To: 5.1.2e [5.1.2e @lcdk.nl]
From: 5.1.2e
Sent: Sat 9/19/2020 12:03:46 AM
Subject: FW: Report (specificity and sensitivity) MVZ Synlab Leverkusen
Received: Sat 9/19/2020 12:03:52 AM

Dag 5.1.2e

5.1.2a

Zoals het er nu uitziet voldoen ze beiden nog niet aan de kwaliteitseis.

Hoe werkt dat met contract en inschakelen voor analyseren monsters uit Nederland?

Met vriendelijke groeten,

5.1.2e

From: opschalingslabs
Sent: zaterdag 19 september 2020 01:59
To: 5.1.2e , Dr.' < 5.1.2e @synlab.com>; 5.1.2e < 5.1.2e @synlab.com>
Cc: 5.1.2e < 5.1.2e @synlab.com>; 5.1.2e < 5.1.2e @synlab.com>; 5.1.2e < 5.1.2e @synlab.com>; 5.1.2e >; 5. 5.1.2e < 5.1.2e @synlab.com>
Subject: RE: Report (specificity and sensitivity) MVZ Synlab Leverkusen
Importance: High

Dear 5.1.2e and colleagues,

We have some concerns about the Ct cutoff of over 35 you are applying to consider specimens with CT >35 as fraglich/questionable. How will these be reported in CoronIT as the municipal health service cannot take action based on a questionable result. What will be your advice to the municipal health service?
Although you were able to detect also the specimen labeled educational, the specimen with 82.6 digital copies RNA/ml was expected to be judged as a true positive specimen and the 8.26 digital copies RNA/ml actually as well. Although this later specimen has a viral load around the LOD of many SARS-CoV-2 RT-PCR assays as explained by the figures shared by John. Therefore, we want to receive as soon as possible a higher number of clinical specimens for confirmation, say 20 positives of which 10 with Ct range in the third quartile and 10 in the fourth quartile (especially those with Ct >35) of the Ct value distribution you have obtained so far. In addition 20 SARS-CoV-2 negative specimen from highly suspect cases.

Also anxious to know whether you are planning to use the Hologic equipment for Dutch specimens, as if so we want to know asap the results of panel testing on this platform. In your hands, how do both workflows compare? Especially for those specimens with Ct>35 in your RT-PCR workflow. What result do these give on the Hologic Panther and what is the judgement of the result. Also fraglich or positive?

These actions and answers to questions are urgently needed to be able to advise the LCDK/ministry of health appropriately on the performance of the Synlab laboratories for analyzing Dutch specimems.

Best regards,

5.1.2e

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5.1.2e , 5.1.2e
5.1.2e National Influenza Centre location Bilthoven
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Division Virology
Centre for Infectious Disease Research, Diagnostics and *laboratory* Surveillance (IDS) / PB22
National Institute for Public Health and the Environment (RIVM)
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3721 MA Bilthoven
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Together with ErasmusMC, Rotterdam, being the National Influenza Centre (NIC) in the Netherlands
WHO COVID-19 reference laboratory

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

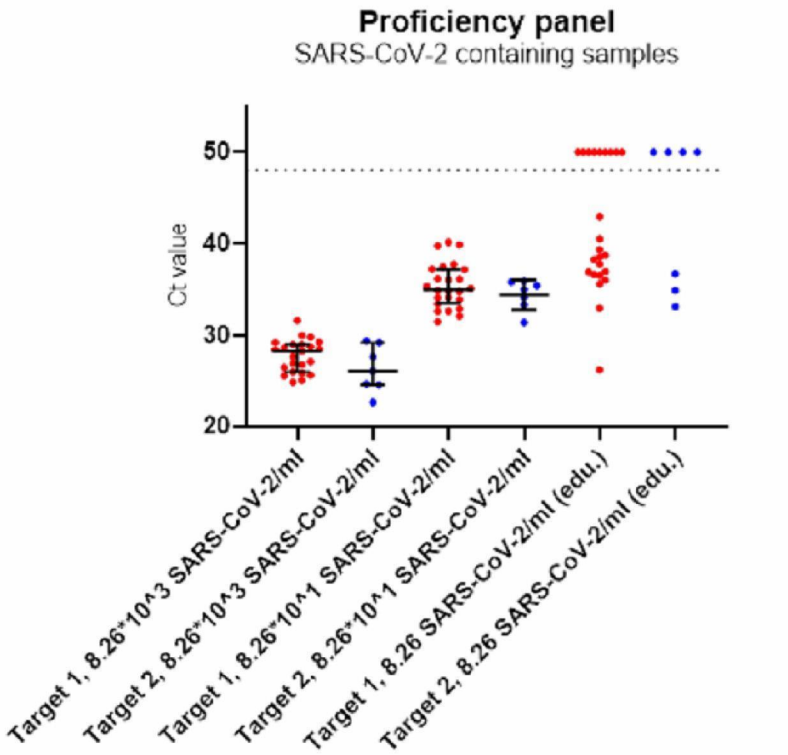
For COVID-19 see (click or scan):

From: 5.1.2i < 5.1.2e @rivm.nl>
Sent: woensdag 16 september 2020 13:01
To: 5.1.2e , Dr.' < 5.1.2e @synlab.com>; 5.1.2e < 5.1.2e @synlab.com>
Cc: 5.1.2e < 5.1.2e @synlab.com>; 5.1.2e < 5.1.2e @synlab.com>; 5.1.2e
< 5.1.2e @synlab.com>; 5.1.2e >; 5. 5.1.2e
< 5.1.2e @synlab.com>
Subject: RE: Report (specificity and sensitivity) MVZ Synlab Leverkusen

