Offer for Laboratory support for seroepidemiology studies NP/2020/DPR/23584

The State of the Netherlands, represented by the Dutch Minister of Public Health, Welfare and Sport, represented by the 5.1.2e of the Rijksinstituut voor Volksgezondheid en Milieu (the National Institute for Public Health and the Environment) (RIVM), 5.1.2e with registered offices at Antonie van Leeuwenhoeklaan 9 at 3721 MA Bilthoven, the Netherlands (P.O. Box 1, 3720 BA Bilthoven),

- hereinafter referred to as 'RIVM' or 'contractor' -

and,

Scientist of contractor: Dr. 5.1.2e, principal virologist of the RIVM,

provides,

The European Centre for Disease Prevention and Control,

- hereinafter referred to as 'ECDC' or 'the contracting authority' -

the following offer for the Request for services for laboratory support for sero-epidemiology studies NP/2020/DPR/23584, received 10 November 2020 by email to Dr. 5.1.2e.

1. Technical proposal

1.1 Expertise and organization to accomplish the requested services

The proposed lead expert for this project is 5.1.2e. 5.1.2e is the coordinator of the Dutch national serology taskforce for SARS-CoV-2 and of the WHO COVID-19 reference laboratory at RIVM. The Dutch national serology taskforce advises the Dutch government and the National Outbreak Management Team during the SARS-CoV-2 pandemic on the role of serology in the clinical and public health response, and on the use of specific immuno-assays. In this context a coordinated validation of immuno-assays was organised involving >40 Dutch laboratories, resulting in weekly status reports, which were shared among the Dutch laboratories, ECDC and WHO.
5.1.2e and supporting staff have extensive experience with virus neutralisation tests (VNT), both for SARS-CoV-2 and a wide variety of other related and non-related viruses. This means that working laboratory protocol(s) for virus neutralisation testing services, as well as all necessary laboratory equipment and material and an electronic data management system are operational.
Furthermore, 5.1.2e is the coordinator of the ECDC-funded laboratory network '5.1.2e'. In this role 5.1.2e was responsible for the coordination and organisation of several EQAs and diagnostic training courses and offered on-line diagnostic support to network members in the early phase after the emergence of the SARS-CoV-2, even before it was known to have reached Europe at the end of January. Overall 5.1.2e and supporting staff have extensive expertise to facilitate exchange of information, organising meetings and teleconferences, preparation of reports and quality control delivered services, that enable an efficient implementation of the requested services.

1.2 Requested services

The services and deliverables as requested in the request for services for Laboratory support for seroepidemiology studies will all be delivered as proposed with the following specific remarks:

Task 1

DL1.1

- A draft detailed scheduled project plan is shown in appendix 1. Please note that the protocols that are part of the project plan were not developed under this request for tender and remain intellectual property of RIVM.

DL1.2

- No further remarks.

Task 2

In the description of task 2 it is proposed that "the contractor shall support the Member States for setting up the overall and national-level infrastructure for the study". With regard to this support, the contractor will be able to provide method protocols, advice on sample preparation, trouble-shooting, advice on storage and transport conditions. However, support will not include arrangement of ethical and/or administrative approvals, and within country logistics.

DL2.1

- No further remarks.

DL2.2

- If multiple laboratories from the same country want to participate in the study the maximum number of samples that will be tested per country is 100. If this number is exceeded, we prioritise which samples will be included. This will be done in coordination with ECDC and the specific criteria will be discussed during the kick-off meeting. RIVM is not responsible for the within-country approval of the study protocol that was agreed upon with the participating laboratories and ECDC (e.g. medical, legislative, administrative approval).

DL2.3

- No further remarks.

DL2.4

- No further remarks.

DL2.5

- If the data collected do not warrant an international, peer-reviewed scientific publication, the draft manuscript will be replaced by a final report for which ECDC will provide the template. This is e.g. dependent on the number of laboratories that will participate in this study. The decision on the nature of the output will be made in coordination with ECDC.

Task 3
DL3.1

- The maximum number of VNTs that can be performed for task 3 is 50 specimen / laboratory for up to 40 laboratories, i.e. 2000 VNTs in total. Since ECDC may update the list of laboratories eligible for confirmatory testing during the contract, it is theoretically possible that the number of laboratories interested in confirmatory testing will exceed 40. In this case the number of specimen / laboratory or the number of laboratories would need to be reduced, in order to maintain the maximum number of VNTs for this task. This point will also be discussed during the kick-off meeting. In addition, RIVM will request laboratories, if possible, to submit their samples to RIVM in batches to reduce shipping and handling, laboratory costs.

