

☒NEW TEST ☒TEST CHANGE

NOTIFICATION DATE: 09/26/2024

EFFECTIVE DATE: 09/30/2024

2T Sequential Screen (2TSEQ)

On the effective date, Northwell Health Laboratories will now perform 2T Sequential Screen testing in-house using ThermoFisher BRAHMS Kryptor Gold Immunoanalyzers based on TRACE (Time-Resolved Amplified Cryptate Emission) technology and employing free β hCG instead of total hCG improving overall screening efficiency and turnaround time.

2T Sequential Screen combines a patient's previous 1T Aneuploidy screen (1TANEU) with a second trimester QUAD Screen to test for the two most common fetal aneuploidies, trisomies 21 and 18. The test also detects Open Neural Tube Defects (ONTD'S) such as Open Spina Bifida (OSB) and Anencephaly (see 2T AFP). 2T Sequential screen measures second trimester maternal serum AFP, Free beta hCG, Inhibin A and uE3. These results are then combined with the results with the patients first trimester PAPP-A, nuchal translucency (NT) and nasal bone (NB - optional). An increased risk result means that further screening (ultrasound, NIPT) and/or diagnostic testing (amniocentesis) may be offered.

Regardless of risk results, extreme analyte results (AFP MoM > 2.5 or < 0.25 , free β hCG MoM ≥ 2.5 , Inhibin A MoM > 2.0 , uE3 MoM < 0.5 or < 0.25 , and certain combinations as well as PAPP-A $\leq 5\%$ 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 < 24 weeks, fetal loss < 24 weeks, fetal loss > 24 weeks, low birth weight, placenta accreta, preeclampsia and Smith-Lemli-Opitz.

Test Requirement/Parameters	New 2T Sequential Screen	Previous Second Trimester Screen Sequential 2
Analyte(s):	AFP, free β hCG, Inhibin A and uE3	AFP, hCG Inhibin A and uE3
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:	15w0d – 21w6d 16w0d – 18w6d (optimal)	15w0d – 23w6d 16w0d – 18w6d (optimal)
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.

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

Test Requirement/Parameters	New 2T Sequential Screen	Previous Second Trimester Screen Sequential 2
Specimen Stability:	Room temperature 6 days Refrigerated 14 days	Room temperature 7 days Refrigerated 14 days
Additional Data:	From earlier 1TANEU: PAPP-A Nuchal Translucency (NT) Nasal bone (NB) (Optional)	From earlier Sequential 1: PAPP-A Nuchal Translucency (NT)
Reference Range:	Down Syndrome Risk < 1/270 T18 Risk < 1/100 ONTD Risk : AFP MoM < : Singleton: 2.5 Black: 2.8 IDD: 1.95 Twins 5.0	Down Syndrome Risk < 1/270 T18 Risk < 1/100 ONTD Risk - AFP MoM < : Singleton: 2.5 Black: 2.8 IDD: 2.0 Twins 4.5
Test Order:	2TSEQ	ULTRASCR LC
Computer Interface Code:	PDM # 241468	PDM #225275
CPT Code:	AFP- 82105 Free βhCG -84704 Inhibin A – 86336 uE3 – 82677 Alternative MAA Code - 81510	82105 82677 84702 86336

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