Prenatal Paternity Testing on Maternal Blood

<table>
<thead>
<tr>
<th>Case: 12345</th>
<th>MOTHER</th>
<th>Alleged FATHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Doe, Jane</td>
<td>Smith, John</td>
</tr>
<tr>
<td>Race</td>
<td>Caucasian</td>
<td>Caucasian</td>
</tr>
<tr>
<td>Sample</td>
<td>15186-1-MB</td>
<td>15186-1-FB</td>
</tr>
<tr>
<td>Date Collected</td>
<td>06/14/2011</td>
<td>06/13/2011</td>
</tr>
</tbody>
</table>

**Paternity Inclusion:** The alleged father is not excluded as the biological father of the fetus. The probability that the alleged father contains the genetic markers required of the biological father is 99.9% when compared with random individuals. This conclusion is based on the testing results obtained from analyzing 317,000 individual DNA markers.

A “degree of relatedness” metric is calculated for each of >5,000 unrelated individuals and the alleged father. The grey curve is the plot of each result for the unrelated individuals. The inverted triangle is the result for the alleged father. If the result for the alleged father falls solidly within the grey curve (range of unrelated individuals) he is excluded as the father; outside of the curve he is included; and within the “Indeterminate” tail region of the curve a result cannot be conclusively determined.

Test accuracy has been validated in broad ethnic populations. If two or more alleged fathers are direct relatives, or from a population that has been genetically isolated, it is possible that due to genetic similarity each alleged father could produce a paternity inclusion result if tested individually. For this reason samples from all alleged fathers are required under these circumstances.

I, the undersigned Executive Director, verify that the interpretation of the results is correct as reported on July 15, 2011.

Stefan A. Long, Executive Director
Testing Methodology
The non-invasive prenatal paternity test utilizes cell-free circulating fetal DNA (cfDNA) isolated from the plasma of the mother’s blood, along with DNA samples from the mother and alleged father. The DNA samples are analyzed using a dense microarray chip to examine 317,000 genetic markers known as single nucleotide polymorphisms (SNPs). An informatics algorithm (Parental Support™) is used to compute the similarity of genetic markers between the fetal DNA and the alleged father’s DNA, as well as to unrelated random individuals. If the probability that the alleged father contains the genetic markers required of the biological father is greater than 99.9% when compared with random individuals, the result is a Paternity Inclusion. If the similarity falls within the range of non-fathers, the result is a Paternity Exclusion.

Results
There are four possible testing results:

1. **Paternity Inclusion**: The alleged father is not excluded as the biological father of the fetus. The probability that the alleged father contains the genetic markers required of the biological father is 99.9% when compared with random individuals. This conclusion is based on the testing results obtained from analyzing 317,000 individual DNA markers.

2. **Paternity Exclusion**: The alleged father is excluded as the biological father of the fetus. This conclusion is based on the testing results obtained from analyzing 317,000 individual DNA markers. The alleged father lacks the genetic markers that must be contributed to the child by the biological father.

3. **Insufficient fetal DNA for reliable analysis**: An insufficient amount of fetal DNA was isolated, therefore no conclusion regarding paternity is possible. The amount of fetal DNA in maternal serum varies greatly from pregnancy to pregnancy but in general increases with advancing gestation. A second blood draw and re-analysis later in the pregnancy is recommended.

4. **Unable to determine paternity**: No conclusion regarding paternity is possible based on the genetic testing performed. The statistical value obtained for the tested alleged father is indeterminate regarding paternity and thus he can neither be included nor excluded as the biological father of the child. This can occur for a variety of reasons including, but not limited to, close genetic similarity between the alleged father and true father.

Testing Requirements for Relatives and Genetically Isolated Populations
Test accuracy has been validated in broad ethnic populations. If two or more alleged fathers are direct relatives, or from a population that has been genetically isolated, it is possible that due to genetic similarity each alleged father could produce a paternity inclusion result if tested individually. For this reason samples from all alleged fathers are required under these circumstances.

Twins/Multiple Gestation
Test performance has been validated for single pregnancies only.

Chain of Custody
Testing procedures follow proper custody, or control, of the DNA samples throughout the testing process to meet “Chain of Custody” criteria:

- Identity of the pregnant mother and alleged father is confirmed at the time of the blood draw by a neutral third party
- All samples and paperwork delivered to the testing laboratory are examined for evidence of tampering
- The sample IDs are tracked and documented throughout the testing process
- This process enables the laboratory to produce notarized test results that are court admissible

Laboratory Certification
The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). Testing is performed by Gene Security Network (GSN) at its CLIA certified facility located at 2686 Middlefield Road, Suite C, Redwood City, CA.