SCOPE OF ACCREDITATION TO ISO/IEC 17043:2010

INSTITUTE FOR QUALITY MANAGEMENT IN HEALTHCARE (IQMH)
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PROFICIENCY TESTING PROVIDER

Valid To: June 30, 2026 Certificate Number: 3059.01

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:

Discipline	PT Program code	PT Program Name	Types of PT Material	Frequency Per Year
Microbiology	BACT[2,6]	Routine Bacteriology	Lyophilized and "fresh" simulated material (varies from survey to survey)	3
	BACT CD[2,6]	C. difficile Antigen and/or Toxin Detection	Lyophilized fecal specimens derived from authentic clinical samples suitable for all currently available methods including molecular.	2
	BACT AF[2,6]	Smears for Acid Fast Stain	Smears of decontaminated, homogenized, concentrated sputum prepared from authentic clinical samples.	2
	PARA[1,6]	Parasitology	SAF-preserved feces from authentic clinical samples	2
	MYCO[2,5,6]	Mycology	Fresh cultures on agar slants	2
Virology	VIRO HEP[1,6]	Hepatitis A, B, C	Human serum or plasma	2
	VIRO HIV[1,6]	Anti -HIV	Human serum or plasma	2
	VIRO RV[1,6]	Rubella Serology	Human serum or plasma	2
	VIRO RP[1,6]	Respiratory Pathogens	Liquid suspension of infected cells mixed with non-infected cells and extracellular virus.	2
	VIRO IM[1,6]	Infectious Mononucleosis	Human serum or plasma	2

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Discipline	PT Program code	PT Program Name	Types of PT Material	Frequency Per Year
	VIRO COV[1,6]	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	Fibroblast cells and with/without Whole SARS-CoV-2 cDNA genome.	3
Molecular Microbiology	MOLE – CGC[2,6]	C. trachomatis/N. gonorrhoeae (CGC)	Liquid samples of *C. trachomatis* and *N. gonorrhoeae*	2
Chemistry	CHEM[1,4]	Chemistry	Lyophilized human serum reconstituted with 5 mL diluent (provided)	3
	CHEM UR[1,7]	Chemistry Urine	Lyophilized human urine reconstituted with 10 mL deionized water	3
	CHEM BG[1]	Blood Gases	Aqueous commercial preparation	2
	CHEM HB[4]	HbA1c	Single donor whole blood	3
	CHEM-OX[1]	Oximetry	Hemolysate of purified bovine hemoglobin	2
	DRUG[1]	Drug Monitoring	Pooled human serum supplemented with selected drugs	2
	DRUG UR[1,7]	Urine Drug Screen	Human urine supplemented with selected drugs	2
	CHEM-UCG[6]	Chemistry Urine Human Chorionic Gonadotropin (hCG) Qualitative	Human urine (simulated)	3
	ENDO – A[1]	Endocrinology and Tumor Markers	Lyophilized human serum	3
	ENDO - B[1]	Endocrinology Special	Lyophilized human serum	3
	ENDO PSA[1]	Endocrinology - Prostate Specific Antigen (PSA)	Lyophilized human serum	3
	ENDO PTH	Parathyroid Hormone	Lyophilized human serum	3
	IMGY[1,2]	Immunology	Converted human serum	3
	CHEM FOB[1]	Fecal Occult Blood	Simulated fecal product	3
	CHEM FIT[2]	Fecal Occult Blood — Fecal Immunochemical Test	Lyophilized human protein-based material	12

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Cytogenetics	GENE[1,3,6]	Cytogenetics	Clinical sample may be: • Whole blood • Fixed cell pellet • Cell culture • Bone marrow • Slides Digital images (may include G-banded and/or FISH stained preparations)	2
Hematology	FLOW HV[1,3]	Flow Cytometry – Lymphocyte Phenotyping for HIV	Commercially-prepared stabilized whole blood control material	2
	FLOW SC[1,3]	Flow Cytometry - CD34+ Stem Cell Enumeration	Commercially-prepared stabilized whole blood control material	2
	FLOW HD[1,3]	Flow Cytometry-Leukocyte Immunophenotyping for Hematologic Disorders	***Part 1*** Commercially-prepared stabilized whole blood control material ***Part 2*** Digital flow cytometry data files — provided with clinical information	2
	HEMA LD[1]	Automated Blood Cell Count and Leukocyte Differential	Commercially-prepared material composed of human erythrocytes, leukocytes (simulated or mammalian) and mammalian platelets suspended in a plasma-like fluid with preservatives. Provided in tubes with pierceable caps unless	2
	HEMA RE[1]	Reticulocyte Count	Commercially-prepared material composed of human and mammalian erythrocytes, suspended in a plasma-like fluid with preservatives. Provided in tubes with pierceable caps unless otherwise noted.	2
	HEMA BF[1]	Manual Body Fluid Cell Count	Control material composed of mammalian erythrocytes and leukocytes suspended in a plasma-like fluid with preservatives.	2

