

SCHEDULE OF ACCREDITATION

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 issued on: 28th June 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**

| <p><u>Permanent Address of Laboratory:</u> Avicenastraat #16 Oranjestad Aruba</p> <p><u>Postal Address</u> PO Box 447 Aruba</p> <p>Tel : 297-588-5654 Fax : 297-588-2919 e-mail: alphainterlabcenter@gmail.com</p> | | <p><u>Management Signatories:</u> Bianca Salviche</p> <p><u>Technical Signatories:</u> Dr Eddy Balentien</p> <p><u>Nominated Representative:</u> Mercedes Oduber</p> <p><u>Certificate of Accreditation</u> Issue No. : 01</p> |
|--|--|--|
| Materials/Products Tested | Types of Tests/Properties Measured, Range of Measurement | Standard Specifications, Equipment/Techniques Used |
| <p><i>Instruction: add rows as needed below and enter the <u>FIELD</u> where necessary (e.g. Chemical, Microbiological, Mechanical).</i></p> | | |
| <u>CLINICAL CHEMISTRY</u> Serum | 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 |
| <u>CLINICAL CHEMISTRY</u> Serum | 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 |
| <u>CLINICAL CHEMISTRY</u> 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 |
| <u>CLINICAL CHEMISTRY</u> Serum | TO P 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 |
| <u>CLINICAL CHEMISTRY</u> Serum | 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 |
| <u>CLINICAL CHEMISTRY</u> Serum | CALCIUM Linearity: 0 - 4.3 mmol / l. The automatic repetition of the analyzer goes up to a maximum of 6.45 mmol / l | IMOLA Colorimetric Method Arsenazo III |

| | | |
|------------------------------------|---|--|
| 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 | CREATININ Linearity: up to 2844 μ mol / l. The automatic repetition of the analyzer goes up to a maximum of 7821 μ mol / 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 | INORGANIC PHOSPHORUS 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 186lg traceable calibration |
| CLINICAL CHEMISTRY Serum | GGT 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 Serum | URINE GLUCOSE Linearity: up to 45.2 mmol / l. | IMOLA UV Hexokinase Method. NIST 917b and NIST 965a traceable calibration |
| CLINICAL CHEMISTRY Serum | 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 | SODIUM Linearity: up to 182 mmol / l | IMOLA ISE method |

| | | |
|------------------------------------|---|---|
| Serum | | |
| CLINICAL CHEMISTRY Serum | TOTAL BILIRRUBINE Linearity: up to 496 $\mu\text{mol} / \text{l}$. The automatic repetition of the analyzer goes up to a maximum of 2310 $\mu\text{mol} / \text{l}$ | 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 | 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 | 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 | TSH Calibration range: up to 75 $\mu\text{UI} / \text{ml}$ | IMMULITE Siemens SN 13627 # 022 Solid phase competitive chemiluminescent enzyme immunoassay |
| SPECIAL CHEMISTRY Serum | F4 Reportable range: 0.3-6.0 ng / dl | IMMULITE Solid phase competitive chemiluminescent enzyme immunoassay |
| SPECIAL CHEMISTRY Serum | F3 Calibration range: 1- 40 pg / ml | IMMULITE Competitive immunoassay based on an analog |
| SPECIAL CHEMISTRY Serum | HCG Reportable range: up to 5000 mIU / ml | IMMULITE Solid phase chemiluminescent immunometric assay |

| | | |
|--------------------------------|--|--|
| | Linearity: up to 1/8 remained in parallel | |
| SPECIAL CHEMISTRY Serum | 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 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 | FERRITINE 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 | 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 | 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 | 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 | ALBUMIN 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 | FSH Calibration range: Up to 170m IU / ml WHO 2nd IRP 78/549 Linearity: up to 1/8 remained in parallel | IMMULITE Immunometric Assay with Two Solid Phase Chemiluminescent Binding Sites |
| SPECIAL CHEMISTRY Serum | CA 15.3 Reportable range: 1-300 U / ml Linearity: up to 1/16 remained in parallel | IMMULITE Chemiluminescent Two-Step Sequential Immunometric Assay |