DL3.2

- No further remarks.

DL3.3

- No further remarks.

Task 4
DL4.1

- No further remarks. Support including report will not exceed 7 working days on expert level.

Task 5
DL5.1

- No further remarks.

General.
Final deliverables are DL2.5 and DL5.1. Nature of these deliverables will be agreed on with ECDC.

1.3 Risk mitigation and quality assurance

Description of risk	WP	Proposed risk-mitigation measures
Poor quality of the team delivering the service	1	The team consists of one lead expert, two scientific experts, as well as multiple staff members with extensive experience in the field of serology and specifically regarding virus neutralisation tests, reducing the risk for poor management. 5.1.2e and supporting staff have extensive experience with virus neutralisation tests (VNT), both for SARS-CoV-2 and a wide variety of other viruses. This means that working laboratory protocol(s) for virus neutralisation testing services, as well as all necessary laboratory equipment and material and a data management systemre immediately operational.
Lack of sufficient well defined clinical samples for the proposed sero-epidemiology studies	2, 3	In the request for offer ECDC states that the contractor will be provided "an initial list of around 40 COVID-19 serology performing laboratories in the EU/EEA countries". In the unlikely event that less than the required 10 Member States serology performing laboratories are willing to share serological specimen for comparative testing, ECDC will be informed in a timely manner and additional invitations can be send out.

Lack of sufficiently well maintained database for the proposed sero-epidemiology studies	2, 3	The contractor is already using a database that allows for the registration of all required parameters mentioned in the request for offer. This database is in accordance with normal good laboratory practices.
National laws prohibiting exchange of materials (Nagoya, import/export regulations)	2, 3	The contractor cannot guarantee that potential legislative issues will be solved within the indicated time-frame of the tender. However, the contractor will support and advice were possible to solve any issues.
Project costs surpass the amounts in the offer for tender	2, 3	The contractor assesses this risk to be very low. The request for offer clearly states the maximum number of confirmatory testing services per laboratory. In case the estimated maximum number of participating laboratories were to exceed 40, prioritisation of samples would be decided in coordination with ECDC.
Equivocal results in reference testing	2, 3	In case of any doubts on the results of the confirmatory testing, the tests would be repeated. If necessary additional material and / or information might be requested from the sending laboratory.
Loss of key staff resources (e.g. ongoing pandemic, large cross border outbreak situation, national outbreak situation, staff leaving their position)	all	In case of emergencies of unexpected extent like the SARS-CoV-2 outbreak, contractor and ECDC will evaluate the situation and reach an agreement on deliverables to be cancelled and deliverables with adapted timelines. The team delivering the service consists of multiple members that are able to carry out the required service, i.e. virus neutralisation tests.
Poor quality English language (All communications and deliverables are in English language).	all	All members of the team are proficient in the English language. Nevertheless, if deemed necessary, products will be submitted for proofreading to English language experts.

1.4 Involvement of proposed key experts

Role	Planned activities	Covered analysis, investigations
Lead expert: 5.1.2e 5.1.2e	Project management (incl. timelines), coordination kick-off teleconference between ECDC and contractor, communication with ECDC and participating laboratories, draft scientific manuscripts, review of interim and final reports, scientific advice regarding any serological questions that arise	all work packages
Scientific expert: 5.1.2e 5.1.2e	Coordination of practical work, communication with ECDC and participating laboratories, invitations to EU/EEA countries to participate in the study, draft scientific manuscripts, draft interim and final reports, practical support in the laboratory, organisation of shipment with participating laboratories	all work packages
Scientific expert: 5.1.2e 5.1.2e	Review scientific manuscripts, reports. Substitute lead/scientific expert if circumstances are such that support is needed.	WP 2, 3, 5

Staff	Performance of laboratory work, registration and accurate maintenance of the database, organisation of shipment with participating laboratories	all work packages

2. Signature

For the RIVM:
Place and date 5.1.2e

5.1.2e

This offer is valid 3 months after the signature date.

