Recommended quality control for newborn screening for sickle cell disease

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.

In-house quality control material must be prepared:

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

**Recommended quality control measures for this semi quantitative work**

**High-performance liquid chromatography: variant newborn screening (VNBS)**
The manufacturer provides the retention markers as part of the sickle cell short reagent kit. They comprise lyophilised material containing: 1) FAES in vial one; and 2) FADC in vial 2. Retention markers should be analysed as per manufacturer’s recommendations.

**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.

**Capillary electrophoresis**
The manufacturer provides lyophilised FASC quality control material and this material should be analysed as per their recommendations. If capillary electrophoresis is used without in-house control material for HbD\textsuperscript{Punjab} and HbE the alternate procedure must include control material for these haemoglobins.

**Mass spectrometry – SpotOn Diagnostics**
The manufacturers are currently developing quality control material that will be available in 2017. This material will be set at levels to control the action values set by the screening programme. In the absence of these controls, laboratories using ratios only must have control material containing all haemoglobins under investigation at levels appropriate for the action values. Laboratories unable to achieve ratio controls can use material that controls each haemoglobin by means of the intensity. In this case both intensity and ratios must be reviewed.

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