SCHEDULE OF ACCREDITATION

TRINIDAD AND TOBAGO laboratory Accreditation Service

ALPHA INTERLAB CENTER N.V.

Medical Laboratory No.: LAS-001M

is an accredited Laboratory which fulfils the requirements of *ISO 15189:2012 – Medical laboratories - requirements for quality and competence*, and has demonstrated competence to carry out tests for:

CLINICAL TESTING

as specified in and at locations identified in this schedule. This document may be revised from time to time based on accreditation requirements. The most current issue is available on TTLABS website: https:\\gottbs.com/ttlabs

While this schedule remains valid, the Accredited Laboratory named above is authorized to issue TTLABS-endorsed certificates.

Karlene Carolyn Lewis

Manager, TTLABS

"Recognised as the official national laboratory accrediting body by the Ministry of Trade and Industry of the Republic of Trinidad and Tobago."

Initial Accreditation date: 28th June 2021

This schedule was re-issued on: 11th November 2021 **This schedule expires on: 27th June 2024**

"This laboratory is accredited in accordance with the recognized International Standard ISO 15189:2012. This accreditation demonstrated technical competence for a defined scope and the operation of a laboratory quality management system. (refer to joint ISO-ILAC-IAF Communiqué dated 18 June 2005)"

Medical Laboratory Number: **LAS-001M**

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Mercedes Oduber

Certificate of Accreditation
Issue No. : 01

Materials/Products Tested	Types of Tests/Properties Measured, Range of Measurement	Standard Specifications, Equipment/Techniques Used
Instruction: add rows as needed below and enter the FIELD where necessary (e.g. Chemical, Microbiological, Mechanical).		
CLINICAL CHEMISTRY **Serum**	**Alanine Transferase (ALT)** Linearity: ... - 666 U / L. The automatic repetition of the analyzer goes up to a maximum of 2264 U / L	**IMOLA** Randox SN 72320105 # 001 Tris buffer without P5P 37 °C
CLINICAL CHEMISTRY **Serum**	**Amylase (AMYL)** Linearity: up to 1245 U / L. The automatic repetition of the analyzer goes up to a maximum of 4357 U / L	**IMOLA** Liquid Ethylidene pNPG7 37 °C
CLINICAL CHEMISTRY **Serum**	**Albumin** Linearity: 0-50.6 g / L. The automatic repetition of the analyzer goes up to a maximum of 300 g / L	**IMOLA** Bromocresol Green
CLINICAL CHEMISTRY **Urine**	**Alkaline Phosphatase (ALP)** Linearity: up to 843 U / L. The automatic repetition of the analyzer goes up to a maximum of 3372 U / L	**IMOLA** Diethanolamine buffer DEA 37 °C
CLINICAL CHEMISTRY **Serum**	**Aspartate Aminotransferase (AST)** Linearity: up to 657 U / L. The automatic repetition of the analyzer goes up to a maximum of 2628 U / L, alternatively if the sample exceeds this value dilute 1 + 3 with NaCl 0.9% and re-test. Multiply by 4	**IMOLA** Tris buffer without P5P 37 °C
CLINICAL CHEMISTRY **Serum**	**CALCIUM** Linearity: 0 - 4.3 mmol / L. The automatic repetition of the analyzer	**IMOLA** Colorimetric Method Arsenazo III