Appendixes

1. Detailed scheduled project plan
2. Financial Proposal Form
3. Curriculum vitae lead expert and two scientific experts

Bij vragen: mail "juridische zaken RIVM"

Geleideformulier 1 Internationaal, PPS en Media/Politiek gevoelig

Formulier 1 is van toepassing bij een **internationale wederpartij**, , en/of **goedgekeurde Publiek-Private Samenwerking** (PPS) en/of **media- of politiek gevoelige documenten** (die bijv. de onafhankelijke positie van het RIVM kunnen bedreigen). **De hoogte van het betrokken geldelijk belang is irrelevant; alleen de DG mag deze stukken tekenen.**

*Daarnaast is uitsluitend **de minister van VWS** bevoegd in de volgende gevallen:*

-Er uit het document belangrijke politieke, bestuurlijke of financiële gevolgen voor de minister van VWS kunnen voortvloeien;
-Van (mede-)oprichting van een privaatrechtelijke rechtspersoon;
-Van borgtochtovereenkomsten, vaststellingsovereenkomsten, overeenkomsten van geldlening en overeenkomsten waarbij zaken worden verhuurd of verkocht.
-Neem in deze gevallen contact op met BDR.

1. **De opsteller (initiator) vult in Word de vaste tekstblokken in, geeft bij de "routing parafen" aan welke opties van toepassing zijn (deze parafen zijn dan ook *verplicht*) en print daarna het formulier uit:**
   Algemene informatie over document:
   - Soort document: Offer for tender voor ECDC support (bijv. raamovereenkomst)
   - Onderwerp: offer for Laboratory support for seroepidemiology studies NP/2020/DPR/23584
   - Korte omschrijving (aanleiding/doelstelling): Nieuw contract voor leveren support aan ECDC voor seoepidemiological stidues
   - Opsteller (initiator) van het document: ECDC

   Looptijd document (indien van toepassing):
   - Begindatum: december 2020
   - Einddatum: duur 11 maanden
   - Verlengingsoptie/opzegtermijn: nvt (aangeven wat van toepassing is en toelichten)

   Financiële consequenties (indien van toepassing): geen
   Wederpartij/geadresseerde (naam én volledig adres): ECDC, Solna, Sweden
   Evt. opmerkingen/bijzonderheden: geen

2. **De opsteller (initiator) volgt de ondertekeningsrouting :** de benodigde parafen (met namen) worden via onderstaande routing opgehaald. Daarna wordt het geleideformulier met het document bij de tekenbevoegde (de DG) ter ondertekening aangeboden, waarna de handtekening door de DG op het document kan worden gezet.

Routing parafen	datum	paraaf
1. Bij een document met een geldelijk belang tot **€ 250.000 incl. BTW: OBP-C&A Controller van betreffende domein** **Boven € 250.000 incl. BTW:** Stafhoofd FCC Naam: 5.1.2e	Vul in: ja of nvt: ja	
2. Optie: FCC-BJV-Juridische Zaken (JZ) (alleen als er is afgeweken of geen gebruik is gemaakt van de RIVM-modellen Naam: 5.1.2e	Vul in: ja of nvt: ja	
3. Laagste lijnverantwoordelijke met volmacht **tot 250.000:** (let op: Ctrl+muisklik voor deze link) Naam:	nvt	

3. **Administratieve afhandeling na ondertekening van het document:**
   - De opsteller (initiator) van het document, verzorgt de verzending van het getekende document inclusief de bijlagen naar de wederpartij(en).
   - In geval van een **contract** draagt de opsteller er zorg voor dat de wederpartij het contract getekend aan het RIVM terugstuurt.
   - Na retourontvangst van een volledig ondertekend **contract** scant de opsteller het contract (inclusief bijlagen) én het geleideformulier in ter interne administratie **en** indien JZ betrokken is geweest (zie paraaf), stuurt de opsteller de ingescande versie (pdf) ook naar Juridische Zaken RIVM (= interne mailadres). JZ slaat dit soort (afwijkende) contracten op in een speciaal systeem.
   - In geval van een **verkoopcontract** bij een opdracht van een niet-reguliere opdrachtgever aan het RIVM (tegen door de Minister vastgestelde RIVM-tarieven), stuurt de opsteller tevens een kopie naar OBP/C&A met het verzoek hiervoor een verkooporder in SAP te maken en daarbij de overeenkomst als bijlage in SAP toe te voegen.

4. **Archivering contracten:**
   - In geval van een **contract** stuurt de opsteller het getekende origineel (hard copy) naar het Centraal Archief via het speciale formulier: "Formulier overdracht contracten aan Centraal Archief" te downloaden via intranet.
   - In geval van een **inkoopcontract**, stuurt de opsteller een volledig ondertekend origineel contract naar **OBP-IUC**. Daarnaast dient ook de Inkoopprocedure te worden gevolgd voorafgaand aan de totstandkoming van het contract.