



# CERTIFICATE OF ACCREDITATION

## ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

**Medical Center CITO Ltd.**  
**0179, Paliashvili Str. 40**  
**Tbilisi Georgia**

has been assessed by ANAB and meets the requirements of international standard

**ISO 15189:2012**

while demonstrating technical competence in the fields of

**MEDICAL AND CLINICAL LABORATORIES**

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

AM-2063

Certificate Number

  
ANAB Approval

Certificate Valid Through: 07/06/2020  
Version No. 005 Issued: 06/18/2019





**SCOPE OF ACCREDITATION TO ISO 15189:2012**

**Medical Center CITO Ltd.**

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**MEDICAL/CLINICAL TESTING**

Valid to: **July 6, 2020**

Certificate Number: **AM-2063**

**General Laboratory (Clinical)**

Sub-Specialty	Test-analyte	Method	Matrix
General Chemistry	Alanine Aminotransferase	IFCC, but without pyridoxal-5'-phosphate	Serum, Plasma
General Chemistry	Aspartate Aminotransferase	IFCC, but without pyridoxal-5'-phosphate	Serum, Plasma
General Chemistry	Alkaline phosphatase	Colorimetric assay, IFCC, DGKC	Serum, Plasma
General Chemistry	$\gamma$ -Glutamyltransferase	Enzymatic colorimetric assay (acc. To Szasz and IFCC)	Serum, Plasma
General Chemistry	$\alpha$ -Amylase	Enzymatic colorimetric assay acc. to IFCC Liquid stable Ethylidene blocked pNPG7	Serum, Urine
General Chemistry	Creatine Kinase	Standardized method acc. to DGKC and IFCC	Serum, Plasma
General Chemistry	Lactate Dehydrogenase	Standardized method acc. to DGKC, IFCC	Serum, Plasma
General Chemistry	Lipase	Enzymatic colorimetric assay with 1.2-O-dilauryl-rac-glycero-3-glutaric acid (6-methyl resorufin) ester as substrate	Serum, Plasma
General Chemistry	Albumin	Colorimetric assay with endpoint method (bromcresol green-BCG)	Serum
General Chemistry	Total Bilirubin	Diazo method, Vanadate oxidation method	Serum, Plasma



General Laboratory (Clinical)

Sub-Specialty	Test-analyte	Method	Matrix
General Chemistry	Direct Bilirubin	Diazo method, Vanadate oxidation method	Serum, Plasma
General Chemistry	Calcium	Colorimetric method - Calcium ions react with 5-nitro-5'-methyl-Barta (NM-BARTA) under alkaline conditions to form a complex. Colorimetric method – Arsenazo III.	Serum
General Chemistry	Magnesium	Colorimetric method with Chlorophosphonazo III, Colorimetric method with Xylidyl Blue	Serum
General Chemistry	Iron	FerroZine method	Serum
General Chemistry	Unsaturated Iron-Binding Capacity	Direct determination with FerroZine.	Serum
General Chemistry	Total Iron- Binding Capacity	Colorimetric method	Serum
General Chemistry	Phosphate (Inorganic)	UV Endpoint method with sample blanking (ammonium phosphomolybdate complex).	Serum
General Chemistry	Bicarbonate liquid	Bicarbonate reacts with phosphoenolpyruvate (PEP) in the presence of PEPC to produce oxaloacetate and phosphate	Serum, Plasma
General Chemistry	Creatinine	Colorimetric method- Enzymatic, colorimetric method Alkaline picrate	Serum, Urine
General Chemistry	Glucose	Enzymatic reference method with hexokinase and glucose oxidase	Serum
General Chemistry	Cholesterol	Enzymatic colorimetric (endpoint) method	Serum, Plasma
General Chemistry	LDL-Cholesterol	Homogeneous enzymatic (direct) colorimetric assay	Serum, Plasma
General Chemistry	HDL-Cholesterol	Homogeneous enzymatic (direct) colorimetric assay	Serum, Plasma
General Chemistry	Triglycerides	Enzymatic colorimetric test (GPO-PAP)	Serum, Plasma



