1 A detailed project plan for the EQA with targets for baseline performance should be included describing the different steps for the EQA schedule and each panel in the offer.

DL2.1 Interim report on the progress of the implementation of deliverables. Preparation of the EQA sera together with the detailed EQA protocol per scheme (including the panels, methods and safety instructions). Setup of data collection and automated analysis. Invitation letter sent to the potential EQA participants and the final participants agreed with ECDC.

DL2.2 Distribution of the EQA specimens together with the detailed EQA protocol per scheme (including the panels, methods and safety instructions).

DL3 Raw data at institute level to be sent to ECDC within 1 week of receipt of EQA results. Individual and country laboratory feedback reports to each of the participating laboratories and country, with a copy to ECDC, in order to allow each participant and country to rate their performance against expected results; the collected raw data of the EQA exercises should be provided in an electronic database.

DL4 A detailed final report of each EQA exercise performed under the specific contract, including presentation of data on methods and performance sent to ECDC within two months of completion of the EQA scheme by all participating laboratories, preferably no later than 30 April 2021 depending on the EQA delivery date. A preliminary version of the final report should be sent to ECDC for review and approval. The final report should be provided either in the format of an ECDC report or as a draft manuscript (to be discussed and agreed with ECDC project manager).

3. Timeframe and payments

The timeframe for this project is estimated at 9 months, 30 June 2021 latest.

The following **interim deliverables** are to be provided by 3 weeks after contract signature:

DL1: Detailed project plan for the organisation of the EQA (to be paid at 100% upon delivery after being accepted by ECDC);

DL2.1: An interim report on the progress of the implementation of deliverables, specimen preparation with the detailed EQA protocol per scheme and data collection and analysis setup (to be paid up to 50% upon the report being accepted by ECDC).

The following ***final deliverables*** shall be delivered no later than 8 months from the starting date of provision of the services or by May 2021 latest:
DL2.2: Distribution of the EQA specimens together with the detailed EQA protocol per scheme (including the panels, methods and safety instructions).
DL3: Raw data at institute level to be sent to ECDC within 1 week of receipt of EQA results. Individual and country laboratory feedback reports to each participating laboratories and country, with a copy to ECDC, up to 80 reports to be delivered ;
DL4: A detailed final annual report of the conducted EQA.

Conditions

Within 10 working days of this request for services being sent, ECDC shall receive the completed specific tender back, duly signed and dated and sent to the following email address:
5.1.2e @ecdc.europa.eu and copy to 5.1.2e @ecdc.europa.eu

Prices and payments should be according to the framework contract (Articles I.5 and I.6). The estimated budget for this assignment is up to 5.1.1c Euro.

ECDC is not bound with a contract in connection with this request for services. The Contractor cannot demand ECDC for compensation for any costs incurred for the offer.

Yours sincerely,

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[Electronically signed]