| | | |
|--|--|--|
| <u>SPECIAL CHEMISTRY</u> Serum | 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 |
| <u>SPECIAL CHEMISTRY</u> Serum | ESTRADIOL Reportable range: 20-2000 pg / ml Linearity: up to 1/8 remained in parallel | IMMULITE Solid phase competitive chemiluminescent enzyme immunoassay |
| <u>SPECIAL CHEMISTRY</u> Serum | PROLACTIN Reportable range: Up to 150ng/mm | IMMULITE Immunometric Sequential Assay with Two Solid Phase Chemiluminescent Binding Sites |
| <u>SPECIAL CHEMISTRY</u> Serum | PROGESTERONE Reportable range: 0.2 - 40 ng / ml Calibration range: 0.2-2.0 ng / mm | IMMULITE Solid Phase Sequential Immunometric Assay |
| <u>SPECIAL CHEMISTRY</u> Serum | 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 |
| <u>SPECIAL CHEMISTRY</u> Serum | 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 |
| <u>HEMATOLOGY</u> Blood | WBC N/A | MINDRAY BC5380 SN 5C101093 # 010 Cytodensitometry |
| <u>HEMATOLOGY</u> Blood | RBC N/A | MINDRAY Cytodensitometry |
| <u>HEMATOLOGY</u> Blood | HGB N/A | MINDRAY Cytodensitometry |
| <u>HEMATOLOGY</u> Blood | HCT N/A | MINDRAY Cytodensitometry |
| <u>HEMATOLOGY</u> Blood | MCV N/A | MINDRAY Cytodensitometry |
| <u>HEMATOLOGY</u> Blood | MCH N/A | MINDRAY Cytodensitometry |
| <u>HEMATOLOGY</u> Blood | MCHC N/A | MINDRAY Cytodensitometry |
| <u>HEMATOLOGY</u> Blood | PLATELETS N / A | MINDRAY Cytodensitometry |

| | | |
|--|--|--|
| HEMATOLOGY Blood | GRANULOCITOS N/A | MINDRAY Cytodensitometry |
| HEMATOLOGY Blood | SICKLE CELLS N/A | MANUAL Turbidimetry |
| HEMATOLOGY Blood | RETICULOCITOS N/A | MANUAL Bromocresil blue staining |
| HEMATOLOGY Blood | BSE N/A | MANUAL Cell sedimentation |
| IMMUNO- HEMATOLOGY Blood | ABO Rh COOMBS | Anti-A, DIAGAST France Anti-B, DIAGAST France Anti-D, DIAGAST France Anti-human Glob. Test Wiener |
| SEROLOGY Serum | CRP N/A | MANUAL Agglutination of latex particles |
| SEROLOGY Serum | ASO N/A | MANUAL Agglutination of latex particles |
| SEROLOGY Serum | VDRL N/A | MANUAL Agglutination of latex particles |
| SEROLOGY Serum | MONOTEST N/A | MANUAL Agglutination of latex particles |
| SEROLOGY Serum | FR N/A | MANUAL Agglutination of latex particles |
| SEROLOGY Serum | HIV N/A | MANUAL Direct qualitative immunochromatographic assay |
| SEROLOGY Serum | HCV N/A | MANUAL Direct qualitative immunochromatographic assay |
| SEROLOGY Serum | HBsAg N/A | MANUAL Direct qualitative immunochromatographic assay |
| SEROLOGY Serum | HCG N/A | MANUAL Direct qualitative immunochromatographic assay |
| SEROLOGY Serum | COC N/A | MANUAL Direct qualitative immunochromatographic assay |
| SEROLOGY Serum | TCH N/A | MANUAL |

| | | |
|---|--|---|
| | | Direct qualitative immunochromatographic assay |
| <u>UROANALYSIS</u> Urine | STRIP 11 PARAMETERS Microscopic observation of urinary sediment. | URIT 560. SN 560-00134E. URIT GLOBAL DIAGNOSTICS Reflectance photometry |
| <u>COPROANALYSIS</u> Copro | HEMASCREEN N/A | MANUAL Colorimetric |
| <u>COPROANALYSIS</u> Copro | H. PYLORI Microscopic observation of cells and parasites | MANUAL Fresh preparation |
| <u>COAGULATION</u> Plasma with sodium citrate | PT-PTT N/A | BFT II Siemens SN H2197244 # 019 Time measurement of mesh formation (clot) |

END OF SCHEDULE OF ACCREDITATION