General Laboratory (Clinical)

Sub-Specialty	Test-analyte	Method	Matrix
General Chemistry	Total Protein	Colorimetric assay (Biuret method)	Serum
General Chemistry	Uric Acid	Enzymatic colorimetric test	Serum, Plasma, Urine
General Chemistry	Urea / BUN	Kinetic test with urease and glutamate dehydrogenase	Serum, Plasma, Urine
General Chemistry	Tina-quant Hemoglobin A1c (Hemolysate Application)	Standardized method according to IFCC transferable to DCCT/NGSP. The HbA1c determination is based on the turbidimetric inhibition immunoassay (TINA) for hemolysed whole blood (using TTAB). Latex agglutination inhibition assay.	Whole blood
General Chemistry	Antistreptolysin O	Latex Enhanced Immunoturbidimetric assay	Serum
General Chemistry	C-Reactive Protein (Latex)	Particle enhanced immune-turbidimetric assay	Serum, Plasma
General Chemistry	Rheumatoid Factor	Latex agglutination	Serum
General Chemistry	Sodium	Ion-selective electrodes, using automatically diluted specimens ISE Indirect/ ISE Direct	Serum, Plasma, Urine
General Chemistry	Potassium	Ion-selective electrodes, using automatically diluted specimens ISE Indirect/ISE Direct	Serum, Plasma, Urine
General Chemistry	Chloride	Ion-selective electrodes, using automatically diluted specimens; ISE Indirect/ISE Direct	Serum, Plasma, Urine
Diagnostic Immunology	HBs Ag Ultra	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	HBsAg	Immunochromatography	Serum, whole blood, plasma
Diagnostic Immunology	HBsAb	Enzyme Linked Immunosorbent Assay Immunocapture, sandwich method	Serum. Plasma
Diagnostic Immunology	Anti-HBc Total	Enzyme Linked Fluorescent Assay based on an inhibition principle.	Serum, Plasma



General Laboratory (Clinical)

Sub-Specialty	Test-analyte	Method	Matrix
Diagnostic Immunology	HIV	Enzyme Linked Fluorescent Assay Sandwich method based on the combined detection of HIV1 p24 antigen, and anti HIV1 and anti-HIV2 immunoglobulins G and M (ELFA and ELISA)	Serum, Plasma
Diagnostic Immunology	HIV-1/2	Immunochemistry	Serum, whole blood, plasma
Diagnostic Immunology	Anti HCV	Two step enzyme immunoassay sandwich method with a final fluorescent detection of IgG antibodies to hepatitis C virus Immunochemistry	Serum, Plasma Serum, whole blood, plasma
Diagnostic Immunology	ANA	Indirect solid phase enzyme immunoassay (ELISA).	Serum, Plasma
Diagnostic Immunology	Toxoplasmosis IgM	Enzyme Linked Fluorescent Assay – Immunocapture	Serum
Diagnostic Immunology	Toxoplasmosis IgG	Enzyme Linked Fluorescent Assay. Indirect sandwich method	Serum, Plasma
Diagnostic Immunology	Rubella IgG	Enzyme Linked Fluorescent Assay. Indirect sandwich method	Serum, Plasma
Diagnostic Immunology	Rubella IgM	Enzyme Linked Fluorescent Assay – Immunocapture	Serum
Diagnostic Immunology	Cytomegalovirus IgG	Enzyme Linked Fluorescent Assay. Indirect sandwich method	Serum
Diagnostic Immunology	Cytomegalovirus IgM	Enzyme Linked Fluorescent Assay Indirect sandwich method with automated adsorption	Serum
Diagnostic Immunology	Epstein- Barr virus VCA IgM	Enzyme Linked Fluorescent Assay – Immunocapture	Serum
Diagnostic Immunology	Epstein- Barr virus VCA IgG	Two step enzyme immunoassay sandwich method with a final fluorescent detection	Serum
Diagnostic Immunology	Epstein- Barr virus EBNA IgG	Two step enzyme immunoassay sandwich method with a final fluorescent detection	Serum
Diagnostic Immunology	Herpes Simplex Virus Type 1+2 IgM	Enzyme Linked Immunosorbent Assay Sandwich method	Serum, Plasma



