TECHNICAL BULLETIN

☒NEW TEST ☒TEST CHANGE

NOTIFICATION DATE: 09/26/2024
EFFECTIVE DATE: 09/30/2024

1T Aneuploidy Screen (1TANEU)

On the effective date, Northwell Health Laboratories will now perform first trimester aneuploidy screen testing (1TANEU) in-house using ThermoFisher BRAHMS Kryptor Gold Immunoanalyzers based on TRACE (Time-Resolved Amplified Cryptate Emission) technology improving overall screening efficiency and turnaround time.

1T Aneuploidy Screen is a first trimester screening test for the three most common fetal aneuploidies, trisomy 21, trisomy 18 and trisomy 13. The test combines the ultrasound evaluation of fetal nuchal translucency (NT) and fetal nasal bone (NB – Optional) with the first trimester maternal serum analytes AFP, free βhCG, Inhibin-A, PAPP-A and PlGF. An increased risk result means that further screening (NIPT) and/or diagnostic testing (CVS or amniocentesis) may be offered.

The test does not screen for Open Neural Tube Defects (ONTD'S) such as Open Spina Bifida (OSB) and Anencephaly (see 2T AFP).

Regardless of risk results, extreme analyte results (free βhCG ≤ 1%tile or PAPP-A ≤ 5%tile) 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.

The data from 1T ANEU may later be used as part 1 of a Sequential screen when a 2T Sequential Screen (2TSEQ) is ordered in the second trimester. The decision to perform sequential screening need not be determined at the time of the first trimester screen.

Test Requirement/Parameters	**New 1T Aneuploidy Screen**	**Previous Maternal Fetal First Trimester Screen First Trimester Screen Sequential 1**
Analyte(s):	AFP, free βhCG, Inhibin, PAPP-A and PlGF.	hCG, Inhibin A and PAPP-A
Method:	Time-Resolved Amplified Cryptate Emission (TRACE)	Chemiluminescent immunoassay
Specimen Requirements:	Maternal Serum	Maternal Serum
Submission Container/Tube:	Gold top serum separator tube	Gold top serum separator tube
Specimen Volume/Minimum Volume:	3ml (0.5 ml min)	3ml (0.5 ml min)
Gestational Age Range:	10w0d – 13w6d	10w0d – 13w6d

If you have any questions, please contact Client Services at (800) 472-5757.

Test Requirement/Parameters	New 1T Aneuploidy Screen	Previous Maternal Fetal First Trimester Screen First Trimester Screen Sequential 1
Collection Instructions:	Allow blood to clot, avoiding hemolysis. Separate serum from cells by centrifugation. Transport spun tube to testing laboratory.	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	Room temperature 7 days Refrigerated 14 days
Ultrasound	NT and NB 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	The NT measurement must be performed by a sonographer credentialed by the Fetal Medicine Foundation or other equivalent entity. The sonographer's credential/certification number must be provided
Reference Range:	Down Syndrome Risk < 1/250 T18/13 Risk < 1/100	Down Syndrome Risk < 1/250 T18/13 Risk < 1/100
Test Order:	**1TANEU**	**MFSTI LC** **ULTRA1 LC**
Computer Interface Code:	**PDM # 241467**	**PDM #211346** **PDM #221533**
CPT Code:	**AFP- 82105** **Free βhCG -84704** **Inhibin A – 86336** **PAPP-A – 84163** **PlGF - 83520**	**84163** **84702** **86336**

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