Name	**Sample ID**
Date of birth	**Sample collected**
Sample type	**Sample received**
Provider	**Report date**

CLINICAL INFORMATION

Gestational age: 6 + 0	**Pregnancy type:** Singleton	**IVF pregnancy:** No	**Oocytes:**
Clinical indication: Non evolving gestation			

PregnancyLoss

Fetal fraction: 3%

CHROMOSOMES TESTED	RESULTS CONSISTENT WITH	INTERPRETATION
Chromosomes 21, 18, 13	Absence of aneuploidy	**Low risk of aneuploidy**
Fetal sex	Absence of Y Chromosome	**Female fetus**
Sex chromosomes	Absence of aneuploidy	**Low risk of aneuploidy**
Other chromosomes	Presence of trisomy 20	High risk of aneuploidy Genetic counseling is recommended to evaluate confirmation of the result
Deletions and duplications (CNVs) > 7Mb	Absence of deletions and duplications	**Low risk of deletions and duplications**

ANALYSIS METHOD

Cell-free DNA extraction from plasma, paired-end Next Generation Sequencing (NGS) and bioinformatic analysis to determine the risk of aneuploidy as requested (VeriSeq NIPT v2 CE-IVD, Illumina Inc.).

LIMITATIONS AND PERFORMANCE

PregnancyLoss is a test designed to screen for fetal aneuploidies in all chromosomes, as also for partial imbalances (CNVs) of at least 7 megabases (Mb) in all the autosomes. Test results might not reflect the true fetal chromosome constitution as false positives or false negatives could occur. Among the main known causes of discrepancies, the most frequent are due to biological factors included but not limited to the presence of a vanishing twin, fetal mosaicism of low proportion, confined placental mosaicism or unrecognized maternal chromosomal abnormalities.
The test has not been designed to determine the risk of other genetic disorders such as chromosomal mosaicisms, triploidy, partial aneuploidies of less than 7Mb and single gene defects so that a low risk result does not guarantee a healthy pregnancy or fetus and does not eliminate the presence of other genetic or structural alterations such as neural tube defects.
Some rare chromosomal aneuploidies can only occur in mosaic form. The clinical consequences depend on the chromosome involved and may not be elucidated prenatally.

Performance data:

	Trisomy 21	Trisomy 18	Trisomy 13	Other aneuploidies	CNVs (>7Mb)
Sensitivity	>99%	>99%	>99%	96.40%	74.10%
Specificity	99.90%	99.90%	99.90%	99.80%	99.80%

VeriSeq NIPT v2 CE-IVD Product insert (Singleton gestations excluding mosaicics)

Fetal sex results concordance		
100% XX, XY, XXX, XXY	90.5% XO	91.7% XYY

DISCLAIMER

Non-invasive prenatal screening based on the analysis of the cell-free DNA cannot be considered diagnostic tests. The results should be interpreted with all the clinical information available by the prescribing physician to provide appropriate advice on pregnancy management. No irreversible clinical decisions should be made based solely on these results. A result consistent with the presence of a chromosomal abnormality should be confirmed by a diagnostic test performed on a fetal sample.