Discipline	PT Program code	PT Program Name	Types of PT Material	Frequency Per Year
	HEMA ABF[1]	Automated Body Fluid Cell Count	Commercially-prepared material composed of human erythrocytes and bovine leukocytes suspended in a fluid with preservatives.	2
	COAG[1,3]	Routine Coagulation	Commercially-prepared lyophilized plasma spiked with selected analytes based on the assay selected.	2
	COAG DD[1,3]	D-dimer Assay	Commercially-prepared lyophilized plasma which may be spiked with purified D-dimer.	2
	COAG FA[1,3]	Factor Assay	Commercially-prepared lyophilized immune-depleted plasma.	2
	COAG TH[1,3]	Thrombophilia Investigation	Commercially-prepared frozen immune depleted plasma.	2
	RCD HQ[1,3]	Red Cell Disorders - Hemoglobin Fraction Quantitation	Commercially-stabilized whole blood products or lyophilized whole blood	2
	RCD HS[1,3]	Sickle Cell Solubility Screen	Commercially-prepared survey material comprised of whole blood control samples	2
	MORP-VSB[1,2,3,6]	Peripheral Blood Film Virtual Slide-based	Digital scanned image(s) of a Romanowsky-stained peripheral blood film.	3
	BONE-SB[1,2,3,6]	Bone Marrow Slide-Based	Stained bone marrow slide preparations (aspirate and/or biopsy) and peripheral blood film, may include digital images.	2
POCT	POCT GL[1]	Point of Care Testing- Glucose	Stabilized bovine plasma	2
	POCT HIV[1,6]	Point of Care-HIV	Human serum	2
Cytopathology	CYTO- NG[2,3,6]	Cytopathology – Non-Gynecological	Papanicolaou-stained direct smears or liquid-based preparations.	1
	CYTO - G[2,3,6]	Cytopathology - Gynecological	Papanicolaou-stained direct smears or liquid-based preparations.	1

Discipline	PT Program code	PT Program Name	Types of PT Material	Frequency Per Year
Pathology	PATH IHC[2,3,6]	Immuno-histochemistry	Pre-cut unstained tissue section(s) and/or cell block(s) on positively-charged glass slides. Site submitted test material will be requested for some IHC surveys.	2
	PATH SS[2,3,6]	Routine Oversight Stain (H&E or HPS) and/or Special Stains	Pre-cut unstained tissue section(s) and/or cell block(s) on positively-charged glass slides. Site submitted test material will be requested for some IHC surveys.	2
	PATH ER[2,3,6]	Estrogen Receptor	Pre-cut testing section(s) and/or cell blocks on positively-charged glass slides Tissue section and/or cell block	1
	PATH PR[2,3,6]	Progesterone Receptor	Pre-cut testing section(s) and/or cell blocks on positively-charged glass slides Tissue section and/or cell block	1
	PATH HER2[2,3,6]	HER2/neu Immunochemistry	Pre-cut testing sections(s) and/or cell blocks on positively-charged glass slides Tissue section and/or cell block	1
	PATH-FISH ED[2,3,6]	Immuno-histochemistry-ISH (Predictive Markers)	Pre-cut testing sections(s) and/or cell blocks on positively-charged glass slides Tissue section and/or cell block	2
	PATH – SM (2,3,6)	Site Material – Special Stains	Site submitted test material	1
Transfusion Medicine	TMED AAU[1,6]	Transfusion Medicine - Manual and/or Automated	Human serum; red cells suspended in preservative	3
	HEMA FMH[1,6]	Fetal - Maternal Hemorrhage	Commercially-prepared survey material comprised of whole blood control samples.	2

[1] Assigned values and associated uncertainties are determined by consensus values from participants
[2] Assigned values and associated uncertainties are determined by consensus values from expert participants/laboratories.
[3] Assigned values and associated uncertainties are known values.
[4] Assigned values and associated uncertainties are reference values.
[5] Assigned values and associated uncertainties are certified reference values.

[6] Qualitative test and/or uncertainties do not apply.
[7] Assigned values and associated uncertainties are obtained from formulation and validated by consensus values from participants.

Accredited Proficiency Testing Provider

A2LA has accredited

INSTITUTE FOR QUALITY MANAGEMENT IN HEALTHCARE (IQMH)

Toronto, Ontario, CANADA

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 23rd day of June 2022.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3059.01
Valid to June 30, 2026

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