Vanadis® NIPT

A High-Precision Non-Invasive Prenatal Test (NIPT) for All Women

Safe, convenient and performed with high-precision providing a minimal no-call rate at a price that makes testing more affordable, Vanadis® NIPT is optimized to provide the benefits of NIPT for common aneuploidies to all women.

Features and Benefits:

- Accurate screening for the three most common trisomy disorders: Trisomy 21, 18 and 13
- High-precision designed to reduce the no-call rate allowing more patients to receive reliable results
- Simple and safe screening from a single blood draw as early as 10 weeks gestation
- Reliable results available within 7-10 days
- Optional selection of fetal sex determination

Clinical Performance of Vanadis® NIPT:

<table>
<thead>
<tr>
<th></th>
<th>Serum Screening 1</th>
<th>PCR-Based NIPT*</th>
<th>Vanadis® NIPT**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trisomy 21 Detection Rate</td>
<td>81 - 92%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Trisomy 18 Detection Rate</td>
<td>80 - 93%</td>
<td>97 - 98%</td>
<td>92%</td>
</tr>
<tr>
<td>Trisomy 13 Detection Rate</td>
<td>80%</td>
<td>94 - &gt;99%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>False Positive Rate</td>
<td>4.5 - 5%</td>
<td>0.1 - 0.2%</td>
<td>0.4%</td>
</tr>
<tr>
<td>No-Call Rate</td>
<td>N/A</td>
<td>1 - 7%</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

*Based on publicly published data  
**Based on unpublished internal data

The Technology Powering Vanadis® NIPT

Performed without PCR amplification and unlike other complex sequencing-based NIPTs, Vanadis® NIPT directly captures target chromosomal fragments and labels them for high-yield counting which enables high-performance screening for fetal aneuploidies at an affordable price (Figure 1).
Understanding the Benefits of Our High-Precision Assay

The high-precision of Vanadis® NIPT, greatly reduces variation and tightens the Z-Score distribution. This allows for accurate screening of aneuploidies even in samples with lower fetal fractions and provides one of the lowest no-call rates among NIPTs. The image below demonstrates the benefits of utilizing a high-precision assay when analyzing samples with low fetal fractions.

Steps Taken to Achieve the High-Precision of Vanadis® NIPT

✓ Counting more molecules: The Vanadis® NIPT counts, on average, 3x more molecules from target chromosomes than traditional sequencing-based NIPT tests.
✓ Eliminating errors propagated by PCR: The Vanadis® NIPT utilizes rolling-circle-replication, rather than PCR, to reduce variability.
✓ Utilizing full automation: The Vanadis® NIPT is performed on a fully automated system utilizing a DNA extraction protocol to enrich fetal fraction.

Why NIPT for All Women?

Non-invasive prenatal testing has demonstrated superior performance for screening for common aneuploidies over traditional serum screening, helping patients avoid unnecessary invasive procedures and thereby, reducing the risk of fetal loss4. However, the complexity, cost and high no-call rate of PCR-based NIPTs has limited access to the advantages of NIPT results in the general population. With the affordable price and low no-call rate of Vanadis® NIPT, the benefits of a reliable NIPT are now accessible to more women.

References


The content of this pamphlet is provided for informational purposes only, not as medical advice. It is not intended to substitute the consultation, diagnosis, and/or treatment provided by a qualified licensed physician or other medical professional.