General Laboratory (Clinical)

Sub-Specialty	Test-analyte	Method	Matrix
Diagnostic Immunology	Herpes Simplex Virus Type 1+2 IgG	Enzyme Linked Immunosorbent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	Chlamydia trachomatis IgM	Enzyme Linked Immunosorbent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	Chlamydia trachomatis IgG	Enzyme Linked Immunosorbent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	Chlamydia trachomatis IgA	Enzyme Linked Immunosorbent Assay Sandwich method, Indirect Antibody EIA	Serum, Plasma
Diagnostic Immunology	Thyroid-stimulating hormone	Enzyme Linked Fluorescent Assay Sandwich method ELFA Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Free thyroxine	Immunoassay competition method, ELFA Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Free triiodothyronine	Enzyme Linked Fluorescent Assay Immunoassay competition method ELFA Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Thyroid peroxidase autoantibodies (anti TPO)	Enzyme Linked Fluorescent Assay Two step enzyme immunoassay sandwich method Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Thyroglobulin autoantibodies (anti-Tg)	Enzyme Linked Fluorescent Assay Two step enzyme immunoassay sandwich method Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Thyroglobulin (Tg)	Indirect Enzyme Linked Immunosorbent Assay	Serum
Diagnostic Immunology	Total IgE	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	C-Peptide	Enzyme Linked Immunosorbent Assay based on the principle of competitive binding Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma





General Laboratory (Clinical)

Sub-Specialty	Test-analyte	Method	Matrix
Diagnostic Immunology	Insulin	Enzyme Linked Immunosorbent Assay Sandwich method Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Human Chorionic Gonadotropin	Enzyme Linked Fluorescent Assay Sandwich method Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Luteinizing hormone	Sandwich method, ELFA, ELISA	Serum, Plasma
Diagnostic Immunology	Prolactin	Enzyme Linked Fluorescent Assay Sandwich method Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Progesterone	Enzyme Linked Fluorescent Assay Sandwich method. Immunoassay competition method Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	17- $\alpha$ -OH Progesterone	Enzyme Linked immunosorbent Assay, based on the principle of competitive binding	Serum, Plasma
Diagnostic Immunology	Estradiol	Enzyme Linked Fluorescent Assay. Immunoassay competition method	Serum, Plasma
Diagnostic Immunology	Testosterone	Enzyme Linked Fluorescent Assay. Immunoassay competition method	Serum, Plasma
Diagnostic Immunology	Free Testosterone	Enzyme Linked Immunosorbent Assay Competitive immunoenzymatic colorimetric method	Serum, Plasma
Diagnostic Immunology	DHEA-S	Enzyme Linked Immunosorbent Assay, based on the principle of competitive binding. Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Follicle stimulating hormone	Enzyme Linked Fluorescent Assay Sandwich method Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	Anti-Mullerian hormone	Enzyme Linked Fluorescent Assay (ELFA) Three step sandwich type immunoassay (ELISA)	Serum, Plasma



**General Laboratory (Clinical)**

<b>Sub-Specialty</b>	<b>Test-analyte</b>	<b>Method</b>	<b>Matrix</b>
Diagnostic Immunology	CA 15-3	Enzyme Linked Fluorescent Assay Sandwich method Chemiluminescent Microparticle Immunoassay (CMIA)	Serum, Plasma
Diagnostic Immunology	CA 19-9	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	CA 125	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	AFP	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	CEA	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	TPSA	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	D-Dimer	Enzyme Linked Fluorescent Assay Two-step enzyme immunoassay sandwich method	Plasma
Diagnostic Immunology	Troponin I	Enzyme Linked Fluorescent Assay Sandwich method (One step)	Serum, Plasma
Diagnostic Immunology	Ferritin	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	25 OH Vitamin D	Enzyme Linked Fluorescent Assay Sandwich method	Serum, Plasma
Diagnostic Immunology	Cortisol	Enzyme Linked Fluorescent Assay Immunoassay competition method	Serum, Plasma
Diagnostic Immunology	PTH intact	Enzyme Linked Immunosorbent Assay based on the sandwich principle. Chemiluminescent Microparticle Immunoassay (CMIA)	Serum
Diagnostic Immunology	Calcitonin	Enzyme Linked Immunosorbent Assay based on the sandwich principle.	Serum
Diagnostic Immunology	Adrenocorticotrophic Hormone(ACTH)	Two-Site Enzyme Linked Immunosorbent Assay	Plasma
Diagnostic Immunology	Anti-TSH-Receptor (TRAb)	Enzyme Linked Immunosorbent Assay, competitive method	Serum
Diagnostic Immunology	PAPP-A	Enzyme Linked Immunosorbent Assay based on the sandwich principle.	Serum, Plasma





