One of Europe’s leaders in diagnostic testing
Chromosomal abnormalities, such as trisomy 21 (Down syndrome), occur in 1-2% of all fetuses. A large range of prenatal tests are available to evaluate the healthy development of the future baby prior to birth. LABCO has pioneered prenatal screening by incorporating new scientific advances to offer a state-of-the-art non-invasive prenatal test, backed by the expertise and reliability of one of Europe’s leading laboratories.
“Gives me the confidence of a state-of-the-art test along with the assurance and expertise of one of Europe’s leading laboratories”

**ACCURATE**
Detects more than 99.9% of pregnancies with Down and Patau syndromes

**SIMPLE**
A single blood test from the mother

**SAFE**
Non-invasive for the fetus
Supported by LABCO, one of Europe’s pioneers and leaders in prenatal testing

Results typically available in 5 working days

Based on cutting-edge technology
La correlación de la prueba con los resultados ecográficos u otros datos de rendimiento son limitados. Por lo tanto, es importante realizar un análisis complementario para confirmar los resultados. Los resultados deben considerarse junto con datos clínicos adicionales y los consejos genéticos. Las pruebas adicionales pueden ser necesarias en algunos casos para obtener una conducción más precisa.

**Descripción de la Prueba**

La prueba neoBona es una prueba de cribado que ha sido diseñada para detectar posibles aneuploidías en el feto. La prueba se realiza a partir de una muestra de sangre materna. Los resultados de la secuenciación de ADN permiten determinar la presencia de aneuploidías en los cromosomas 21, 18, 13, monosomía X, XXX, XXY o XYY en el feto.

**Datos de Rendimiento Clínico**

- **Sensibilidad**: 97,6% (243/249)
- **Especificidad**: 99,2% (257/259)
- **Precisión**: 99,8% (409/410)
- **Positividad**: 99,9% (483/488)
- **Negatividad**: 99,7% (475/478)

**Pruebas adicionales**

- Las pruebas de cribado están indicadas para detectar posibles aneuploidías en el feto. Para un diagnóstico preciso, se deben realizar pruebas adicionales.

**Riesgos Clínicos**

- Los resultados de las pruebas no eliminan la posibilidad de que el embarazo tenga asociadas otras anomalías cromosómicas o subcromosómicas. Es importante realizar un análisis complementario para confirmar los resultados.

**Consejo Genético**

- Existe una pequeña proporción de resultados falsos negativos y positivos. Existe una pequeña posibilidad de que la prueba no detecte algunas anomalías cromosómicas.

- Los resultados deben considerarse junto con datos clínicos adicionales y los consejos genéticos. Las pruebas adicionales pueden ser necesarias en algunos casos para obtener una conducción más precisa.
• The new generation of non-invasive prenatal test.

• Detects the most frequent chromosomal abnormalities that occur during pregnancy, by studying the cell-free fetal DNA present in maternal blood.

• Incorporates the latest technology from Illumina, a world leader in DNA sequencing, who in collaboration with LABCO, has applied state-of-the-art technologies to provide a novel genetic prenatal screening test with outstanding sensitivity and accuracy. This technology is available exclusively from LABCO – SYNLAB.

• The test analyses the amount of cell-free fetal DNA present in the maternal blood (the "fetal fraction"), and uniquely includes the analysis of cell-free DNA fragment size, for the highest accuracy.
I am pregnant, is neoBona suitable for me?

**neoBona** is available from the 10th week of pregnancy (10 weeks + 0 days).

**neoBona** can be performed in cases of assisted reproduction, including IVF after egg or sperm donation.

**neoBona** is suitable for twin pregnancies.

**neoBona** is a genetic screening test and, as such, must be prescribed by your physician.
Why choose

- **CONFIDENCE.** neoDon® offers parents confidence that chromosomal abnormalities in the fetus can be detected early during pregnancy. A non-invasive test does not carry any risk to the future baby.

- **PROFESSIONAL COUNSELLING.** neoDon® is the only prenatal test available that has the support of the extensive team of over 1,000 medical professionals and genetics experts to support your clinician.

