



SCOPE OF ACCREDITATION TO ISO/IEC 17043:2010

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PROFICIENCY TESTING PROVIDER

Valid To: February 29, 2024

Certificate Number: 3233.01

In recognition of the successful completion of the A2LA evaluation process, this proficiency testing provider has been found to meet the ISO/IEC 17043:2010, “Conformity assessment-General Requirements for Proficiency testing”. Accreditation is granted to this provider to provide proficiency testing samples in the following programs:

<u>PROGRAM NAME</u>	<u>FREQUENCY</u>	<u>ANALYTES MEASURED¹</u>
CATEGORY B: BIOLOGICAL AND CLINICAL PROPERTIES		
Blood Gas Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These liquid proficiency samples are prepared from a buffered aqueous solution with no added constituents of human or animal origin. Analytes: 1. Calcium, Ionized 2. Chloride 3. Glucose 4. Lactate (Lactic Acid) 5. Magnesium 6. pCO ₂ 7. pH 8. pO ₂ 9. Potassium 10. Sodium
Blood Typing Program	Three distributions of 3 samples + 1 donor sample every 4 months.	These liquid proficiency samples are a suspension of red blood cells in a preservative diluent with added preservatives. Parameters: 1. ABO Group 2. Antibody Screen 3. Rh(D)

<u>PROGRAM NAME</u>	<u>FREQUENCY</u>	<u>ANALYTES MEASURED¹</u>
Blood Typing Program (Continued)		<ol style="list-style-type: none"> 4. Antibody Identification 5. DAT (Direct Antiglobulin Test) 6. Compatibility (Cross-match)
Cardiac Markers Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	<p>These liquid frozen proficiency samples are prepared from human serum, plasma and proteins with added chemicals and preservatives.</p> <p>Analytes:</p> <ol style="list-style-type: none"> 1. Brain Natriuretic Peptide (BNP) 2. CK-MB 3. D-dimer 4. Homocysteine 5. hs-CRP 6. Myoglobin 7. N-terminal pro BrainNatriuretic Peptide (NT-ProBNP) 8. Troponin I 9. Troponin T
Clinical Chemistry (Monthly) Program	One distribution of 12 samples every 12 months. One sample to be tested every month	<p>These lyophilized proficiency samples are prepared from human serum with added chemicals, purified biochemicals (tissue extracts of human and animal origin) and stabilizers.</p> <p>Analytes:</p> <ol style="list-style-type: none"> 1. Acid Phosphatase (Total) 2. Alanine Aminotransferase (ALT/SGPT) 3. Albumin 4. Alkaline Phosphatase (ALP) 5. Amylase (Pancreatic) 6. Amylase (Total) 7. Aspartate Aminotransferase (AST/SGOT) 8. Bilirubin (Direct) 9. Bilirubin (Indirect) 10. Bilirubin (Total) 11. Carbon Dioxide (CO₂) 12. Calcium (Ionized) 13. Calcium (Total) 14. Chloride 15. Cholesterol (HDL) 16. Cholesterol (LDL) 17. Cholesterol (Total) 18. Cholinesterase 19. Copper 20. Cortisol 21. Creatine Kinase (CK) 22. Creatinine 23. Gamma Glutamyl Transferase (GGT) 24. Glucose

<u>PROGRAM NAME</u>	<u>FREQUENCY</u>	<u>ANALYTES MEASURED¹</u>
Clinical Chemistry (Monthly) Program (Continued)		25. Iron 26. Iron Binding Capacity, Total (TIBC) 27. Iron Binding Capacity, Unsaturated (UIBC) 28. Lactate (Lactic Acid) 29. Lactate Dehydrogenase (LDH) 30. Lipase 31. Lithium 32. Magnesium 33. Osmolality 34. Phosphorus 35. Potassium 36. Protein (Total) 37. Sodium 38. Thyroid Stimulating Hormone (TSH) 39. Thyroxine (T4), Free 40. Thyroxine (T4), Total 41. Transferrin 42. Triglycerides 43. Triiodothyronine (T3), Free 44. Triiodothyronine (T3), Total 45. Urea 46. Urea Nitrogen 47. Uric Acid 48. Zinc
Coagulation Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These lyophilized proficiency samples are prepared from human plasma with added chemicals and stabilizers. Analytes: 1. Activated Partial Thromboplastin Time (APTT) 2. Antithrombin III (ATIII) 3. D-dimer 4. Factor VIII 5. Fibrinogen 6. International Normalized Ratio (INR) 7. Prothrombin Time (PT) 8. Protein C 9. Protein S 10. Thrombin Time (TT) 11. Von Willibrand Factor (vWF)
Ethanol/Ammonia Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These liquid proficiency samples are prepared from human serum and purified chemicals with added preservatives and stabilizers. Analytes: 1. Ethanol 2. Ammonia