General Laboratory (Clinical)

Sub-Specialty	Test-analyte	Method	Matrix
Diagnostic Immunology	Vitamin B12 (active)	Enzyme immunoassay for the quantitative determination of holotranscobalamin (Holo TC) in human serum. Chemiluminescent Microparticle Immunoassay (CMIA)	Serum
Diagnostic Immunology	Anti CCP	Enzyme Linked Immunosorbent Assay Sandwich method	Serum
Diagnostic Immunology	QuantiFERON-TB Gold Plus (QFT-Plus)	The whole blood IFN- $\gamma$ test measuring responses to ESAT-6 and CFP-10 peptide antigens (ELISA).	Whole Blood
Hematology	Complete blood count- CBC Celltac F 5D	Impedance Spectrophotometric - Cyanmethemoglobin optical detection Light scatter by laser	Blood
Hematology	Complete blood count- CBC SFRI HEMIX 5-60	Spectrophotometry for HGB Volumetric impedance change for WBC, RBC, PLT Light scattering measurement: LYM, MON, NEU, EOS, BASO	Blood
Hematology	Erythrocyte Sedimentation Rate- ESR	Westergren Method	Blood
Urinalysis	Complete Urine analyze	Reflectance photometry, Microscopy	Urine
Microscopy	Common analyze in fecal	Native samples Microscopy	Fecal
Diagnostic Immunology	Fecal occult blood test	Immuno-chromatographic method	Fecal
Semen Analysis	Spermogram - semen clinical analysis	Native and stained Microscopy	Semen
Microscopy	Common test in sputum	Native and stained Samples Microscopy	Sputum
Coagulation	Prothrombin Time, Index, INR	Clotting time detection	Plasma
Coagulation	APTT	Clotting time detection	Plasma
Coagulation	Fibrinogen	Clotting time detection	Plasma
Hematology	Blood group and rhesus factor	Agglutination	Blood



General Laboratory (Clinical)

Sub-Specialty	Test-analyte	Method	Matrix
Bacteriology	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Enterococcus</i> , <i>Neisseria</i> , <i>Haemophilus</i> , <i>Enterobacteriaceae</i> , Non fermenting gr(-) bacteria, <i>Corynebacteria</i> , <i>Listeria</i> , Yeasts, Anaerobes	Cultural, colorimetric / photo colorimetric	Blood
Bacteriology	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Enterococcus</i> , <i>Enterobacteriaceae</i> , Non fermenting gr(-) bacteria, <i>Corynebacteria</i> , Yeasts, Anaerobes	Microscopic, Cultural (quantitative) Colorimetric / photo colorimetric	Urine
Bacteriology	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Enterococcus</i> , <i>Neisseria</i> , <i>Haemophilus</i> , <i>Enterobacteriaceae</i> , Non fermenting gr(-) bacteria, <i>Corynebacteria</i> , <i>Listeria</i> , Yeasts, Anaerobes, <i>Gardnerella</i> , <i>Trichomonas vaginalis</i>	Microscopic, Cultural Colorimetric / photo colorimetric, Immuno- chromatographic method	Urogenital discharge
Molecular Microbiology	<i>Ureaplasma</i> spp. <i>Mycoplasma hominis</i>	Cultural (Semi-quantitative) / Colorimetric Dilution test method in Semi-Solid Agar	Urogenital discharge
Bacteriology	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Neisseria</i> , <i>Haemophilus</i> , <i>Enterobacteriaceae</i> , Non fermenting gr(-) bacteria, <i>Listeria</i> , Yeasts, Anaerobes	Microscopic, Cultural Colorimetric / photo colorimetric	Spinal fluid and other biological sterile fluids