	goes up to a maximum of 6.45 mmol / L	
CLINICAL CHEMISTRY **Serum**	**Calcium in Urine** Linearity: up to 5.91 mmol / L. The automatic repetition of the analyzer goes up to a maximum of 8.87 mmol / L	**IMOLA** Colorimetric Method Arsenazo III
CLINICAL CHEMISTRY **Serum /Urine**	**Creatinine** Linearity: up to 2844 µmol / L. The automatic repetition of the analyzer goes up to a maximum of 7821 µmol / L	**IMOLA** Alkaline picrate without deproteinization
CLINICAL CHEMISTRY **Serum**	**Cholesterol** Linearity: up to 16.6 mmol / L. The automatic repetition of the analyzer goes up to a maximum of 166 mmol / L	**IMOLA** Cholesterol Oxidase
CLINICAL CHEMISTRY **Serum**	**HDL Cholesterol** Linearity: up to 16.6 mmol / L. The automatic repetition of the analyzer goes up to a maximum of 166 mmol / L	**IMOLA** Colorimetric method. CRMLN traceable calibration
CLINICAL CHEMISTRY **Serum /Urine**	**Inorganic Phosphorous** Linearity: up to 10.0 mmol / L in serum and up to 112.5 mmol / L in urine. The automatic repetition of the analyzer goes up to a maximum of 15.0 mmol / L (in urine)	**IMOLA** UV method. NIST 186Ig traceable calibration
CLINICAL CHEMISTRY **Serum**	**Gamma-Glutamyl Transpeptide** Linearity: up to 1397 U / L. The automatic repetition of the analyzer goes up to a maximum of 5588 U / L	**IMOLA** Colorimetric method L-γ-Glutamyltransferase. IFCC. AD542 (IFCC) and JSCC TS01 traceable calibration
CLINICAL CHEMISTRY **Serum**	**Glucose** Linearity: up to 35 mmol / L.	**IMOLA** UV Hexokinase Method. Calibration
CLINICAL CHEMISTRY **Urine**	**Urine Glucose** Linearity: up to 45.2 mmol / L.	**IMOLA** UV Hexokinase Method. NIST 917b and NIST 965a traceable calibration
CLINICAL CHEMISTRY **Blood**	**Hemogloin A1c (HbA1c)** N/A	**IMOLA** Total hemoglobin: colorimetric method HbA1c fraction: latex agglutination by inhibition
CLINICAL CHEMISTRY **Serum**	**Potassium** Linearity: up to 10 mmol / L.	**IMOLA** ISE method

CLINICAL CHEMISTRY **Serum**	**Sodium** Linearity: up to 182 mmol / L	**IMOLA** ISE method
CLINICAL CHEMISTRY **Serum**	**Total Bilirubin** Linearity: up to 496 µmol / L. The automatic repetition of the analyzer goes up to a maximum of 2310 µmol / L	**IMOLA** Colorimetric method Diazo Reactive
CLINICAL CHEMISTRY **Serum**	**Total Protein** Linearity: up to 124 g / L. The automatic repetition of the analyzer goes up to a maximum of 248 g / L	**IMOLA** Biuret's reactive colorimetric method. NIST 927d traceable calibration
CLINICAL CHEMISTRY **Serum**	**Triglycerides** Linearity: up to 12.7 mmol / L	**IMOLA** GPO-PAP method. Traceable ID-GC / MS calibration
CLINICAL CHEMISTRY **Serum/Urine**	**Uric Acid** Linearity: up to 1.37 mmol / L in serum; in urine it is up to 8.9	**IMOLA** Colorimetric enzymatic method
CLINICAL CHEMISTRY **Serum/Urine**	**Urea** Linearity: up to 56.7 mmol / L. The automatic repetition of the analyzer goes up to a maximum of 113 mmol / L	**IMOLA** Enzymatic kinetic UV method. NIST 909b traceable calibration
ELISA **Serum**	**Folates** Linear up to 25 ng / mL (according to figure 1 of the insert)	**STAT FAX** Awareness Technology, Inc. SN 4200-1103 # 021 Competitive ELISA
ELISA **Serum**	**H. Pylori IGG, IGM, IGA** Linearity up to 100 U / mL in undiluted samples (according to insert 12.1.10)	**STAT FAX** Direct ELISA
SPECIAL CHEMISTRY **Serum**	**Thyroid-Stimulating Hormone (TSH)** Calibration range: up to 75 µUI / mL	**IMMULITE** **Siemens** **SN 13627** **# 022** Solid phase competitive chemiluminescent enzyme immunoassay
SPECIAL CHEMISTRY **Serum**	**Free Thyroxine (FT4)** Reportable range: 0.3-6.0 ng / dL	**IMMULITE** Solid phase competitive chemiluminescent enzyme immunoassay
SPECIAL CHEMISTRY **Serum**	**Free Triiodothyonine (FT3)** Calibration range: 1- 40 pg / mL	**IMMULITE** Competitive immunoassay based on an analog