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Hematology Program	Four distribution of 3 samples every 12 months. One sample to be tested every month.	These liquid proficiency samples are prepared from human erythrocytes, mammalian leukocytes and platelets with preservatives. Analytes: <ol style="list-style-type: none"> 1. Hematocrit (HCT) 2. Hemoglobin (Total) 3. Mean Corpuscular Hemoglobin (MCH) 4. Mean Corpuscular Hemoglobin Concentration (MCHC) 5. Mean Corpuscular Volume (MCV) 6. Mean Platelet Volume (MPV) 7. Platelets (PLT) 8. Red Blood Cells (RBC) 9. Red Blood Cell Distribution Width (RDW) 10. Red Blood Cell Distribution Width Standard Deviation (RDW-SD) 11. White Blood Cells (WBC)
Hemoglobin Program	One distribution of 12 samples every 12 months. One sample to be tested every month	These lyophilized proficiency samples are prepared from human whole blood with added stabilizers and preservatives. Analytes: <ol style="list-style-type: none"> 1. Hemoglobin A1C 2. Hemoglobin A2 3. Hemoglobin (Total Glycated)
HIV/Hepatitis Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These liquid samples are prepared with human source material with added constituents of animal origin and preservatives. Analytes: <ol style="list-style-type: none"> 1. Anti HAV 2. HAV IgG 3. HAV IgM 4. Anti HBc 5. HBc IgM 6. Anti HBe 7. Anti HBs 8. Anti HCV 9. Anti HIV-1 10. Anti HIV-2 11. Anti HIV 1/2 12. Anti HTLV-1 13. HBe Ag 14. HBs Ag 15. HIV-1 Ag

PROGRAM NAME	FREQUENCY	ANALYTES MEASURED ¹
Immunoassay (Monthly) Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	<p>These lyophilized proficiency samples are prepared from human serum with added constituents of human and animal origin, chemicals and therapeutic drugs</p> <p>Analytes:</p> <ol style="list-style-type: none"> 1. 11-Deoxycortisol 2. 17- α -OH-Progesterone 3. 25-OH Vitamin D 4. β-2 Microglobulin 5. ACTH 6. Aldosterone 7. Alphafetoprotein (AFP) 8. Androstenedione 9. Angiotensin Converting Enzyme (ACE) 10. C-Peptide 11. CA 125 12. CA 15-3 13. CA 19-9 14. CA 27-29 15. Carbamazepine 16. Carcinoembryonic Antigen (CEA) 17. Cortisol 18. DHEA 19. DHEA Sulfate 20. Digoxin 21. Estradiol 22. Estriol, Free (UE3) 23. Ferritin 24. Folate 25. Follicle Stimulating Hormone (FSH) 26. Gastrin 27. Human Chorionic Gonadotropin (hCG) 28. Human Growth Hormone (hGH) 29. Immunoglobulin E (IgE) 30. Insulin 31. Intact PTH 32. Luteinizing Hormone (LH) 33. Neuron Specific Enolase (NSE) 34. Phenobarbital 35. Phenytoin 36. Plasma Renin Activity 37. Progesterone 38. Prolactin 39. Prostate Specific Antigen (PSA), Free 40. PSA- Free/Total (Ratio) 41. Prostate Specific Antigen (PSA), Total 42. Renin (Direct) 43. S100 Protein 44. Sex Hormone Binding Globulin (SHBG) 45. T-Uptake 46. T3 Uptake 47. Testosterone 48. Theophylline 49. Thyroglobulin (Tg) 50. Thyroid Stimulating Hormone (TSH)

PROGRAM NAME	FREQUENCY	ANALYTES MEASURED¹
Immunoassay (Monthly) Program (Continued)		51. Thyroxine (T4), Free 52. Thyroxine (T4), Total 53. Thyroxine Binding Globulin (TBG) 54. Transferrin 55. Triiodothyronine (T3), Free 56. Triiodothyronine (T3), Total 57. Valproic Acid 58. Vitamin B12
Lipids Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These liquid proficiency samples are prepared from human serum with added constituents of human origin, preservatives and stabilizers. Analytes: 1. Apolipoprotein A1 2. Apolipoprotein B 3. Cholesterol, HDL 4. Cholesterol, LDL 5. Cholesterol, Total 6. Triglycerides 7. Lipoprotein(a)
Serum Proteins Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These lyophilized proficiency samples are prepared from human serum with added constituents of animal origin, chemicals Analytes: 1. α -1-Acid Glycoprotein 2. α -1 Antitrypsin 3. α -2 Macroglobulin 4. β -2 Microglobulin 5. Albumin 6. Antistreptolysin O (ASO) 7. C-Reactive Protein (CRP) 8. Ceruloplasmin 9. Complement C3 10. Complement C4 11. Haptoglobin 12. Immunoglobulin A (IgA) 13. Immunoglobulin E (IgE) 14. Immunoglobulin G (IgG) 15. Immunoglobulin M (IgM) 16. Kappa Light Chain 17. Lambda Light Chain 18. Prealbumin 19. Protein (Total) 20. Rheumatoid Factor 21. Transferrin

