



SCOPE OF ACCREDITATION TO ISO 15189:2012

MOLECULAR PATHOLOGY LABORATORY NETWORK, INC.
 250 East Broadway Avenue
 Maryville, TN 37804
 Dr. Mark Stonecypher Phone: 865 380 9746

CLINICAL

Valid To: May 31, 2023

Certificate Number: 3765.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following types of testing on human samples, including **Bone Marrow (BM) Core Biopsy, Bone Marrow (BM) Aspirate, Peripheral Blood (PB), Formalin Fixed Paraffin Embedded (FFPE) and Fresh Tissue, Pathology Material, Fine Needle Aspirations (FNA), Amniotic Fluid, Cerebrospinal Fluid (CSF), Cervical Swabs, Urethral Swabs, Urine (U), and Other Bodily Fluids (BF):**

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Histopathology			
		Bone Marrow Pathology Evaluation	Microscopic Evaluation of Bone Marrow Biopsy / Clot Prep (H&E) and Peripheral / Aspirate Smears; Additional Stains as Required (Special Stains, Immunohistochemistry)	BM Core Biopsy, BM Aspirate, BM Blot, PB
		Image Analysis	Aperio System	FFPE
		Immunohistochemistry Antibodies / Markers	Automated Immunohistochemistry Staining	FFPE
		Special Stains	Manual Histochemistry Staining	FFPE
		Surgical Pathology Consultation	Microscopic Evaluation of Previously Prepared Surgical Specimens (H&E Slides and Other Material); Additional Stains or Studies as Required (Special Stains, Immunohistochemistry, Gene Rearrangement, etc.)	Pathology Material
	Histopathology – Immunostains			
		34BE12 (CK HMW)	Immunohistochemistry Staining	FFPE
		Alk-1 (CD246)	Immunohistochemistry Staining	FFPE

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Histopathology – Immunostains (cont.)			
		Androgen Receptor	Immunohistochemistry Staining	FFPE
		ALK 2p23 Rearrangement Anaplastic Large Cell Lymphoma	FISH	FNA, FFPE
		Annexin A1	Immunohistochemistry staining	FFPE
		Arginase-1	Immunohistochemistry Staining	FFPE
		Bcl-2	Immunohistochemistry Staining	FFPE
		Bcl-6	Immunohistochemistry Staining	FFPE
		BerEP4	Immunohistochemistry Staining	FFPE
		BRAF	Immunohistochemistry Staining	FFPE
		CA 19.9	Immunohistochemistry Staining	FFPE
		Caldesmon	Immunohistochemistry Staining	FFPE
		Calretinin	Immunohistochemistry Staining	FFPE
		Cam 5.2 (CK7/CK8)	Immunohistochemistry Staining	FFPE
		CD10	Immunohistochemistry Staining	FFPE
		CD103	Immunohistochemistry Staining	FFPE
		CD117	Immunohistochemistry Staining	FFPE
		CD138	Immunohistochemistry Staining	FFPE
		CD15	Immunohistochemistry Staining	FFPE
		CD163	Immunohistochemistry Staining	FFPE
		CD19	Immunohistochemistry Staining	FFPE
		CD1a	Immunohistochemistry Staining	FFPE
		CD2	Immunohistochemistry Staining	FFPE
		CD20	Immunohistochemistry Staining	FFPE

