

23rd September 2021

To whom it may concern,

We are writing to inform you of some changes to the **HbA1c** service at King's College Hospital, Denmark Hill. From **Monday 11th October 2021** all inpatient, outpatient and GP requests will be moved from the Menarini boronate affinity HPLC method in the Diabetic Clinic Lab to the Roche Gen 3 Tina-Quant (TQ3) HbA1c immunoassay on the c513 in the Blood Sciences Laboratory. Our verification studies have shown that the new method, whilst a different analytical principle, compares well with the existing HbA1c method and no clinically significant differences in results are expected. There will be no change in the interpretation guide reported with all HbA1c results or to sample requirements. The Menarini boronate affinity method will continue to be used for the Diabetic Clinic samples.

The Roche TQ3 immunoassay method specifically detects the first four amino acids of the N-terminal of the Hb β -globin chain (i.e. including the N-terminal valine) and thus meets IFCC criteria for standardisation of HbA1c measurement. Multiple studies have demonstrated that the TQ3 method is not affected by interferences from the common haemoglobin variants (HbAS, HbAE, HbAC, HbAD) or acetylated or carbamylated haemoglobins; however the assay is affected by HbF concentrations >7% and a small number of very rare (<5 cases worldwide) Hb variants affecting the first four amino acids of the Hb β -globin chain. Hb variant studies have also shown that patients with haemoglobinopathies (HbSS, HbSC, HbSF) are unlikely to give reportable results using the Roche method.

In patients with HbF >7% or are known carriers of rare Hb variants, HbA1c analysis by the Menarini is recommended, please contact the Duty Biochemist on 020 3299 0359 to discuss. In cases where the Roche is unable to give a result due to a suspected haemoglobinopathy the Menarini method will be reflexed.

Please do not hesitate to contact us if you have any queries.

Yours faithfully,



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