

PATIENT INFORMATION		REFERRAL INFORMATION	
NAME		CLINIC NAME MedEx-Lab Minsk	
ID NUMBER		CLINIC ID 17886	
DATE OF BIRTH (DD/MM/YYYY)	GESTATIONAL AGE Week: Day:	REFERRING CLINICIAN Ekaterina Venskevich	
IVF STATUS No	NUMBER OF FETUSES One	CLINIC FAX	

SAMPLE INFORMATION			
ORDER NUMBER	LAB NUMBER	DATE OF COLLECTION (DD/MM/YYYY) 12/04/2022	DATE RECEIVED (DD/MM/YYYY) 18/04/2022

VERACITY PRENATAL SCREENING TEST RESULTS	
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
Presence/Absence of Y Chromosome	The results show the presence of Y chromosome
VERY LOW RISK NIPT Results	
FETAL FRACTION	
13.6%	

INTERPRETATION
 The results show very low risk for all tested conditions. The fetal fraction is 13.6%, which is sufficient for analysis. Please consult Test Method and Test Description sections below for information on the method, performance and limitations of the test. The results should be communicated by the referring clinician with appropriate counselling.

TEST METHOD


VERACITY is a Laboratory Developed Test (LDT) from NIPD Genetics Public Company Ltd for prenatal screening that analyses cell-free DNA (cfDNA) from maternal plasma. Multiplexed parallel analysis of specific regions of interest was applied for the copy number determination of chromosomes 21, 18,13 and upon request aneuploidies of X, Y chromosomes, select microdeletion including, DiGeorge (22q11.2 deletion), 1p36 deletion syndrome, Smith-Magenis (17p11.2 deletion), Wolf Hirschhorn (4p16.3 deletion) and Y chromosome 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 chromosomes, select microdeletions and Y chromosome 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 or use of a surrogate mother 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, or recent transfusion, 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. 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 maybe requested.

Validation studies are carried out for all conditions by NIPD Genetics Public Company Ltd. The test is not intended and not validated for mosaicism, triploidy, partial trisomy or translocations. A very high risk 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 Ltd, 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: 
 DATE OF REPORT (DD/MM/YYYY): **28/04/2022**

Elena Kyri, Ph.D, ASCP

Approved by: 

Philippos Patsalis, Ph.D, HCLD, Laboratory Director