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Histopathology – Immunostains (cont.)			
		CD21	Immunohistochemistry Staining	FFPE
		CD22	Immunohistochemistry Staining	FFPE
		CD23	Immunohistochemistry Staining	FFPE
		CD25	Immunohistochemistry Staining	FFPE
		CD3	Immunohistochemistry Staining	FFPE
		CD30	Immunohistochemistry Staining	FFPE
		CD31	Immunohistochemistry Staining	FFPE
		CD33	Immunohistochemistry Staining	FFPE
		CD34	Immunohistochemistry Staining	FFPE
		CD36	Immunohistochemistry Staining	FFPE
		CD38	Immunohistochemistry Staining	FFPE
		CD4	Immunohistochemistry Staining	FFPE
		CD42b	Immunohistochemistry Staining	FFPE
		CD43	Immunohistochemistry Staining	FFPE
		CD45	Immunohistochemistry Staining	FFPE
		CD45RO	Immunohistochemistry Staining	FFPE
		CD5	Immunohistochemistry Staining	FFPE
		CD56	Immunohistochemistry Staining	FFPE
		CD57	Immunohistochemistry Staining	FFPE
		CD61	Immunohistochemistry Staining	FFPE
		CD68	Immunohistochemistry Staining	FFPE
		CD7	Immunohistochemistry Staining	FFPE
		CD79a	Immunohistochemistry Staining	FFPE
		CD8	Immunohistochemistry Staining	FFPE

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Histopathology – Immunostains (cont.)			
		CD99	Immunohistochemistry Staining	FFPE
		CDK4	Immunohistochemistry Staining	FFPE
		CDX 2	Immunohistochemistry Staining	FFPE
		CEA	Immunohistochemistry Staining	FFPE
		Chromogranin	Immunohistochemistry Staining	FFPE
		CK 5/6	Immunohistochemistry Staining	FFPE
		CK 8/18	Immunohistochemistry Staining	FFPE
		CK20	Immunohistochemistry Staining	FFPE
		CK7	Immunohistochemistry Staining	FFPE
		CMV	Immunohistochemistry Staining	FFPE
		c-MYC	Immunohistochemistry Staining	FFPE
		Cyclin D1	Immunohistochemistry Staining	FFPE
		Cytokeratin AE1/AE3	Immunohistochemistry Staining	FFPE
		D2-40 Podoplanin	Immunohistochemistry Staining	FFPE
		Desmin	Immunohistochemistry Staining	FFPE
		DOG1	Immunohistochemistry Staining	FFPE
		E-cadherin	Immunohistochemistry Staining	FFPE
		EGFR	Immunohistochemistry Staining	FFPE
		EMA	Immunohistochemistry Staining	FFPE
		Epstein Barr Virus Early RNA	Automated Chromogenic In-situ Hybridization Staining	FFPE
		ER	Immunohistochemistry Staining	FFPE
		ERA	Immunohistochemistry Staining	FFPE
		Factor XIIIa	Immunohistochemistry Staining	FFPE

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Histopathology – Immunostains (cont.)			
		GCDFP-15 (BRST2)	Immunohistochemistry Staining	FFPE
		Glycophorin A	Immunohistochemistry Staining	FFPE
		Granzyme B	Immunohistochemistry Staining	FFPE
		<i>Helicobacter pylori</i>	Immunohistochemistry Staining	FFPE
		Hep-Par-1 (HSA)	Immunohistochemistry Staining	FFPE
		HER2 (Ventana)	Immunohistochemistry Staining	FFPE
		HMB45	Immunohistochemistry Staining	FFPE
		HSV 1 & 2	Immunohistochemistry Staining	FFPE
		Human Herpesvirus Type 8	Immunohistochemistry Staining	FFPE
		Kappa Immunoglobulin Light Chains	Automated Chromogenic In-situ Hybridization Staining	FFPE
		Kappa ISH	Immunohistochemistry Staining	FFPE
		Ki-67	Immunohistochemistry Staining	FFPE
		Lambda Immunoglobulin Light Chains	Automated Chromogenic In-situ Hybridization Staining	FFPE
		Lambda ISH	Immunohistochemistry Staining	FFPE
		Mammaglobin	Immunohistochemistry Staining	FFPE
		MDM2	Immunohistochemistry Staining	FFPE
		Melan A (Mart1)	Immunohistochemistry Staining	FFPE
		MLH-1	Immunohistochemistry Staining	FFPE
		MSH2	Immunohistochemistry Staining	FFPE
		MSH6	Immunohistochemistry Staining	FFPE
		MUC-1	Immunohistochemistry Staining	FFPE
		Multiple Myeloma Oncogene 1	Immunohistochemistry Staining	FFPE
		Myeloperoxidase	Immunohistochemistry Staining	FFPE

