

TECHNICAL BULLETIN

☒NEW TEST ☒TEST CHANGE

NOTIFICATION DATE: 11/22/2022

EFFECTIVE DATE: 12/05/2022

Non-Invasive Prenatal Testing (NIPT)

On the effective date, Northwell Health Laboratories will update the Non-Invasive Prenatal Testing. This testing will now be sent directly to Illumina Laboratories™ using the test codes **Verifi** and **VerifiMD**. The current tests, Claritest NIPT and Claritest NIPT with 22q 11.2 Deletion will be discontinued. The Illumina NIPT shows $\geq 99.9\%$ sensitivity and specificity for detection of trisomies 13, 18, 21 and offers the option of detection of microdeletion or duplication syndromes $\geq 7\text{Mb}^1$. It is the most well-studied NIPT platform with the lowest published failure rate². Please note: Verifi and VerifiMD tests require one Black and Tan speckle top Streck tube. The white top Roche tubes will not be accepted. Any white top Roche tubes received will be sent to Bioreference for the ClariNIPT test.

Test Requirement/Parameters	New Requirement Verifi, Verfi with mMD	Previous Requirement “Claritest NIPT” and “Claritest NIPT with 22q11.2 deletion”
Method:	Whole genome next generation sequencing, Illumina platform	Microarray quantitation including DANSR assay and the FORTE algorithm
Specimen Requirements:	10 mL whole blood Minimum- 7ml	10-15 mL whole blood Minimum each tube- 7ml
Container/Tube:	One Streck BCT tube	Two Cell-free DNA white top Roche tube
Specimen Stability:	Room Temperature- 5 days	Room Temperature - 5 days
Computer Interface Code:	Verifi PDM # 1459886, Verifi with MD PDM #1559072	Claritest PDM# 1759835 Claritest w/22q deletion PDM# 1759834
Test Order:	VERIFI, VERIFIMD	ClariNIPT, ClariNIPTM

If you have any questions, please contact Client Services at (516) 719-1100

1. Pertile MD, Flowers N, Vavrek D, et al. Performance of a Paired-End Sequencing-Based Noninvasive Prenatal Screening Test in the Detection of Genome-Wide Fetal Chromosomal Anomalies. Clin Chem. 2021;67(9):1210-1219. doi:10.1093/clinchem/hvab067
2. Illumina, Inc. Analytical Validation of the verifi® prenatal test: Enhanced Test Performance for Detecting Trisomies 21, 18, and 13 and the Option for Classification of Sex Chromosome Status. 2012.