



TURKISH ACCREDITATION AGENCY

ACCREDITATION CERTIFICATE

As a Medical Testing Laboratory

GENTAN ÖZEL SAĞLIK HİZMETLERİ ANONİM ŞİRKETİ

Central Address: KAZIMDIRİK MAH. ÜNİVERSİTE CAD. NO:79/11 BORNOVA İzmir / Türkiye

is accredited in accordance with TS EN ISO 15189:2013 standard within the scope given in Annex following the assessment conducted by TURKAK.

Accreditation Number : AB-0068-TL

Accreditation Date : 05.02.2021

Revision Date / Number : 10.11.2023 / 04

This certificate shall remain in force until **03.02.2025**, subject to continuing compliance with the standard **TS EN ISO 15189:2013**, related regulations and requirements.

Gülden Banu Müderrisoğlu
Secretary General




Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) in the scope of ISO 15189.

This document has been signed by Gülden Banu Müderrisoğlu with a secure electronic signature in accordance with the electronic signature law numbered 5070. Use the QR code to verify the e-signed document.

 <p>Medical Testing TS EN ISO 15189 AB-0068-TL</p>	GENTAN ÖZEL SAĞLIK HİZMETLERİ ANONİM ŞİRKETİ		
	Accreditation Nr: AB-0068-TL Revision Nr: 04 Date: 10.11.2023		
Medical Testing Laboratory			
Address : KAZIMDIRİK MAH. ÜNİVERSİTE CAD. NO:79/11 BORNOVA İzmir / Türkiye		Phone : +90 232 463 8287 Fax : +90 232 463 6482 Email : gentan@gentan.com Website : www.gentan.com	


Genetic Testing			
Medical Fields, Materials or Products Examined / Tested	Examination-Test-Parameter	Testing Method (National, International Standards, In-house Methods (SOP)/ Equipment/Techniques Used	Taking Primary Samples
Peripheral Blood, Bone Marrow, Chorionic Villus, Cord Blood, Amniotic Fluid, Skin Biopsy	Chromosome Analysis from Tissue Culture	GNT.LAB.TÇT.02 Cytogenetics Test Work Instructions G Band, C Band Manual	Peripheral Blood, Bone Marrow, Chorionic Villus, Cord Blood, Amniotic Fluid, Skin Biopsy
Peripheral Blood, Bone Marrow, Chorionic villus, Cord Blood, Amniotic Fluid, Skin Biopsy	Chromosome Analysis from Cell Culture	GNT.LAB.TÇT.02 Cytogenetics Test Work Instructions G Band, C Band Manual	Peripheral Blood, Bone Marrow, Chorionic Villus, Cord Blood, Amniotic Fluid, Skin Biopsy
Peripheral Blood, Chorionic Villus, Amniotic Fluid, Serum, Fresh Tissue, Paraffin Tissue, Cervical and Urogenital Swab	DNA Isolation	DNA Isolation GNT.LAB.TÇT.14 Manual DNA Isolation Test Work Instructions Manual	Peripheral Blood, Chorionic Villus, Amniotic Fluid, Fresh Tissue, Paraffin Tissue, Cervical And Urogenital Swab
Nucleic Acid Isolate	Fragment Analysis (Factor V Leiden Mutation)	Fragment Analysis GNT.LAB.TÇT.08 Thrombophilia 7-Panel Test Work Instructions Applied Biosystems Hitachi 3130XL Genetic Analyzer	Peripheral Blood
Nucleic Acid Isolate	Fragment Analysis (Factor II (20210) Prothrombin Mutation)	Fragment Analysis GNT.LAB.TÇT.08 Factor II (20210) Thrombophilia 7-Panel Factor II (20210) Prothrombin Test Work Instructions Applied Biosystems Hitachi 3130XL Genetic Analyzer	Peripheral Blood
Nucleic Acid Isolate	Fragment Analysis (MTHFR (677) Mutation)	Fragment Analysis GNT.LAB.TÇT.08 MTHFR (677) Thrombophilia 7-Panel Test Work Instructions Applied Biosystems Hitachi 3130XL Genetic Analyzer	Peripheral Blood
Peripheral Blood, Chorionic Villus, Amniotic Fluid, Serum, Fresh Tissue, Paraffin Tissue, Cervical and Urogenital Swab	RNA Isolation	RNA Isolation Method GNT.LAB.TÇT.09 Manual RNA Isolation Test Work Instructions Manual	Blood, Chorionic Villus, Amniotic Fluid, Fresh Tissue, Paraffin Tissue, Cervical and Urogenital Swab
Nucleic Acid Isolate	Investigation of Mutations in Single Gene Diseases (MEFV,HBB,BTD,BRCA1,BRCA2,CFTR)	Next Generation Sequencing GNT.LAB.TÇT.25 Next Generation Sequencing Tests Work Instructions MGISEQ-2000	Blood
Nucleic Acid Isolate	Searching for Mutations at the DNA level Comprehensive Exonic Profiling Analysis (Whole Exome Sequencing, WES)	Next Generation Sequencing GNT.LAB.TÇT.23 Whole Exom Sequencing Test Work Instructions MGISEQ-2000	Blood
Nucleic Acid Isolate	Searching for Mutations at the DNA level Exonic Profiling Analysis (Clinical Exome Sequencing, CES)	Next Generation Sequencing GNT.LAB.TÇT.24 Clinical Exom Sequence Test Work Instructions MGISEQ-2000	Blood



