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10th February 2021

Dear Client,

As management and monitoring of HCV infection continues to move forward since the advent of DAAs (Directly Acting Antivirals), and in the light of increased test requests, it is important to continue to strive to use more 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 COBAS AmpliPrep HIV-1 and HCV procedures with the COBAS 4800 HIV-1 and HCV quantification IVD/CE-marked assays. This change will come into effect by the end of March 2021 and will ensure we continue to meet the needs and requirements of users. These assays have the same reportable results ranges that we currently generate (HCV and HIV-1 lower limits for quantitation are 15 IU/mL and 20 copies/mL, respectively).

The Cobas 4800 HCV quantitative assay requires a greater volume of serum / plasma so we request that clients send at least 1.2 mL serum or plasma separated within the first 24 hours post blood draw. Samples with volume lower than that requested will be subject to dilution prior to testing and positive and negative results will be reported with an adjusted result to take into account the dilution factor. All diluted results will be caveated appropriately. Please be aware that this may reduce accuracy in quantification values, particularly as the lower limit of detection is approached.

There is a 1.2 mL plasma or CSF requirement for the Cobas 4800 HIV-1 quantitative assay. Samples with lower volumes will be diluted accordingly and positive and negative results will be reported with an adjusted result to take into account the dilution factor. All diluted results will be caveated appropriately. CSF is not validated by the manufacturer for this assay; however, this sample type has been validated in-house to enable testing to be performed and so respond to clinical needs.

Please note that serum is **not** a validated sample type on the Cobas 4800 HIV-1 assay.

Where multiple tests are required, we request that at least 2mL sample is provided. It should be noted that the request of multiple tests may result in a slight delay in reporting some of the requested test results due to the sample workflows within the laboratory.

If it is anticipated that a large proportion of your samples will fail to meet this increased volume requirement, or you wish to discuss this change in more detail, please contact us by telephone (02476 323222) or email (info@micropathology.com).

Finally, as a result of this change in assay, differences in quantification results may be observed over the next few months in patients being monitored. Please be aware that this is an effect of changeover in assay chemistry, not necessarily virus breakthrough. We advise users to contact the laboratory if there are any concerns.

Yours Sincerely,

Dr Paul Scott (Clinical Scientist - Virology).