NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Equality impact assessment – Scoping

Genedrive MT-RNR1 ID Kit for detecting single nucleotide polymorphism m.1555A>G in neonates

The impact on equality has been assessed during this assessment according to the principles of the NICE Equality scheme.

1. Have any potential equality issues been identified during the scoping process (scoping workshop discussion, assessment subgroup discussion), and, if so, what are they?

- The PharmGKB allele frequency table for the *MT-RNR1* gene reports that frequencies of the m.1555A>G variant differ by ethnic family background, so testing may be particularly beneficial in some groups.
- Tests that do not detect all relevant variants in the *MT-RNR1* gene could disproportionately affect different ethnic groups based on the prevalence of these alleles.
- Mothers from a minority ethnic family background or those with a lower socioeconomic status may have an increased risk of early-onset neonatal infection and may be more likely to need treatment with antibiotics.
- The acceptability and consent for genetic testing may differ according to religious or philosophical beliefs.

2. What is the preliminary view as to what extent these potential equality issues need addressing by the Committee?

The committee will need to consider the potential increased benefit of testing in populations with higher prevalence of *MT-RNR1* variants in its decision-making. To help with this, the scope specifies that analysis in which a higher prevalence of *MT-RNR1* variants is modelled should be provided (see section 6) if data are not available to allow subgroup analysis to be done for babies of different ethnicities (as specified in table 1).

When making decisions about recommending testing, the committee should consider that some groups, such as people from a minority ethnic family background or those with a lower socioeconomic status, may have higher incidence of neonatal infection and testing could be particularly beneficial.

Only 1 technology has been identified for the assessment and this only detects the m.1555A>G variant in the *MT-RNR1* gene. The committee will therefore not be able to consider the differential effectiveness of alternative tests based on which variants in the *MT-RNR1* gene they detect (that may differ in prevalence between different ethnic groups) in decision making. If recommending testing, the committee may also need to consider the nature and extent of information provided to people prior to the testing being done, and level of consent required prior to testing.

3. Has any change to the draft scope been agreed to highlight potential equality issues?

   Following the scoping workshop and ASG meeting, the following changes were made to highlight potential equality issues:

- Detail was added to section 3.4 describing how acceptability and consent for genetic testing may depend on religious or philosophical beliefs

4. Have any additional stakeholders related to potential equality issues been identified during the scoping process, and, if so, have changes to the stakeholder list been made?

   No

Approved by Associate Director (name): Rebecca Albrow

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