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23rd December 2022

Dear Client,

We are writing to inform you of a change to platform that we use for HCV RNA and HIV-1 RNA quantitation assays that are currently run on the Roche cobas 4800 instrument. It is planned that this change will occur by the end of January 2023. We are switching to our new Roche cobas 5800 instruments.

As management and monitoring of HCV and HIV-1 infection continues to move forward, and in the light of increased test requests from our users, including the necessity to act at short notice as contingency for many laboratories around the UK, it is important to continue to strive to use the most appropriate instruments and assays that will continue to enable service provision for the future.

As part of our ongoing quality improvement of procedures at Micropathology Ltd, we are replacing our existing Roche cobas 4800 HIV-1 and HCV quantification IVD/CE-marked assays with those for the new cobas 5800 system. We have already verified the first of these new instruments and validated the HIV-1 RNA quantitation assay for CSF as an additional sample type. Results generated by the cobas 5800 HCV RNA and HIV-1 RNA assays are comparable to those produced by the outgoing cobas 4800 system and have been verified/validated against the relevant higher order reference standards. The second system will be installed and the cobas 4800 instrument removed on the 30th January 2023.

This change will ensure we continue to meet the needs and requirements of users, while significantly increasing testing capacity and local contingency. These assays have the same reportable results ranges that we currently generate, and the chemistry remains unchanged (HCV and HIV-1 lower limits for quantitation are 15 IU/mL and 20 copies/mL, respectively).

The Cobas 5800 quantitative assays requires a lower minimum volume of serum / plasma than the 4800 instrument, but we would like to continue to request that clients send at least 1.2 mL serum or plasma separated within the first 24 hours post blood draw to enable seamless continuation of service when we switch over in the coming months.

CSF is not validated by the manufacturer for the HIV-1 assay; however, we have validated this sample type in-house to enable testing to be performed and so respond to clinical needs, in the same way that we currently have for the current instrument. The new cobas 5800 instrument is comparable to the cobas 4800 in terms of result generation and report format.

Please note that serum will remain as an unvalidated sample type on the Cobas 5800 HIV-1 assay.

We have also verified the cobas 5800 instrument for HBV DNA quantitation. This is to enable us to perform EPP worker monitoring testing once it becomes accredited in our next UKAS assessment cycle (expected mid-2023). It will also allow us to rapidly expand testing capacity, should users require it.

If you wish to discuss this in more detail, please contact us by telephone (02476 323222) or email (info@micropathology.com).

Yours Sincerely,

Dr Paul Scott (Clinical Scientist - Virology).