General Laboratory (Clinical)

Sub-Specialty	Test-analyte	Method	Matrix
Bacteriology	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Moraxella</i> , <i>Neisseria</i> , <i>Haemophilus</i> , <i>Enterobacteriaceae</i> , <i>Corynebacteria</i> , Yeasts	Cultural, Colorimetric / photo colorimetric	Upper respiratory tract
Bacteriology	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Moraxella</i> , <i>Neisseria</i> , <i>Haemophilus</i> , <i>Enterobacteriaceae</i> , Non-fermenting gr(-) bacteria, Yeasts, Anaerobes	Microscopic, Cultural (Semi-quantitative) Colorimetric / photo colorimetric	Lower respiratory tract
Bacteriology	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Enterobacteriaceae</i> , Non fermenting gr(-) <i>Corynebacteria</i> , Yeasts, <i>Moraxella</i> , <i>Neisseria</i> , <i>Haemophilus</i> , Anaerobes	Cultural Colorimetric / photo colorimetric	Purulent discharge (from eye and ear)
Bacteriology	<i>Staphylococcus</i> , <i>Streptococcus</i> , <i>Enterobacteriaceae</i> , Non fermenting gr(-) <i>Corynebacteria</i> , Yeasts, Anaerobes	Cultural Colorimetric / photo colorimetric	Purulent discharge (general)
Bacteriology	<i>Salmonella</i> spp., <i>Shigella</i> spp., Enteropathogenic <i>E.coli</i> , <i>Yersinia</i> <i>enterocolitica</i>	Cultural Colorimetric / photo colorimetric, Serology	Feces
Bacteriology	Investigation of large intestine microflora	Cultural (quantitative) Colorimetric / photo- colorimetric	Feces
Bacteriology	<i>Staphylococcus</i> , <i>Enterobacteriaceae</i> , Non fermenting gr(-)	Cultural Colorimetric / photo colorimetric,	Mother's milk



**General Laboratory (Clinical)**

Sub-Specialty	Test-analyte	Method	Matrix
Bacteriology	<i>Streptococcus</i> , <i>Enterobacteriaceae</i> , <i>Enterococcus</i> , Non fermenting gr(-) Yeasts, Anaerobes	Cultural Colorimetric / photo colorimetric	Duodenal content
Bacteriology	Antimicrobial Susceptibility Testing	Serial dilution method in a semi- solid agar (ATB, VITEK 2 Compact) / diffusion method (bio discs, E test)	Strain
Diagnostic Immunology	Syphilis	Flocculation reaction, Indirect hemagglutination reaction	Blood serum / plasma

**General Laboratory (Clinical)**

Sub-Specialty	Test-analyte	Method	Matrix
Molecular Microbiology	Chlamydia trachomatis- DNA	Real-time PCR	Urine, Genital swab
Molecular Microbiology	Neisseria gonorrhoea - DNA	Real-time PCR	Urine, Genital swab
Molecular Microbiology	Ureaplasma urealyticum and Ureaplasma parvum - DNA	Multiplex real-time PCR	Urine, Genital swab
Molecular Microbiology	Mycoplasma hominis and Mycoplasma genitalium - DNA	Multiplex real-time PCR	Urine, Genital swab
Molecular Microbiology	Human Papillomavirus (HPV) Genotyping	Multiplex real-time PCR	Genital swab
Molecular Microbiology	Hepatitis C virus (HCV) RNA – Qualitative and Quantitative	Real-time PCR	Serum

**Sampling**

Substance Sampled	Sampling Procedure
Blood ➤ Capillary ➤ Venous	Sampling Manual
Urogenital Sample (Genital Discharge)	Sampling Manual
Mucous membranes discharge of the upper respiratory tract, eye, ear	Sampling Manual

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AM-2063.



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Vice President

