VERACITY
non-invasive prenatal test

PATIENT INFORMATION		REFERRAL INFORMATION	
NAME **tt6 normal**		CLINIC NAME **XXXXXXXXXX**	
ID NUMBER **893247**		CLINIC ID **331**	
DATE OF BIRTH (DD/MM/YYYY) **02/03/1985**	GESTATIONAL AGE **Week: 12 Day: 0**	REFERRING CLINICIAN **Dr.XXXXXXXXXXX**	
IVF STATUS **No**	NUMBER OF FETUSES **One**	CLINIC FAX **000000000000000000**	

SAMPLE INFORMATION			
ORDER NUMBER **V302787**	LAB NUMBER **567567**	DATE OF COLLECTION (DD/MM/YYYY) **20/08/2017**	DATE RECEIVED (DD/MM/YYYY) **20/08/2017**

VERACITY PRENATAL SCREENING TEST RESULTS

NEGATIVE for aneuploidies and microdeletions

FETAL FRACTION
5.7%

CONDITION	REMARK
Trisomy 21	The results show very low risk for trisomy 21
Trisomy 18	The results show very low risk for trisomy 18
Trisomy 13	The results show very low risk for trisomy 13
Trisomy X	The results show very low risk for trisomy X
Monosomy X	The results show very low risk for monosomy X
XXY Constitution	The results show very low risk for XXY constitution
XYY Constitution	The results show very low risk for XYY constitution
Microdeletions: (DiGeorge,1p36 deletion syndrome,Smith-Magenis, Wolf Hirschhorn)	The results show very low risk for microdeletions (DiGeorge (22q11), 1p36 deletion syndrome, Smith-Magenis (17p11.2), Wolf Hirschhorn (4p16.3))
Presence of Y Chromosome	The results show the presence of Y chromosome

INTERPRETATION

The results show very low risk for all tested conditions. The fetal fraction is 5.7%, which is sufficient for analysis.The results should be communicated by the referring clinician with appropriate counselling.

TEST METHOD

VERACITY is a Laboratory Developed Test (LDT) from NIPD Genetics for prenatal screening that analyses cell-free DNA from maternal plasma. Multiplexed parallel analysis of specific regions of interest was applied for the copy number determination of chromosomes 13, 18, 21, aneuploidies of X, Y, select microdeletions including, DiGeorge (22q11 deletion), 1p36 deletion syndrome, Smith-Magenis (17p11.2 deletion), Wolf Hirschhorn (4p16.3 deletion) and Y detection.

TEST DESCRIPTION

Test performance is valid only for full chromosomal aneuploidies for chromosomes 21, 18, and 13 and upon request aneuploidies of X, Y, select microdeletions and Y detection. It does not exclude other chromosomal abnormalities, birth defects or other complications. VERACITY is available for singleton, twin and vanished twin pregnancies including in-vitro fertilization (IVF) pregnancies of at least 10 weeks of gestation. Singleton pregnancies conceived by IVF with egg donation are also eligible. Sex chromosome aneuploidies are not reportable for twin and vanished twin gestations. Patients with malignancy or a history of malignancy, patients with bone marrow or organ transplant, as well as twin and vanished twin pregnancies conceived through in-vitro fertilization (IVF) with egg donation or use of a surrogate mother are not eligible for the test.

Validation studies are carried out for all conditions by NIPD Genetics Public Company Limited. The test is not intended and not validated for mosaicism, triploidy, partial trisomy or translocations. A positive result for twin pregnancies indicates high risk for the presence of at least one affected fetus. In twin pregnancies, detection of Y indicates the presence of at least one Y chromosome. Although this test is highly accurate, there is still a small possibility for false positive or false negative results. This may be caused by technical and/or biological limitations, including but not limited to confined placental mosaicism (CPM) or other types of mosaicism, maternal constitutional or somatic chromosomal abnormalities, residual cfDNA from a vanished twin or other rare molecular events. This test has been validated on full region deletions and maybe unable to detect deletion of smaller regions. The test will not identify all deletions associated with each microdeletion syndrome. The VERACITY test is not diagnostic but a screening test and results should be considered in the context of other clinical criteria. Clinical correlation with ultrasound findings, and other clinical data and tests is recommended. If definitive diagnosis is desired, amniocentesis is necessary. The referral clinician is responsible for counselling before and after the test including the provision of advice regarding the need for additional invasive genetic testing.

The VERACITY non-invasive prenatal test development and performance evaluation was carried out by NIPD Genetics Public Company Limited, which is regulated under the Clinical Laboratory Improvement Act of 1998 (CLIA) as qualified to perform high-complexity testing. VERACITY is intended for clinical purposes and should not be regarded as investigational or for research. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA), which does not require this test to go through premarket FDA review.

Approved by: Elena Kypri, Ph.D, ASCP

Approved by: Philippos Patsalis, Ph.D, HCLD, Laboratory Director

DATE OF REPORT (DD/MM/YYYY): **23/08/2017**

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