SPECIAL CHEMISTRY **Serum**	**Human Chorionic Gonadotropin (hCG)** Reportable range: up to 5000 mIU / mL Linearity: up to 1/8 remained in parallel	**IMMULITE** Solid phase chemiluminescent immunometric assay
SPECIAL CHEMISTRY **Serum**	**Prostate-Specific Antigen (PSA)** Working range: 0.08-150ng / mL Linearity: up to 1/8 remained in parallel	**IMMULITE** Solid phase competitive chemiluminescent enzyme immunoassay
SPECIAL CHEMISTRY **Serum**	**FREE Prostate-Specific Antigen (PSA)** Reportable range: 0.07-25 ng / mL Linearity: until 1/32 remained in parallelism	**IMMULITE** Chemiluminescent Immunometric Assay sequential in solid phase
SPECIAL CHEMISTRY **Serum**	**Ferritin** Reportable range: up to 1500 ng / mL Linearity: up to 1/8 remained in parallel WHO 2nd IS 80/578	**IMMULITE** Chemiluminescent Immunometric Assay in solid phase labeled with enzymes
SPECIAL CHEMISTRY **Serum**	**Carcinoembryonic Antigen (CEA)** Calibration range: up to 550 ng / mL Linearity: up to 1/8 remained in parallel	**IMMULITE** Immunometric Sequential Assay with Two Solid Phase Chemiluminescent Binding Sites
SPECIAL CHEMISTRY **Serum**	**Immunoglobulin E (IgE)** Calibration range: up to 2000 IU / mL 2nd IRP 75/502 Linearity: Due to the heterogeneity of IgE, parallelism can be lost in some dilutions.	**IMMULITE** Chemiluminescent Immunometric Assay in solid phase
SPECIAL CHEMISTRY **Serum**	**Vitamin B-12 (VB12)** Calibration range 150- 1200 pg / mL Linearity: up to 1/8 remained in parallel	**IMMULITE** Solid phase competitive chemiluminescent enzyme immunoassay
SPECIAL CHEMISTRY **Serum**	**Alubumin** Calibration range: 2.5-60 ug / mL Linearity: up to 1/4 remained in parallel	**IMMULITE** Solid phase competitive chemiluminescent enzyme immunoassay
SPECIAL CHEMISTRY **Serum**	**Follicle Stimulating Hormone (FSH)** Calibration range: Up to 170m IU / mL WHO 2nd IRP 78/549	**IMMULITE** Immunometric Assay with Two Solid Phase Chemiluminescent Binding Sites

	Linearity: up to 1/8 remained in parallel	
SPECIAL CHEMISTRY **Serum**	**Cancer Antigen 15-3 (CA 15-3)** Reportable range: 1-300 U / mL Linearity: up to 1/16 remained in parallel	**IMMULITE** Chemiluminescent Two-Step Sequential Immunometric Assay
SPECIAL CHEMISTRY **Serum**	**Cancer Antigen 19-9 (CA 19-9)** Calibration range: Up to 1000m U / mL Linearity: up to 1/8 remained in parallel	**IMMULITE** Immunometric Assay with Two Solid Phase Chemiluminescent Binding Sites
SPECIAL CHEMISTRY **Serum**	**Estradiol** Reportable range: 20-2000 pg / mL Linearity: up to 1/8 remained in parallel	**IMMULITE** Solid phase competitive chemiluminescent enzyme immunoassay
SPECIAL CHEMISTRY **Serum**	**Prolactin** Reportable range: Up to 150ng/mm	**IMMULITE** Immunometric Sequential Assay with Two Solid Phase Chemiluminescent Binding Sites
SPECIAL CHEMISTRY **Serum**	**Progesterone** Reportable range: 0.2 - 40 ng / mL Calibration range: 0.2-2.0 ng / mm	**IMMULITE** Solid Phase Sequential Immunometric Assay
SPECIAL CHEMISTRY **Serum**	**Cancer Antigen 125 (CA-125)** Calibration range: Up to 500 IU / mL Linearity: up to 1/100 remained in parallel	**IMMULITE** Immunometric Assay with Two Solid Phase Chemiluminescent Binding Sites
SPECIAL CHEMISTRY **Serum**	**Luteinizing Hormone (LH)** Calibration range: Up to 200mUI / mL Linearity: up to 1/8 remained in parallel	**IMMULITE** Immunometric Assay with Two Solid Phase Chemiluminescent Binding Sites
HEMATOLOGY **Blood**	**White Blood Cell Count (WBC)** N/A	**MINDRAY** BC5380 SN 5C101093 # 010 Cytodensitometry
HEMATOLOGY **Blood**	**Red Blood Cell Count (RBC)** N/A	**MINDRAY** Cytodensitometry
HEMATOLOGY **Blood**	**Hemolobin Test (HGB)** N/A	**MINDRAY** Cytodensitometry
HEMATOLOGY **Blood**	**Hematocrit Test (HCT)** N/A	**MINDRAY** Cytodensitometry

