To: [redacted]
Cc: [redacted]
Bcc: [redacted]
From: opschalingslabs
Sent: Sun 9/6/2020 10:48:30 PM
Subject: RE: COVID testing
Received: Sun 9/6/2020 10:48:30 PM
Reporting form for confirmation of first positive and negative specimens.xlsx

Dear [redacted]

For 1) It is essential that the specimens of the panel are tested with the setup/work flow exactly as it will be used for testing specimen coming from The Netherlands. That means using the equipment and reagents for extraction and PCR or other NAAT or all-in-one equipment. This needs to be done for each location separately. How many locations are you planning to include and how many workflows? All with the same equipment and reagents? Each panel comes with an instruction. When results are reported we ask for details of the used work flow. Immediate following reporting of the results we will evaluate them and give you feedback together with a sheet with the expected results.
If you plan to pool specimens for testing additionally a pooling panel should be tested.

For shipment of the panels by courier the lab's physical address, contact person, email and phone number are needed. By location if more than one. We will ship the panels as soon as the lab is operational.

For 2) This can only be done after 1) has been successfully completed and specimens arrive form The Netherlands for testing at the location with the new equipment and reagents used for 1). Specimens for confirmation can be shipped to:

Centre for Infectious Disease Research, Diagnostics and laboratory Surveillance (IDS) / PB22
National Institute for Public Health and the Environment (RIVM)
Antonie van Leeuwenhoeklaan 9
3721 MA Bilthoven
The Netherlands
Attn [redacted]
Deliver at the main gate/reception and call:
Adam 06 [redacted] or Gabriel 06 [redacted]

The attached form should be completed and sent with the specimens as hard copy and by email to [redacted]@rivm.nl. As soon as we have the specimens tested we will report the results back.

For 3) Accreditation is not optional as in *if available*. ISO 15189 with RT-PCR assays in the scope is the preferred accreditation. If not available another ISO accreditation should at least show that procedures meet a certain standard. I understand that with a complete new location ISO accreditation is not immediately available. However, you should be able to show that everything works how it should work. I assume you will perform acceptance tests for the new location before it is taken into production. Results of these acceptance tests could function as proof that the new location is fit for purpose.

Best regards,

[redacted]
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[redacted]
Head Respiratory Viruses Group / National Influenza Centre location Bilthoven
Department Emerging and Endemic Viruses
Division Virology
Centre for Infectious Disease Research, Diagnostics and *laboratory* Surveillance (IDS) / PB22
National Institute for Public Health and the Environment (RIVM)
PO Box [redacted]
3720 BA Bilthoven
The Netherlands

Shipping address:

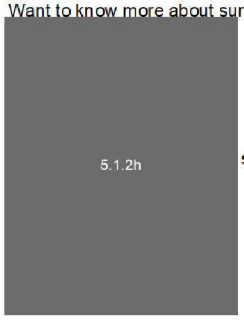
Antonie van Leeuwenhoeklaan 9
3721 MA Bilthoven
The Netherlands

Tel. : .. 31 (0)3 5.1.2e
E-mail : 5.1.2e @rivm.nl

Together with ErasmusMC, Rotterdam, being the National Influenza Centre (NIC) in the Netherlands
WHO COVID-19 reference laboratory

Wednesdays working at the ErasmusMC location of the NIC

Want to know more about surveillance of influenza in the Netherlands? See (click or scan):



scan):

From: 5.1.2e < 5.1.2e @synlab.com>
Sent: zaterdag 5 september 2020 18:29
To: 5.1.2e < 5.1.2e @rivm.nl>
Cc: 5.1.2e , Directeur des Operations France, Synlab, Paris < 5.1.2e @synlab.fr>; 5. 5.1.2e < 5.1.2e @synlab.com>; 5.1.2e < 5.1.2e @lcdk.nl>; 5.1.2e < 5.1.2e @lcdk.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e < 5.1.2e @lcdk.nl>; 5.1.2e < 5.1.2e @synlab.com>; 5.1.2e 5.1.2e < 5.1.2e @synlab.be>
Subject: FW: COVID testing

Dear 5.1.2e

I am making contact per the below in connection with SYNLAB providing Covid PCR testing capacity at the request of the Dutch government, following a constructive discussion with 5.1.2e just now.
In prior exchange w/ LCDK notably via 5.1.2e, we understood that subject to the Dutch Government's approval, RIVM would consider accepting the following quality requirements for Covid PCR testing in participating laboratories established in France, Belgium or Germany, within the SYNLAB network:

1. External EQA testing using RIVM specificity & sensitivity panel for SARS-CoV-2 with good result; detect/identify core specimens correctly and preferably educational specimens
2. 5 SARS-CoV-2 positive specimens and 10 SARS-CoV-2 negative specimens from highly suspect cases confirmed at RIVM
3. *And if available* Valid ISO15189 accreditation for (or equal) with RT-PCR (or equal NAAT) for virus detection in the scope

The latter point being positioned as "if available", on the basis of the verbal feedback received via 5.1.2e, as in the current project discussed with the Dutch Government, we intend to set up purpose-built new Covid-19 RT PCR molecular biology departments within existing SYNLAB Human clinical biology laboratories.
Could I please ask you to share details and practical aspects to implement 1 and 2 above such that we may already progress preparation internally?
Re point 3 above, we intend in particular during the initial/ramp up phase to rely upon existing installed capacity within labs that do possess ISO15189 accreditation as described above.

I look forward to your feedback.

Yours,

5.1.2e

5.1.2e
CEO SYNLAB Belgique

SYNLAB Belgium SRL
Avenue Alexander Fleming 3
BE-6220 Heppignies

Mob. : + 32 5.1.2e
E-mail : 5.1.2e @synlab.com
Web : www.synlab.be

From: 5.1.2e < 5.1.2e @lcdk.nl>
Sent: 05 September 2020 13:30
To: 5.1.2e < 5.1.2e @synlab.com>; 5.1.2e < 5.1.2e @synlab.com>
Cc: 5.1.2e < 5.1.2e @lcdk.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e < 5.1.2e @lcdk.nl>
Subject: COVID testing

Dear 5.1.2e

Yesterday parties have been very busy to arrange coronIT connections needed for COVID testing.
However, I was informed that the RIVM has not been contacted yet to arrange the requirements as stated below. If that is not correct, please let me know.

Contactinformation:
5.1.2e
5.1.2e @rivm.nl

Each laboratory performing COVID-19 molecular diagnostics in/for The Netherlands should fulfil the following requirements:

- Has valid ISO 15189 accreditation (or equal) with RT-PCR (or equal NAAT) for virus detection in the scope
- Pass external EQA testing using RIVM specificity panel for SARS-CoV-2 with good result; detect/identify core specimens correctly and preferably educational specimens
- Pass external EQA testing using RIVM sensitivity panel for SARS-CoV-2 with good result; detect/identify core specimens correctly and preferably educational specimens
- Have 5 SARS-CoV-2 positive specimens and 10 SARS-CoV-2 negative specimens from highly suspect cases confirmed at RIVM

Sincerely,

5.1.2e
Landelijk Coördinatieteam Diagnostische Keten (LCDK) COVID-19
5.1.2e @lcdk.nl | mobiel 06 5.1.2e