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Histopathology – Immunostains (cont.)			
		Napasin A	Immunohistochemistry Staining	FFPE
		NSE	Immunohistochemistry Staining	FFPE
		p16ink4a	Immunohistochemistry Staining	FFPE
		P504S	Immunohistochemistry Staining	FFPE
		p-53	Immunohistochemistry Staining	FFPE
		P57 Kip2	Immunohistochemistry Staining	FFPE
		p-63 (Nuclear Stain)	Immunohistochemistry Staining	FFPE
		Pax-5	Immunohistochemistry Staining	FFPE
		Pax-8	Immunohistochemistry Staining	FFPE
		PD-1	Immunohistochemistry Staining	FFPE
		PD-L1	Immunohistochemistry Staining	FFPE
		PMS2	Immunohistochemistry Staining	FFPE
		PR	Immunohistochemistry Staining	FFPE
		PSA	Immunohistochemistry Staining	FFPE
		PSAP	Immunohistochemistry Staining	FFPE
		RCC	Immunohistochemistry Staining	FFPE
		S-100	Immunohistochemistry Staining	FFPE
		SMA	Immunohistochemistry Staining	FFPE
		Smooth Muscle Myosin	Immunohistochemistry Staining	FFPE
		SOX-11	Immunohistochemistry Staining	FFPE
		Synaptophysin	Immunohistochemistry Staining	FFPE
		TdT	Immunohistochemistry Staining	FFPE
		TTF-1	Immunohistochemistry Staining	FFPE

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Histopathology – Immunostains (cont.)			
		Tyrosinase	Immunohistochemistry Staining	FFPE
		vonWillebrand (F-8)	Immunohistochemistry Staining	FFPE
		Vimentin	Immunohistochemistry Staining	FFPE
		Wilms Tumor	Immunohistochemistry Staining	FFPE
	Molecular Pathology			
		ALK 2p23 Rearrangement Anaplastic Large Cell Lymphoma	FISH	FNA, FFPE
		AML1/ETO t (8;21) [A911 says t(98;21), verify]	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Aneuploidy +13, +18, +21, X, Y	FISH	FFPE POC
		ATM/CEP11 Deletion 11q22.3	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		BCL1; IGH/CCND1 t(11;14)	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		BCL2; IGH/BCL2 t(14;18)	FISH	PB, BM Aspirate, FNA, FFPE, Fresh Tissue
		BCL6 3q27 Rearrangement	FISH	PB, BM Aspirate, FNA, FFPE, Fresh Tissue
		BCR/ABL qRT PCR, Major p210 and Minor p190 Mutations, Minimal Residual Disease	qRT-PCR	PB, BM Aspirate
		BCR/ABL1 t(9;22)	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Bladder Cancer +3, +7, +17, 9p21	FISH	U, Bladder Washings
		Burkitt / Diffuse Large “double hit” B-cell Lymphoma Panel [C-MYC, BCL2, BCL6]	FISH	PB, BM aspirate, FNA, FFPE, Fresh Tissue
		C MYC 8q24 Rearrangement	FISH	PB, BM Aspirate, FNA, FFPE, Fresh Tissue
		CBFB t(16;16), inv(16)	FISH	PB, BM Aspirate, FNA, Fresh Tissue