<u>PROGRAM NAME</u>	<u>FREQUENCY</u>	<u>ANALYTES MEASURED¹</u>
Syphilis/Chagas Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These liquid samples are prepared from human source material with added preservatives. Analytes: <ol style="list-style-type: none"> 1. Non-Treponemal Antibodies 2. Treponema pallidum IgG 3. Treponema pallidum Antibodies 4. Trypanosoma cruzi Antibodies
Therapeutic Drug Monitoring Program	One distribution of 12 samples every 12 months. One sample to be tested every month	These lyophilized proficiency samples are prepared from defibrinated human plasma with added chemicals and therapeutic drugs. Analytes: <ol style="list-style-type: none"> 1. Acetaminophen 2. Amikacin 3. Amitriptyline 4. Caffeine 5. Carbamazepine 6. Cyclosporine 7. Digoxin 8. Ethosuximide 9. Gentamicin 10. Lithium 11. Methotrexate 12. Nortriptyline 13. Phenobarbital 14. Phenytoin 15. Primidone 16. Salicylate 17. Theophylline 18. Tobramycin 19. Tricyclic Antidepressants (TCA) Screen 20. Valproic Acid 21. Vancomycin
ToRCH/EBV/MuMZ Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These liquid samples are prepared from human source material with added preservatives. Analytes: <ol style="list-style-type: none"> 1. Cytomegalovirus (CMV) IgG 2. Cytomegalovirus (CMV) IgM 3. Epstein-Barr Virus (EBNA) IgG 4. Epstein-Barr Virus (VCA) IgG 5. Epstein-Barr Virus (VCA) IgM 6. Herpes Simplex Virus (HSV-1) IgG 7. Herpes Simplex Virus (HSV-2) IgG 8. Herpes Simplex Virus (HSV1/2) IgG 9. Measles Virus (Rubeola) IgG 10. Mumps Virus IgG 11. Rubella Virus IgG 12. Rubella Virus IgM 13. Toxoplasma gondii (Toxo) IgG

<u>PROGRAM NAME</u>	<u>FREQUENCY</u>	<u>ANALYTES MEASURED¹</u>
ToRCH/EBV/MuMZ Program (Continued)		14. Toxoplasma gondii (Toxo) IgM 15. Varicella Zoster Virus (VZV) IgG
Urinalysis Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These liquid samples are prepared with human erythrocytes, constituents of animal origin, chemicals, and preservatives. Analytes: 1. Albumin 2. Albumin-to-Creatinine Ratio 3. Bilirubin 4. Blood (Hemoglobin) 5. Creatinine 6. Glucose 7. Human Chorionic Gonadotropin (hCG) 8. Ketones 9. Leukocytes 10. Nitrite 11. pH 12. Protein (Total) 13. Protein-to-Creatinine Ratio 14. Specific Gravity 15. Urobilinogen
Urine Chemistry Program	One distribution of 12 samples every 12 months. One sample to be tested every month.	These lyophilized proficiency samples are prepared from human urine with added chemicals, hormones and stabilizers. Analytes: 1. 5-Hydroxyindoleacetic Acid (5-HIAA) 2. Calcium (Total) 3. Chloride 4. Cortisol (Free) 5. Creatinine 6. Dopamine 7. Epinephrine 8. Glucose 9. Homovanillic Acid (HVA) 10. Magnesium 11. Metanephrine 12. Microalbumin 13. Norepinephrine 14. Normetanephrine 15. Osmolality 16. Phosphorus 17. Potassium 18. Protein Total 19. Sodium 20. Urea Nitrogen 21. Uric Acid

<u>PROGRAM NAME</u>	<u>FREQUENCY</u>	<u>ANALYTES MEASURED¹</u>
Urine Chemistry Program (Continued)		22. Vanillylmandelic Acid (VMA)

¹Analytes/parameters in each program are targeted per defined specifications. Assigned values and associated uncertainties are known values with results determined by finished product testing of proficiency program.





Accredited Proficiency Testing Provider

A2LA has accredited

BIO-RAD LABORATORIES

Irvine, CA

This accreditation covers the specific proficiency testing schemes listed on the agreed upon Scope of Accreditation.

This provider is accredited in accordance with the recognized International Standard ISO/IEC 17043: 2010 *Conformity assessment - General requirements for proficiency testing*. This accreditation demonstrates technical competence for a defined scope and the operation of a quality management system.



Presented this 9th day of March 2020.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3233.01
Valid to February 29, 2024

For the proficiency testing schemes to which this accreditation applies, please refer to the provider's Scope of Accreditation.