Genedrive MT-RNR1 ID System for detecting single nucleotide polymorphism m.1555A>G in newborn babies (provisional title)

For newborn babies with the single nucleotide polymorphism m.1555A>G, treatment for a bacterial infection with an aminoglycoside such as gentamicin carries the risk of hearing loss.

Genetic testing for the MT-RNR1 variant is not currently standard practice. The Genedrive System and MT-RNR1 ID test kit is a qualitative in vitro diagnostic test that can detect this single nucleotide polymorphism. The test could be used at the point of care and may give results quickly enough to inform antibiotic treatment for newborns, allowing alternatives to aminoglycosides to be used. Reducing hearing loss in newborns would have substantial benefits for newborns and their families and could also reduce health care costs associated with hearing loss.

The NICE diagnostics assessment programme will assess the clinical and cost-effectiveness of the Genedrive MT-RNR1 ID System (and any other alternative technologies identified during scoping) to make recommendations on its use in the NHS.