PATIENT INFORMED CONSENT

VERACITY is a laboratory-developed Non-Invasive Prenatal Test (NIPT) for trisomies of 13,18,21, and upon request aneuploidies of X,Y and fetal gender. The test is safe for both the fetus and the mother. It requires two tubes of blood (20ml) from the pregnant woman using standard phlebotomy practices.

VERACITY is available for singleton and twin pregnancies including in-vitro fertilization (IVF) pregnancies of at least 10 weeks of gestation. Twin pregnancies are not eligible for X and Y aneuploidy detection. Patients with malignancy or a history of malignancy, patients with bone marrow or organ transplant, as well as pregnancies conceived through in-vitro fertilization (IVF) with surrogate egg donation or use of a surrogate mother are not eligible for the test. Twin pregnancies in which loss of a fetus occurred are not eligible. In a small number of cases the amount of fetal DNA present in maternal blood (fetal fraction), is not sufficient for analysis and a redraw may be requested.

The VERACITY non-invasive prenatal test is not intended and is not validated for the detection of mosaicism, partial trisomy or translocations. A positive result for twin pregnancies indicates the presence of at least one affected fetus. In twin pregnancies, detection of Y indicates the presence of at least one male fetus, while absence of Y indicates the presence of two female fetuses. Although this test is highly accurate, there is still a possibility that not all aneuploid fetuses will be detected. A negative result does not always ensure an unaffected pregnancy due to test limitations related to biological reasons. In addition, there is a small possibility that the detected chromosomal abnormality is caused by placental mosaicism or maternal chromosomal changes or other rare events. The VERACITY test is not diagnostic and results should be considered in the context of other clinical criteria. The referral doctor is responsible for counselling before and after the test including the provision of advice regarding the need for additional invasive genetic testing. It is recommended that a positive result is confirmed by amniocentesis.

Samples collected will be used for the purposes of performing the VERACITY test as requested on the sample information form. No additional clinical testing will be performed by NIPD Genetics. However, some sample may remain. As NIPD Genetics requires samples and test data for quality improvement and/or ongoing research efforts, an option is available below in 'Patient Consent' to grant permission to 'code' the remaining sample and test-data for such use. This means upon completion of the test, all personal information and details are removed, and the sample and test results are anonymized. No personal information will be associated with studies or publications.

PATIENT CONSENT

I hereby grant consent for my referral doctor for the collection and transport of a blood sample to NIPD Genetics at Neas Engomis 31, Nicosia, 2409 Cyprus. I also grant permission to NIPD Genetics to use this blood sample to test for trisomies of 13,18,21, and upon request aneuploidies of X,Y and fetal gender using their VERACITY test.

I attest that I have read, or have had read to me, this informed consent and that I understand it. I have had the opportunity to discuss with my referral doctor any aspect of this consent form including the benefits, risks and limitations of the VERACITY test, as well as the reasons for performing the test and availability of alternative testing options to my satisfaction.

I agree that my referral doctor collects my personal and clinical details such as is needed to complete the sample information form and that such details are provided to NIPD Genetics for the purposes of performing the VERACITY test. I affirm that all information provided is true to the best of my knowledge and that I will not hold NIPD Genetics responsible for any consequences as a result of untrue or inaccurate information.

I authorize NIPD Genetics to code, store and use leftover sample and test data for quality improvement and/or research purposes unless otherwise indicated.

☐ I do not authorize NIPD Genetics to store and use my coded sample and test data as described above.

Patient name: __________________________

Signature: __________________________

Date: __________________________

REFERRAL DOCTOR STATEMENT

I certify that the patient has been informed of the content of this consent including the benefits, risks, and limitations of the VERACITY test, and have obtained informed consent from the patient for performing the VERACITY test.

I attest the need to perform the VERACITY test to determine the risk for trisomies of 13,18,21, and upon request aneuploidies of X,Y and fetal gender as part of the patient’s medical care.

Referral Doctor name: __________________________

Signature: __________________________

Date: __________________________