

☒NEW TEST ☒TEST CHANGE

NOTIFICATION DATE: JULY 23,2024

EFFECTIVE DATE: JULY 25, 2024

2T Quad Screen (QUAD)

On the effective date, Northwell Health Laboratories will perform the 2T Quad Screen test in-house replacing the Second Trimester Screen test currently performed at Labcorp. This new test will utilize the ThermoFisher BRAHMS Kryptor Gold Immunoanalyzers which are based on TRACE (Time-Resolved Amplified Cryptate Emission) technology and employ free β hCG instead of total hCG with improved overall screening efficiency and turnaround time.

2T Quad Screen is a second trimester screening test for the two most common fetal aneuploidies, trisomy 21 and trisomy 18. The test also detects Open Neural Tube Defects (ONTD'S) such as Open Spina Bifida (OSB) and Anencephaly (see 2T AFP). 2T Quad Screen incorporates the maternal serum markers AFP, free β hCG, Inhibin A and uE3. 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), 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 Quad Screen	Current Second Trimester Screen, QUAD
Analytes:	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.
Specimen Stability:	Room Temperature 6 days Refrigerated 14 days	Room temperature 7 days Refrigerated 14 days
Reference Range:	Down Syndrome Risk $\leq 1/270$ T18 Risk $\leq 1/100$ ONTD Risk : AFP MoM \leq : Singleton: 2.5 IDD: 1.95 Black: 2.8 Twins 5.0	Down Syndrome Risk $\leq 1/270$ T18 Risk $< 1/100$ ONTD Risk - AFP MoM \leq : Singleton: 2.5 IDD: 2.0 Black: 2.8 Twins 4.5
Computer Interface Code:	PDM # 241466	PDM #225707
Test Order:	QUAD	QUAD LC

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