Dear 5.1.2e

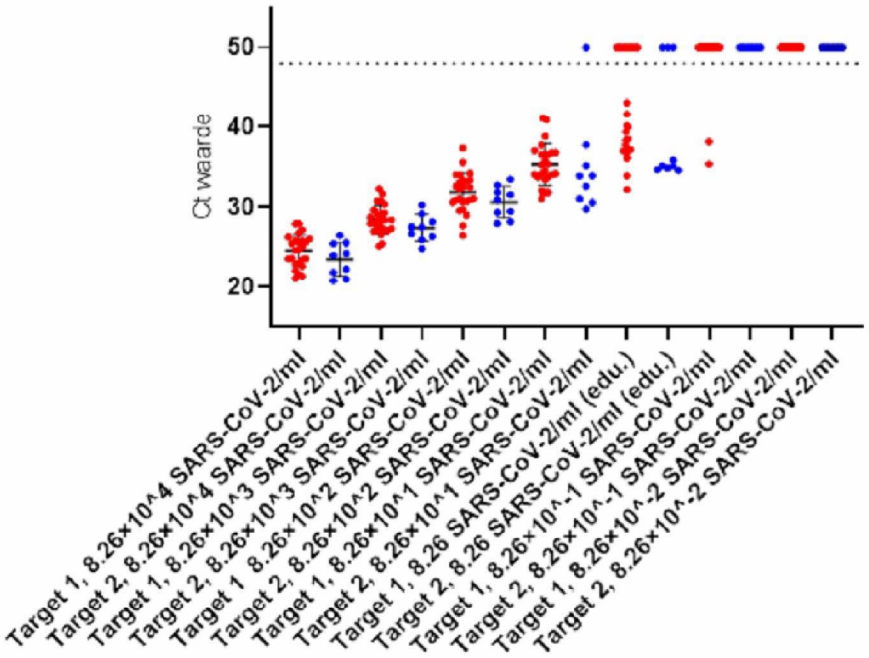
Thank you for reporting your results in such a timely manner.
When testing the specificity panel, you were able to detect SARS-CoV-2 in all SARS-CoV-2-containing samples, including the educational sample (EQA_CoV20-04, containing 8.26 digital copies SARS-CoV-2 RNA, measured using RdRP-gene dPCR).
For the sensitivity panel you obtained a similar result as you were able to detect SARS-CoV-2 up to the educational sample (Sen. Serie-01, containing 8.26 digital copies SARS-CoV-2 RNA, measured using RdRP-gene dPCR) as well.

Below I have summarized the values found by laboratories testing both these panels in three figures.



Concentation on x-axis is digital copies RNAdetermined using RdRP dPCR.
For each laboratory only the two most sensitive targets are shown
Not all laboratories perform tests using two different gene-targets
Ct 50 = Artificial Ct value for a negatieve result
For datasets without negative results, the median with IQR is shown.

Sensitivity serie SARS-CoV-2



Concentation on x-axis is digital copies RNAdetermined using RdRP dPCR.
For each laboratory only the two most sensitive targets are shown
Not all laboratories perform tests using two different gene-targets
Ct 50 = Artificial Ct value for a negatieve result
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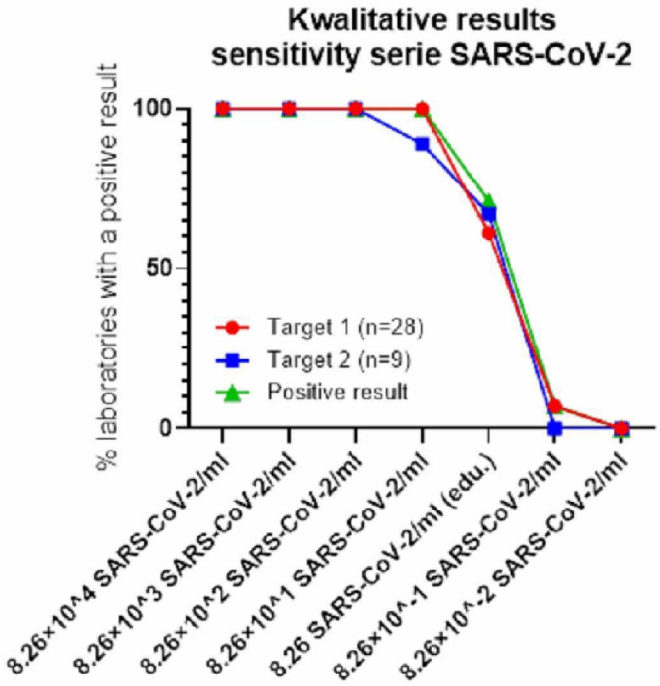

Concentation on x-axis is digital copies RNAdetermined using RdRP dPCR.
For each laboratory only the two most sensitive targets are shown
Not all laboratories perform tests using two different gene-targets
A positive result is granted for a double positive (composite) signal, or for a positive signal from one of the gene targets.
This figure shows the percentage positive results per SARS-CoV-2 concentration measured.

Attached to this email you will find the expected results for both panels.

Concerning your question about the confirmation samples: You are free to send the required samples (including documentation, also attached to the email) of suspected SARS-COV-2 patients to use whenever suits you best to the following address

Rijksinstituut voor Volksgezondheid en Milieu
To the attention of John Sluimer/Adam Meijer
+ 0031 30 274 4485
Antonie van Leeuwenhoeklaan 9
3721 MA
Bilthoven
The Netherlands

With kind regards,

5.1.2e, 5.1.2e

Rijksinstituut voor Volksgezondheid
en Milieu
Ministerie van Volksgezondheid,
Welzijn en Sport

Division of Virology, Centre for Infectious Disease Control

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