- **CLOSE TO YOU.** Through LABCO – SYNLAB, you have access to Europe's largest network of blood collection centres.

- **INNOVATION THROUGH TECHNOLOGY.** Developed with Illumina, a world leader in DNA sequencing, integrating state-of-the-art technology and know-how to offer an innovative non-invasive prenatal test.
FETAL FRACTION. Unlike other prenatal tests, neoDona specifically analyses cell-free fetal DNA through sizing technology, improving the accuracy of the result.

NEXT-GENERATION BIOINFORMATICS. The innovative TSCORE algorithm uses the depth of sequencing, the percentage of fetal DNA, the quantification and measurement of the fragment size, to obtain reliable results even at a low fetal fraction.

ACCURACY. Conventional first-trimester screening consists of blood and ultrasound analysis, and provides only a statistical risk index. neoDona directly analyses cell-free fetal DNA and so provides a greater accuracy: better detection, fewer false positives.

SPECIFICITY. Conventional first-trimester screening has a specificity of 95%. In other words, out of every 100 healthy pregnancies, 5 are incorrectly classified as high risk, leading to anxiety, counselling and further testing, including prenatal diagnosis (for example, amniocentesis).

The very high specificity of neoDona reduces the number of false positive results to less than 1 in 1,000 pregnancies, diminishing anxiety and unnecessary prenatal diagnosis.

SENSITIVITY. Conventional first-trimester screening has a sensitivity of about 90%: out of every 100 fetuses with Down syndrome (trisomy 21), 10 would not be detected (false negative results).

The sensitivity of neoDona is higher than 99.9%, meaning that it detects practically all cases of Down syndrome.
What types of chromosomal abnormalities does neoBona detect?

1. MOST FREQUENT TRISOMIES

A trisomy is caused by the presence of three copies of a chromosome, instead of the normal two.

NeoBona detects the following trisomies:

- **Trisomy 21**, or **Down syndrome**, is the most common trisomy; affected children can have mild to moderate intellectual impairment, heart defects and/or other disorders.

- **Trisomy 18**, or **Edward syndrome**, has a high incidence of miscarriage. Affected infants typically have severe malformations and mental retardation, and rarely survive beyond 1 year of age.

- **Trisomy 13**, or **Patau syndrome**, has a high incidence of miscarriage. Infants with Patau syndrome have severe mental retardation, can exhibit severe congenital heart malformations as well as other pathologies, and rarely survive beyond 1 year of age.

DETECTION RATE

<table>
<thead>
<tr>
<th>Trisomy</th>
<th>Detection Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>T21</td>
<td>&gt;99.9%</td>
</tr>
<tr>
<td>T18</td>
<td>&gt;97%</td>
</tr>
<tr>
<td>T13</td>
<td>&gt;99.9%</td>
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</tbody>
</table>
ALTERATIONS IN SEX CHROMOSOMES

`neoDonia Advanced` can detect alterations in the number of sex chromosomes, which can be associated with a variety of milder conditions including:

- **Turner syndrome (45, X)**, the absence of an X chromosome in girls.
- **Klinefelter syndrome (47, XXY)**, the presence of an extra copy of the X chromosome in boys.
• neoBona:
  Trisomies 21, 18 and 13 +
  Fetal sex (optional)
  Paired-end WGS technology
  Fetal fraction

• neoBona Advanced:
  Trisomies 21, 18 and 13 + Fetal sex
  + Aneuploidy X, Y
  Paired-end WGS technology
  Fetal fraction

* Option available for twins. If the “Fetal Sex” option is selected in twin pregnancies, the presence of Y chromosome is determined.
LABCO Quality Diagnostics
part of SYNLAB

✓ More than 15 years innovating in prenatal diagnosis.
✓ Part of the SYNLAB Group, a European leader in medical laboratory diagnostics.
✓ Operates in more than 35 countries in Europe, Latin America, Asia and Africa.
✓ The company has a network of over 550 laboratories.
✓ Over 1,000 medical professionals and genetics experts.
✓ More than 450 million tests a year.

BIBLIOGRAPHIC REFERENCES
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