Annex to the Certificate of Accreditation No. M-066 dated 01.09.2026.

The Annex is an integral part of the Certificate of Accreditation

Scope of Accreditation

Accredited body: TRISOMYtest, s. r. o.
Novozámocká 67, 949 05 Nitra

Organizational unit performing the activity of the accredited body:
Laboratory

Place of performance of the accredited body:
Novozámocká 67, 949 05 Nitra

Identification number of the accredited body: 615/M-066

Laboratory with fixed scope

Item	Object of examination		Established method		Other specifications (equipment, workplace etc.)
	Biological material / Matrix	Analyte / Parameter	Principle	Identification	
1.	Whole blood, Plasma, Isolated DNA	Trisomies of chromosomes 21, 18 and 13	Massively parallel sequencing	SOP 01 (Ref. No. 1 – 12)	NextSeq 550 / NextSeq 2000 TRISOMY test
2.		Trisomies of chromosomes 21, 18 and 13, aneuploidies of sex chromosomes and panel of microdeletions	Massively parallel sequencing	SOP 02 (Ref. No. 1 – 12)	NextSeq 550 / NextSeq 2000 TRISOMY test +
3.		Trisomies of chromosomes 21, 18 and 13 and aneuploidies of sex chromosomes	Massively parallel sequencing	SOP 03 (Ref. No. 1 – 12)	NextSeq 550 / NextSeq 2000 TRISOMY test XY

References:

1. Streck CELL-Free DNA BCT (www.streck.com)
2. QIAamp DNA Blood Mini Kit, Qiagen, QIAamp DNA Mini Blood Mini Handbook -EN, PN 51104 (www.qiagen.com)
3. Qubit dsDNA HS (High Sensitivity) Assay Kit, ThermoFisher, User Guide: Qubit dsDNA HS Assay Kits, PN Q32854 (www.thermofisher.com)
4. TruSeq Nano DNA Library Preparation Kit, Illumina, TruSeq Nano DNA Library Preparation Kit Reference Guide June 2015, PN FC-121-4003 (www.illumina.com)
5. Watchmaker DNA Library Prep Kit, Watchmaker Genomics, Watchmaker DNA Library Prep Kit User Guide, PN 7K0102-096 (https://www.watchmakergenomics.com/media/wg/asset/%2Fm%2F1%2Fm168_erat_ug_wmg0043_v2-2_0725.pdf)
6. Agilent High Sensitivity DNA Kit, Agilent Technologies, Agilent High Sensitivity DNA Kit Guide Nov 2013, PN 5067-4626 (www.genomics.agilent.com)
7. NextSeq 500/550 High Output v2.5 Kit, PN 20024906; NextSeq 500 System Guide June 2019, PN SY-415-1001; NextSeq 550 System Guide June 2019, PN SY-415-1002 (https://www.illumina.com/products/by-type/sequencing-kits/cluster-gen-sequencing-reagents/nextseq-series-kits-v2-5.html; https://support.illumina.com/content/dam/illumina-support/documents/documentation/system_documentation/nextseq/nextseq-500-system-guide-15046563-06.pdf; https://support.illumina.com/content/dam/illumina-support/documents/documentation/system_documentation/nextseq/nextseq-550-system-guide-15069765-06.pdf)
8. NextSeq 1000/2000 P2/P3 XLEAP-SBS Reagent Kit, PN 20100987/ 20100990; NextSeq 2000 Sequencing System, PN 20038897; NextSeq 1000/2000 Product Documentation (https://www.illumina.com/products/by-type/sequencing-kits/cluster-gen-sequencing-reagents/nextseq-1000-2000-reagents.html#tabgroup-1-tab2 ; https://support-docs.illumina.com/IN/NextSeq10002000/Content/IN/FrontPages/NextSeq10002000.htm)
9. Fan HC, Blumenfeld YJ, et al. (2008). "Noninvasive diagnosis of fetal aneuploidy by shotgun sequencing DNA from maternal blood." Proc Natl Acad Sci USA 105 (42): 16266-71. doi: 10.1073/pnas.0808319105. Epub 2008 Oct 6.
10. Minarik G., Repiska G., et al (2015). „Utilization of Benchtop Next Generation Sequencing Platforms Ion Torrent PGM and MiSeq in Noninvasive Prenatal Testing for Chromosome 21 Trisomy and Testing of Impact of In Silico

record number: 12837/714505

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and Physical Size Selection on Its Analytical Performance." PlosONE 10 (12): e0144811. doi: 10.1371/journal.pone.0144811. eCollection 2015.

11. Gil MM, Accurti V, et al (2017) "Analysis of cell-free DNA in maternal blood in screening for aneuploidies: updated meta-analysis." Ultrasound Obstet Gynecol Apr 11. doi: 10.1002/uog.17484.
12. Zhao CH, Tynan J, Ehrich M, et al.(2015) "Detection of Fetal Subchromosomal Abnormalities by Sequencing Circulating Cell-Free DNA from Maternal Plasma" Clin Chem 61 (4): 608-616.

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