Clarigo is a non-invasive prenatal test (NIPT) starting from cell free fetal DNA obtained from blood of the mother. This simple, robust and highly reliable test screens for the aneuploidy status of chromosomes 21 (Down syndrome), 18 (Edwards syndrome) and 13 (Patau syndrome) as early as 8 weeks in the pregnancy.

The updated Clarigo v2 solution has an improved accuracy for both aneuploidy screening and gender calling. In addition, samples with a fetal fraction as low as 3 % are called automatically. With the updated algorithms, the overall Clarigo calling rate is significantly improved.

The Clarigo test is designed for implementation in clinical laboratories using standard lab equipment and most of the current Next-Generation Sequencing systems.

The test is based on Agilent's Multiplex PCR technology, which facilitates straightforward, targeted and cost-effective analysis of aneuploidies.

The interpretation of Clarigo-generated sequencing data is streamlined by the dedicated data analysis tool: Clarigo Reporter. The updated version includes improved calling algorithms and more quality parameters for an accurate report tailored to the needs of your laboratory. The improved ease-of use across the workflow and result interpretation of the software enable rapid generation of information for healthcare professionals, their patients and families.

The optimized, simple and scalable procedure enables rapid implementation of the test using local resources and infrastructure.

New features:
- Inclusion of Y amplicons for more accurate gender calling
- Automatic trisomy calling down to a fetal fraction of 3 %
- Optimized fetal fraction determination
- High overall call rate
- Extensive quality report

<table>
<thead>
<tr>
<th></th>
<th>Trisomy 21</th>
<th>Trisomy 18</th>
<th>Trisomy 13</th>
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<tbody>
<tr>
<td>Observed sensitivity</td>
<td>100.00 %</td>
<td>100 %</td>
<td>100.00 %</td>
</tr>
<tr>
<td>Observed specificity</td>
<td>99.93 %</td>
<td>99.93 %</td>
<td>99.86 %</td>
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</table>

Figure 1. The entire Clarigo v2 workflow was validated on 1,551 samples, originating from 4 sites. As reference method, the standard of care prenatal test at the respective laboratory was used (Clarigo or other invasive/non-invasive prenatal test). All samples were extracted, amplified, sequenced and analyzed with the Clarigo Reporter v2.0.0.
Key Features

Clarigo test kit(s)
- Ready-to-use reagents
- Specific sample barcodes and adaptors for NGS systems

Clarigo Reporter
- Secure web application data analysis platform
- Trisomy score for chromosomes 21, 18, 13
- Gender calling (optional)
- Fetal fraction determination for each sample
- Automated report including results generated
- Extensive quality report provided to give more insight in the performance and the data

<table>
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<tr>
<th>Cat. No.</th>
<th>Product Name</th>
<th>Genomic Target</th>
<th>Contents</th>
<th>Reactions</th>
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</thead>
<tbody>
<tr>
<td>MR-2501.096</td>
<td>Clarigo v2</td>
<td>NIPT for chromosomes 13, 18, 21, optional Gender calling</td>
<td>1 PCR mix, Taq, AR1 &amp; Clarigo Reporter</td>
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<table>
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<tr>
<th>Cat. No.</th>
<th>Product Name</th>
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<td>MiSeq, HiSeq2500, NextSeq</td>
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<td>MiSeq, HiSeq2500, NextSeq</td>
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For In Vitro Diagnostic Use.

This information is subject to change without notice.