

**To:** 5.1.2e <5.1.2e@lcdk.nl>; 5.1.2e <5.1.2e@lcdk.nl>  
**Cc:** 5.1.2e <5.1.2e@lcdk.nl>  
**From:** 5.1.2e  
**Sent:** Thur 9/24/2020 12:13:05 PM  
**Subject:** FYI status SYNLAB ---- FW: Samples from 5.1.5  
**Received:** Thur 9/24/2020 12:13:07 PM

5.1.2e

FYI: zie hieronder, 5.1.2e geeft aan 5.1.5 aan dat hij toestemming geeft voor een 'live ketentest' met 10 samples.

Enige hick-ups in aanloop naar een live ketentest morgen zijn nu:

1. CoronIT acceptatietest 5.1.2e van 5.1.5 en ik vanuit LCDK pushen nu parallel de GGD en de IT-partij van 5.1.5 die het zou regelen obv gesprek met Topicus en 5.1.2e
2. GGD Gelderland-Zuid heeft net stickers en materiaal ontvangen (fijn!). Mogelijk issue: ontevreden over stickers (2 seconden gesproken met 5.1.2e, 5.1.2e). Ik word zo terug gebeld door 5.1.2e 5.1.2e GGD Gelderland-Zuid om te horen wat het verhaal is.
3. 5.1.2e probeert vanaf testlocatie RAI ondertussen te doen wat hij kan; ik stuur 5.1.2e met issue/vragen over stickers indien nodig door naar 5.1.2e

Groeten,

5.1.2e

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**Van:** 5.1.2e  
**Verzonden:** donderdag 24 september 2020 14:01  
**Aan:** 5.1.2e <5.1.2e@lcdk.nl>  
**Onderwerp:** FW: Samples from 5.1.5  
**Urgentie:** Hoog

5.1.2e klopt dit met jouw communicatie naar 5.1.2e RIVM?  
 We krijgen deze net doorgestuurd omdat ik net 5.1.2e sprak

Groet,

5.1.2e

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**Van:** 5.1.2e <5.1.2e@5.1.5.com>  
**Verzonden:** donderdag 24 september 2020 13:53  
**Aan:** 5.1.2e <5.1.2e@lcdk.nl>; 5.1.2e <5.1.2e@lcdk.nl>  
**Onderwerp:** FW: Samples from 5.1.5

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**From:** 1.2i Functionele emailadressen <5.1.2e@rivm.nl>  
**Sent:** Thursday, September 24, 2020 13:44  
**To:** 5.1.2e, Dr. <5.1.2e@5.1.5.com>; 5.1.2e <5.1.2e@5.1.5.com>; 5.1.2e <5.1.2e@5.1.5.com>  
**Cc:** 5.1.2e <5.1.2e@5.1.5.com>; 5.1.2e <5.1.2e@5.1.5.com>; 5.1.2e <5.1.2e@5.1.5.com>; 5.1.2e <5.1.2e@5.1.5.com>; 5.1.2e <5.1.2e@5.1.5.com>; 5.1.2e <5.1.2e@5.1.5.com>; 5.1.2e <5.1.2e@5.1.5.com>  
**Subject:** RE: Samples from 5.1.5

Dear 5.1.2e

I have advised the LCDK colleagues to go ahead with the pilot with 5.1.5 And solve the cutoff issue simultaneously.

With regard to Ct cutoff in the Netherlands this is highly variable. Most do curve analysis if a system generates curves and do not apply a Ct cutoff, whereas others apply a cutoff because the commercial kit requires to do so. Because there is a high variety in equipment and reagents used, setting one cutoff CT value does not work as each





Danke und viele Grüße | Thank you and regards | Merci et sincères salutations

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5.1.5

**From:** 5.1.2e Functionele emailadressen <5.1.2e@rivm.nl>  
**Sent:** Tuesday, September 22, 2020 16:29  
**To:** 5.1.2e <5.1.2e@5.1.5.com>  
**Cc:** 5.1.2e <5.1.2e@5.1.5.com>  
**Subject:** RE: Samples from 5.1.5

Dear 5.1.2e

Please find attached the Excel form with our results added.

The results can be split in three parts.

Part 1 your results with Ct ≤ 35 (n=8) – all these specimens have been confirmed with two targets (n=6) or with one target only (n=2). The 2 confirmed with 1 target had in your PCR assay Cts of 34.64 and 35.04.

Confirmation with 1 target only most likely related to low viral load and measuring around the LOD of the test. So, this is good.

Part 2 your results with Ct > 35 (n=2) – these specimens were not confirmed using 2 targets. These you would have labelled as fraglich, right? Your signal was true positive and not confirmed due to low viral load around the LOD of used tests and statistical chance to pick it up again with our PCR assays. Or another explanation?

Part 3 your negative results – these were all confirmed negative.

The panels results were quite good if no Ct cutoff is applied as outlined in a previous email.

However in the panels you had several true positive specimens labelled fraglich because of Ct > 35, whereas in the confirmation set the 2 specimens with Ct > 35 could not be confirmed. So, if you apply the cutoff of Ct ≤ 35 for true positive, how much of true positives like they are in the panels will be missed in day-to-day practice? E.g. what is the percentage of these specimens Ct >35 among positive specimens received in the last month?

How would you report Ct > 35 specimens in CoronIT? As 'indeterminate' with remark to send in additional material?

For reporting to LCDK/MoH we would like to solve the issue of the high Ct's of true positives and the application of a cutoff. Please let me know your considerations about this.

Finally, you will get by mail for each specimen of the confirmation set a separate report.

