

MOLECULAR PATHOLOGY DIAGNOSTIC SERVICES

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Dear Service User

The COVID-19 pandemic has placed considerable strain on the supply chain for molecular reagents and kits as manufacturers' resources are diverted to COVID-19 test production. This has led to short-term shortages from manufacturers. MPDS is well placed to deal with these shortages due to the range of technologies employed by the laboratory, offering alternative testing for many of the routine molecular tests.

As a service we have instigated alternative testing when necessary to ensure the service continues and minimising impact on turnaround time. Over the coming months as we continue to experience challenges to reagent availability, we will be utilising combinations of assays to provide molecular results, which may require frequent adaptation, as manufacturers experience supply challenges. All tests used will have been validated as fit for purpose by the laboratory but may not be currently within the laboratory's accreditation scope, which will be identified within the final report. Whilst some tests may not fall under our accreditation scope, they would have undergone the same validation procedure and are performed to the same standards as our accredited tests.

Furthermore, MPDS is implementing changes to KRAS, NRAS and BRAF molecular testing. The service is transitioning from pyrosequencing to real-time PCR using the ROCHE COBAS platform and ROCHE COBAS KRAS and BRAF/NRAS V2 real-time PCR assays. This assay has been validated; it is awaiting submission for consideration within an extension to scope (ETS) application for accreditation.

Mutation analysis performed by real-time PCR using the Roche COBAS KRAS V2 and BRAF/NRAS V2 assay, screens for 28 selected mutations across codons 12, 13, 59, 61, 117 and 146 of KRAS, 25 selected mutations across codons 12, 13, 18, 59, 61, 117 and 146 of NRAS and 11 selected mutations across codons 466, 469, 600 and 601 of BRAF. These mutations collectively constitute > 95% of KRAS, NRAS and BRAF mutations in colon and melanoma cancers. The transition to real-time PCR necessitates a change in testing procedure and therefore all colon cancer referrals will routinely receive KRAS, NRAS and BRAF testing, and melanoma's will

receive NRAS and BRAF testing. To reflect the decrease in multiple testing, the colon cancer turnaround time has been reduced from 7-10 working days to 5-7 working days. Current shortages of the NRAS/BRAF kit has delayed the full implementation of this new pathway, but we expect a go live date of late October to early November

Test costs are under review to reflect the new testing strategy and once finalised you will be notified of any changes. If you have any queries regarding the change in testing strategy please contact the laboratory. Please distribute this notice to all interested parties within your trust.

Yours sincerely



Dr Phillippe Taniere

Molecular Diagnostic Service Clinical Service Lead