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Address : KAZIMDIRİK MAH. ÜNİVERSİTE CAD. NO:79/11 BORNOVA İzmir / Türkiye		Phone : +90 232 463 8287 Fax : +90 232 463 6482 Email : gentan@gentan.com Website : www.gentan.com	
Nucleic Acid Isolate	Fragment Analysis (QF PCR)	Fragment Analysis GNT.LAB.TÇT.17 QF-PCR Test Work Instructions Applied Biosystems Hitachi 3130XL Genetic Analyzer	Whole Blood, Chorionic Villus, Amniotic Fluid, Fresh Tissue, Paraffin Tissue, Cervical and Urogenital Swabs
Nucleic Acid Isolate	Searching for Mutations at the DNA level Mitochondrial Genome (mtDNA) Sequence Analysis	Next Generation Sequenceing GNT.LAB.TÇT.19 mtDNA Sequence Analysis Test Work Instructions MGISEQ-2000	Blood
Nucleic Acid Isolate	mTP-PCR Analysis (Fragile X)	Fragment Analysis GNT.LAB.TÇT.20 Fragil X Analysis Test Work Instructions Applied Biosystems Hitachi 3130XL Genetic Analyzer	Blood
Nucleic Acid Isolate	Qualitative Detection of Mutations (HLA DQ2, HLA DQ8)	Real Time PCR Method GNT.LAB.TÇT.22 HLA DQ2/DQ8 Analysis Test Work Instructions Applied Biosystems 7500 Fast Real-Time PCR	Blood
Nucleic Acid Isolate	MLPA (SMN1, SMN2)	MLPA GNT.LAB.TÇT.21 MLPA Analysis Test Work Instructions Applied Biosystems Hitachi 3130XL Genetic Analyzer	Blood
Hematological Blood, Bone Marrow	FISH (17p13 deletion TP53))	FISH Method Interphase FISH Analysis GNT.LAB.PR.11 FISH Analysis Test Procedure Manual	Hematological Blood, Bone Marrow
Hematological Blood, Bone Marrow	FISH (Trisomy/Monosomy 8)	FISH Method Interphase FISH Analysis GNT.LAB.PR.11 FISH Analysis Test Procedure Manual	Hematological Blood, Bone Marrow
Hematological Blood, Bone Marrow	FISH (t(11;14) [CCND1/IGH])	FISH Method Interphase FISH Analysis GNT.LAB.PR.11 FISH Analysis Test Procedure Manual	Hematological Blood, Bone Marrow
Hematological Blood, Bone Marrow	FISH (t(9;22) BCR;ABL)	FISH Method Interphase FISH Analysis GNT.LAB.PR.11 FISH Analysis Test Procedure Manual	Hematological Blood, Bone Marrow
RNA	Quantitative Detection of Molecular Changes [t(9;22)]	Real Time PCR Method GNT.LAB.TÇT.34 t(9;22) Test Work Instructions Biorad CFX96 Real Time System	Peripheral Blood, Bone Marrow
DNA	Detection of Mutations (JAK2V617F)	Real Time PCR Method GNT.LAB.TÇT.18 JAK-2V617F Real Time PCR Test Work Instructions Biorad CFX96 Real Time System	Peripheral Blood, Bone Marrow



Accreditation Scope

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DNA / cfDNA	KRAS, NRAS, BRAF, EGFR Mutation Analysis	Real Time PCR Method GNT.LAB.TÇTÇ.31 KRAS Test Work Instructions, GNT.LAB.TÇTÇ.32 NRAS,BRAF Tests Work Instructions, GNT.LAB.TÇTÇ.33 EGFR Test Work Instructions, Roshe Cobas Z480	Peripheral Blood, Tissue, liquid biopsy, Plasma
DNA	Investigation of Mutations in Single Gene Diseases (HBB)	Sanger Sequence Analysis GNT.LAB.TÇT.37 HBB Gene Sanger Sequence Analysis Test Work Instructions, Applied Biosystems Hitachi 3130XL Genetic Analyzer	Peripheral Blood

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