Best regards,

5.1.2e

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**From:** 1.2i Functionele emailadressen <5.1.2e@rivm.nl>  
**Sent:** dinsdag 22 september 2020 00:16  
**To:** 5.1.2e <5.1.2e@5.1.5.com> <5.1.2e@rivm.nl>  
**Cc:** 5.1.2e <5.1.2e@5.1.5.com>  
**Subject:** RE: Samples from 5.1.5

Many thanks for the Excel file 5.1.2e

With regard to 'fraglich', which of the specimens would you label as 'fraglich' according to your criteria? The 2 with Ct 36.9 and 36.83. And the one with CT 35.04? Any other because of other reasons? We hope to come back to with the confirmation result asap. For that it would be helpful to have your answers to the above questions.

Best regards,

5.1.2e

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**From:** 5.1.2e <5.1.2e@5.1.5.com>  
**Sent:** maandag 21 september 2020 15:35  
**To:** 1.2i Functionele emailadressen <5.1.2e@rivm.nl>  
**Cc:** 5.1.2e <5.1.2e@5.1.5.com>  
**Subject:** FW: Samples from 5.1.5

Von: 5.1.2e

**Gesendet:** Samstag, 19. September 2020 15:55  
**An:** 1.2i Functionele emailadressen <5.1.2e@rivm.nl>  
**Betreff:** AW: Samples from 5.1.5

I have attached the Excel sheet and here is a snap shot.

641.032.078.001	16.09.2020	oropharynx/nasopharynx	26,06
325.735.296.377	16.09.2020	oropharynx/nasopharynx	34,64
655.323.016.004	16.09.2020	oropharynx/nasopharynx	19,53
655.109.145.609	16.09.2020	oropharynx/nasopharynx	22,59
651.055.585.601	16.09.2020	oropharynx/nasopharynx	17,98
659.903.091.702	16.09.2020	oropharynx/nasopharynx	18,16
659.903.091.202	16.09.2020	oropharynx/nasopharynx	36,9
655.132.603.102	16.09.2020	oropharynx/nasopharynx	35,04
310.075.603.277	16.09.2020	oropharynx/nasopharynx	31,24
310.247.394.699	16.09.2020	oropharynx/nasopharynx	36,83
750.132.299.913	13.09.2020	oropharynx/nasopharynx	neg
644.725.031.901	13.09.2020	oropharynx/nasopharynx	neg
224.425.694.699	13.09.2020	oropharynx/nasopharynx	neg
655.318.243.110	13.09.2020	oropharynx/nasopharynx	neg
655.318.246.302	13.09.2020	oropharynx/nasopharynx	neg

As you can see, there is quite the range of Ct values among the 10 samples we sent you. The negative samples are random samples from samples the adjacent hospital has sent in.

As for 'fraglich', this has been discussed and we can adjust the cut off as for what is pos/neg, according to your countries standards.

We are using  
Positiv: ct <35

Fraglich: CT > 35 or flat curve/low slop (with cts below 35). We are technically evaluating the assays mark samples with flat curves as fraglich, with the recommendation to send in additional material.

Hope that helps.

I will wait for your response how many samples you need in addition. The earliest we can send them out is Monday at 2pm.

Kind regards

5.1.2e

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**Von:** 5.1.2i Functionele emailadressen <5.1.2e@rivm.nl>

**Gesendet:** Samstag, 19. September 2020 14:56

**An:** 5.1.2e <5.1.2e@5.1.5.com>

**Betreff:** RE: Samples from 5.1.5

Dear 5.1.2e

Many thanks for your response.

You are already familiar with the reporting system CoronIT? In that system there are three options for reporting results. Positive, negative or invalid. As in the reporting of the results of the EQA panels you indicated that results with Ct > 35 are reported as 'fraglich' this raises the question how these results would be reported in CoronIT. A result 'fraglich' is difficult to interpret for the municipal health services. So, how would you report specimens with Ct > 35 in CoronIT? In addition, do you have additional criteria like the shape of the amplification curve of specimens to consider a specimen 'positive' or 'fraglich'?

Therefore we would like to perform confirmation of testing at your lab by testing specimen at the RIVM of specimens with Ct values below and above Ct 35. By the way, how many specimens on a normal day are tested, how many considered positive (Ct<=35) and how many 'fraglich' because of having a Ct value >35?

I have now noticed that specimens have been arrived yesterday from your lab and testing has been started. However, in our LIMS the information about your Ct values is not stored. Do you have the Excel file with your data for me? Otherwise I have to wait till Monday to see the hardcopy that you sent with the specimens. Having the completed Excel file by email will also save us time. Or was it already emailed and I missed it? Sorry for that, but could you email it than again in response to this email?

Did the specimen set you submitted contain specimens with Ct values > 35 in your assay? Otherwise we would like to receive in addition a set of specimen that you tested with a Ct > 35.

Your considerations on the negative specimens are exactly what I mean. The negatives that you sent are from such cases or just from screening?

Best regards,

5.1.2e

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**From:** 5.1.2e <5.1.2e@5.1.5.com>

**Sent:** zaterdag 19 september 2020 13:28

**To:** 5.1.2e <5.1.2e@rivm.nl>

**Subject:** Samples from 5.1.5

5.1.2e

Greetings from 5.1.5 I am the one who sent you the samples on Friday.  
I am happy to provide you with more samples.

I am not sure what you consider a negative sample from a highly suspect case. We can sent some emergency samples that turned out negative or some from travelers coming back from high risk areas.  
Could you please specify what you mean.

You'd like to receive:

10 samples (ct between 20 and 30)

10 samples (ct over 35) !?!

We are not planning on using the Hologic system on the Dutch samples.

5.1.2e

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## PCR-Abteilung

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