To: 5.1.2e [5.1.2e @synlab.com]

 Cc:
 5.1.2e
 , Dr.[
 5.1.2e
 @synlab.com]

 Bcc:
 opschalingslabs[
 5.1.2e
 @rivm.nl]

From: 5.1.2e

Sent: Fri 9/25/2020 7:40:18 AM Subject: RE: repeat Sensitivity panel

Received: Fri 9/25/2020 7:40:18 AM

Dear 5.1.2e and 5.1.2e

Many thanks Ute for the retest results.

Very consistent I would say. Sens.serie-01 is the educational specimen with virus equivalent to 8.26 dcopies RdRP gene/ml and will be by chance positive or negative in repeat assays. The next specimen with higher concentration 82.6 dcopies RdRP gene/ml is again nicely positive with a Ct value > 35. Confirms the earlier observation and underlines that it is important that clinical specimens with Ct >35 are reported because the chance is high that they are true positive, especially if Ct not far from the cutoff value. And with the Ridagene assay criteria as 'inconclusive' or in CoronIT terms 'indeterminate'.

To my opinion further testing of panels is not necessary. I will ask my colleague 5.1.2e to prepare a declaration of performance for Synlab Leverkusen that you can use when official bodies or municipal health services in the Netherlands ask for that.

What should be the name on this declaration? MVZ SYNLAB Leverkusen GmbH?

Looking forward to receive the Ct distribution graph.

Best regards,

5.1.2e



