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Yourgene Health receives HSA approval for prenatal screening

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IVD prenatal screening workflow to help improve access to non-invasive genetic screening for patients and clinicians



Yourgene Health, a leading international molecular diagnostics group, has received Health Sciences Authority (HSA) approval for its IONA Nx NIPT Workflow in Singapore. The prenatal screening workflow has been authorised for use in clinical laboratories, providing them with a fully automated and cost-effective testing solution to establish their own fast, accurate and quality-assured non-invasive prenatal testing (NIPT) service. Yourgene's optimised NIPT solution enables efficient workflows, helping to save laboratories time, money and enhance their performance.

The IONA Nx NIPT Workflow is an *in vitro* diagnostic (IVD) tool designed to offer flexibility, simplicity and scalability for prenatal screening. The fully validated workflow uses next-generation sequencing (NGS)-based whole genome analysis to screen for a wide range of clinical conditions in the fetus, including Down's syndrome (Trisomy 21), Edwards' syndrome (Trisomy 18) or Patau's Syndrome (Trisomy 13). It can also be used to screen for autosomal- and sex-chromosome aneuploidies, as well as providing the option of fetal sex determination from 10 weeks gestation. The complete workflow includes sample preparation, DNA extraction and library construction, requiring minimal fetal fraction, as well as sequencing analysis and clinical reporting with full sample traceability.

The approval of the workflow in Singapore will help to expand patient access to non-invasive prenatal screening and provide laboratories with choice as to which IVD NIPT services they are able to offer clinicians. The regulatory authorisation adds to the IONA Nx' existing accreditations, including a CE mark, and now means the workflow is available in many countries across Europe, the Middle East and Asia.