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PerkinElmer Genomics

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Dear Dr Pan,

In accordance with our new SOP CA-RPT-POL-002 "Changes to Test Interpretation" (Policy) we note that the following changes to our Ct cutoff and interpretation rules were made:

- 28Oct2020 (start of testing) – 11Nov2020 – results were reported as per the IFU (cutoff ≤ 42 as "detected"
- 11Nov2020 – 11Dec2020 – a lower Ct cutoff (≤ 37) was set for "detected" results based on Ct value observed during validation, reflecting a change in interpretation from the IFU, results >37 were reported as "not detected"
- 11Dec2020 – 25Jan2021 – high Ct values ($> 37 - \leq 42$) were interpreted as "inconclusive"
- 25Jan2021 – high Ct values ($> 37 - \leq 42$) were interpreted as "presumptive positive"

For patients tested prior to 11Dec2020, we note that a different result would have applied to the laboratory data, had the patients been tested after 11Dec2020, under the current reporting rules.

We are providing you with an Excel spreadsheet list, annotated by date, barcode, original (historical result) and result under the current reporting rules, together with patient identifiers, for your records, and should patient follow-up be required (approx. 9000 samples). We can also provide you with actual PDF copies of the original patient report should you prefer.

Regards,

A handwritten signature in black ink, appearing to read "A. Rosendorff MD".

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