HEMATOLOGY **Blood**	**Mean Corpuscular Volume (MCV)** N/A	**MINDRAY** Cytodensitometry
HEMATOLOGY **Blood**	**Mean Corpuscular Hemoglobin (MCH)** N/A	**MINDRAY** Cytodensitometry
HEMATOLOGY **Blood**	**Mean Corpuscular Hemoglobin Concentration (MCHC)** N/A	**MINDRAY** Cytodensitometry
HEMATOLOGY **Blood**	**Platelets** **N / A**	**MINDRAY** Cytodensitometry
HEMATOLOGY **Blood**	**Granulocytes** N/A	**MINDRAY** Cytodensitometry
HEMATOLOGY **Blood**	**Sickle Cells** N/A	**MANUAL** Turbidimetry
HEMATOLOGY **Blood**	**Reticulocytes** N/A	**MANUAL** Bromocresil blue staining
HEMATOLOGY **Blood**	**BSE Blood Test (BSE)** N/A	**MANUAL** Cell sedimentation
IMMUNO-HEMATOLOGY **Blood**	**Blood Group (ABO; Rh; Coombs)**	Anti-A, DIAGAST France Anti-B, DIAGAST France Anti-D, DIAGAST France Anti-human Glob. Test Wiener
SEROLOGY **Serum**	**C-reactive Protein (CRP)** N/A	**MANUAL** Agglutination of latex particles
SEROLOGY **Serum**	**Antistreptolysin O (ASO)** N/A	**MANUAL** Agglutination of latex particles
SEROLOGY **Serum**	**Syphilis (VDRL)** N/A	**MANUAL** Agglutination of latex particles
SEROLOGY **Serum**	**Mononucleosis Test (Monotest)** N/A	**MANUAL** Agglutination of latex particles
SEROLOGY **Serum**	**Rheumatoid Factor (RF)** N/A	**MANUAL** Agglutination of latex particles
SEROLOGY **Serum**	**HIV** N/A	**MANUAL** Direct qualitative immunochromatographic assay
SEROLOGY **Serum**	**Hepatitis C Virus (HCV)** N/A	**MANUAL** Direct qualitative immunochromatographic assay
SEROLOGY **Serum**	**Hepatitis B Surface Antigen (HBsAg)**	**MANUAL**

	N/A	Direct qualitative immunochromatographic assay
SEROLOGY **Serum/Urine**	**Human Chorionic Gonadotropin (HCG)** N/A	**MANUAL** Direct qualitative immunochromatographic assay
TOXICOLOGY **Urine**	**Drug Metabolite Testing (COC; THC; Amphetamines; Barbiturates; MDMA, Methamphetamines; Opiates** N/A	**MANUAL** Direct qualitative immunochromatographic assay
TOXICOLOGY **Urine**	**Marijuana (THC) Testing** N/A	**MANUAL** Direct qualitative immunochromatographic assay
URINANALYSIS **Urine**	**14-in-1 Strip Test** Microscopic observation of urinary sediment.	URIT 560. SN 560-00134E. URIT GLOBAL DIAGNOSTICS Reflectance photometry
COPRO OCCULT BLOOD	**Hema-Screen** N/A	**MANUAL** Colorimetric
COPRO ANALYSIS **Copro**	**H. Pylori** Microscopic observation of cells and parasites	**MANUAL** Fresh preparation
COAGULATION **Plasma with sodium citrate**	**Coagulation (PT; PTT)** N/A	**BFT II** Siemens SN H2197244 # 019 Time measurement of mesh formation (clot)

END OF SCHEDULE OF ACCREDITATION