TECHNICAL BULLETIN

⊠NEW TEST □**TEST CHANGE**

NOTIFICATION DATE: 05/29/2025 EFFECTIVE DATE: Immediate

1T Maternal-Fetal Screen (1TMFS)

On the effective date, Northwell Health Laboratories will introduce First Trimester Maternal-Fetal Screening using ThermoFisher BRAHMS Kryptor Gold Immunoanalyzers based on Time-Resolved Amplified Cryptate Emission TRACE technology.

The 1T Maternal-Fetal Screen combines the First Trimester Aneuploidy (1TANEU) and Preterm Preeclampsia (1TPTPE) screening tests into a single test. 1TMFS includes the ultrasound evaluations of Nuchal Translucency (NT), fetal Nasal Bone (NB)(optional) and Uterine Artery Doppler Pulsatility Index (UtAD-PI), incorporates the biophysical measurements of Body Mass Index (BMI) and Mean arterial Pressure (MAP), and measures the first trimester maternal serum analytes AFP, free-βhCG, Inhbin-A, PAPP-A and PIGF. A comprehensive risk report provides patient specific risks for Down syndrome, Trisomy 13/18 and pre-term preeclampsia.

The test does not screen for Open Neural Tube Defects (ONTD'S)

Regardless of risk results, extreme analyte results (free $\beta hCG \le 1^{st}$ percentile or PAPP-A $\le 5^{th}$ percentile) will be flagged and valuable comments and references will be provided regarding the risk of other potential adverse pregnancy outcomes such as preterm birth < 34 weeks, fetal loss < 24 weeks, fetal loss ≥ 24 weeks, low birth weight and preeclampsia.

Test Requirement/Parameters	1T Maternal-Fetal Screen	
Analyte(s):	AFP, free-βhCG, Inhibin-A, PAPP-A and PIGF.	
Method:	Time-Resolved Amplified Cryptate Emission (TRACE)	
Specimen Requirements:	Maternal Serum	
Submission Container/Tube:	Gold top serum separator tube	
Specimen Volume/Minimum Volume:	3ml (0.5 ml min)	
Gestational Age Range:	10w0d - 13w6d	
Collection Instructions:	Allow blood to clot, avoiding hemolysis. Separate serum from cells by centrifugation. Transport spun tube to testing laboratory.	
Specimen Stability:	Room Temperature 6 days Refrigerated 14 days	

Ultrasound	NT, NB and UtAD-PI are assessed when CRL is 45-84mm. Sonographer must be credentialed by the Fetal Medicine Foundation and the certification number must be provided. Ultrasound data is submitted to FMF on a regular basis for quality control		
Biophysical Information	Patient weight, height, left arm blood pressure and right arm blood pressure are required		
Reference Ranges:	Down Syndrome Risk T18/13 Risk	< 1/250 < 1/100	
	Pre-Term Preeclampsia Risk	< 1/100	
Computer Interface Code:	PDM # 251466		
Test Order:	1TMFS		