Recommended quality control for antenatal screening for sickle cell and thalassaemia

Due to the limited number of providers of quality control material for haemoglobinopathy testing, the same source material may be marketed by several different suppliers. Therefore proprietary and apparent third party controls may be identical.

If required in-house quality control material to aid haemoglobin variant identification must be prepared:

- from confirmed cases or as a minimum with identical characteristics in the chosen technique
- in proportions that replicate testing of adults

Screening utilises a multi step process to characterise haemoglobin variants. It is not possible to have controls for all haemoglobin variants however laboratories should have controls detailed below within the multistage process.

**Recommended quality control measures for this work**

**High-performance liquid chromatography and capillary electrophoresis:**
The manufacturer should provide calibration and quality control material. This must be analysed as per manufacturer’s recommendations. This control material is sufficient for HbA₂ and HbF measurement. Haemoglobin variants detected by these techniques must have second line testing with appropriate quality control material.

**Alkaline and Acid electrophoresis**
HbF, HbA, HbS and HbC positional controls are sufficient for routine alkaline and acid electrophoresis. It is possible to obtain a commercial FASC control.

**Isoelectric focusing**
This procedure requires positional quality control material. It is possible to obtain a commercial FASC control. Additional in-house material containing HbD\textsuperscript{Punjab} and HbE is required. Ideally two separate mixtures the first containing HbA, HbS and HbD\textsuperscript{Punjab} and the second HbA, HbC and HbE should be prepared. This ensures that the critical separation of the haemoglobins in each mixture occurs satisfactorily.

**Mass spectrometry** –
In house quality control material must be prepared for this technique.