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Dear Client,

As management and monitoring of HCV infection moves forward since the advent of DAAs (Directly Acting Antivirals), including test-of-cure, it is important to continue to strive to use more sensitive assays.

As part of our ongoing quality improvement of procedures at Micropathology Ltd to meet such sensitivity demands and the needs and requirements of our users, we are replacing our existing procedures with the COBAS AmpliPrep HCV quantification assay CE-marked assay (HCVQTV2). This change will come into effect by the end of August 2018. This assay allows detection of HCV RNA below 15 IU/mL, with quantification at 15 IU/mL or above.

This new assay requires a greater volume of serum / plasma so we request that clients send at least 0.7mL 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. Please be aware that this may reduce accuracy in quantification values, particularly as the lower limit of detection is approached. Positive samples which required dilution will be reported with an adjusted result to take into account the dilution factor: Negative samples will be reported with an adjusted lower limit of detection.

Due to the change in HCV testing at least 1mL serum / plasma is required for samples where multiple tests are requested. It should be noted that on occasion, samples may experience a slight delay in reporting some of the requested tests due to the flow of the samples within the laboratory based on requested tests.

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. 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,

A handwritten signature in black ink, appearing to read 'Colin Fink', written over a horizontal line.

Prof. Colin Fink (Medical Director).