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Molecular Pathology (cont.)			
		Chronic Lymphocytic Leukemia (CLL) Panel [MYB (6q23), ATM (11q22.3), +12, DLEU1 (13q14.3), TP53 (17p13)]	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Deletion 13q14.3	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Deletion 20q12	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Deletion 7q22 [D7S796, D7S658] / 7q31.2 [D7S486]	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		EGFR Mutation Analysis	Qiagen Therascreen EGFR RGQ PCR Kit	FFPE, FNA
		EGR1 5q Deletion, Monosomy 5	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		FIPIL1/PDGFRA 4q12 Gene Rearrangement	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		HER2/neu Breast Cancer	FISH	FFPE
		HER2/neu Gastric Cancer	FISH	FFPE
		IGH/FGFR3 t(4;14)	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		IGH/MAF t(14;16)	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		IGH/MALT1 t(14;18)	FISH	PB, BM Aspirate, FFPE, FNA, Fresh Tissue
		IGH/MYC CEP 8 t(8;14)	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		JAK2 V617F Mutation Analysis	PCR	PB, BM Aspirate
		MALT1 18q21	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		MLL 11q23 Gene Rearrangement	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		MYB 6q Deletion	FISH	PB, BM Aspirate, FNA, FFPE, Fresh Tissue
		Myelodysplasia Panel [-5/5q-, -7/7q-, +8,20q-]	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Myeloproliferative Neoplasms Panel [+8, t(9;22), 13q-, 20q-]	FISH	PB, BM Aspirate, FNA, Fresh Tissue

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Molecular Pathology (cont.)			
		Oligodendroglioma, Deletion 1p36, 19q13	FISH	FFPE
		PDGFRB Gene Rearrangement	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Plasma Cell Neoplasms Panel [1p-, 1q+, +5, +9, t(11;14), +15, 13q-, +15, 17p-] Reflex t(4;14) / t(14;16)	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		PML/RARA t(15,17)	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		ROS1	FISH	FFPE
		TEL/AML1, t(12;21)	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		TP53 17p13 Deletion	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Trisomy 12	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Trisomy 5, 9, 15	FISH	PB, BM Aspirate, FNA, Fresh Tissue
		Trisomy 8	FISH	PB, BM Aspirate, FNA, Fresh Tissue
	Genomics			
		AML Mutational Analysis	Next Generation Sequencing (LDT)	PB, BM Aspirate
		B-cell Immunoglobulin Heavy Chain Gene Rearrangement	Next Generation Sequencing	PB, BM Aspirate, FFPE, Frozen Tissue
		B-cell Immunoglobulin Kappa Light Chain Gene Rearrangement	Next Generation Sequencing	PB, BM Aspirate, FFPE, Frozen Tissue
		BRAF Mutation Analysis	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		CALR	Next Generation Sequencing (LDT)	PB, BM Aspirate
		Colon Cancer NGS	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		EGFR Mutation Analysis	Next Generation Sequencing (LDT)	FFPE, FNA, PB, BM Aspirate
		Extended Panel	Next Generation Sequencing (LDT)	PB, BM Aspirate
		GIST NGS	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		IDH1/IDH2 Mutational Analysis	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		IgVH Somatic Hypermutation	Next Generation Sequencing (LDT)	PB, BM Aspirate

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Pathology				
	Genomics (cont.)			
		JAK2 Exon 12	Next Generation Sequencing (LDT)	PB, BM Aspirate
		KIT AML	Next Generation Sequencing (LDT)	PB, BM Aspirate
		KRAS Mutation	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		Lung Cancer NGS	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		Melanoma NGS	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		MPL	Next Generation Sequencing (LDT)	PB, BM Aspirate
		MYD88	Next Generation Sequencing (LDT)	PB, BM aspirate
		Myeloid Extended Panel	Next Generation Sequencing (LDT)	PB, BM Aspirate
		NRAS Mutational Analysis	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		PDGFRA Mutation Analysis	Next Generation Sequencing (LDT)	FFPE, PB, BM Aspirate
		T-Cell Receptor Gamma Gene Rearrangement	Next Generation Sequencing	PB, BM, FNA, Fresh Tissue, Frozen Tissue, FFPE
		TP53 Mutational Analysis	Next Generation Sequencing	PB, BM Aspirate
	Infectious Disease			
		<i>Chlamydia trachomatis</i> , Qualitative	Hologic Aptima COMBO [®] 2 TMA	ThinPrep, SurePath, Cervical Swab, Urethral Swab, U
		Herpes Simplex Virus Type 1 and 2 Qualitative	PCR	PB, Fresh Tissue, Frozen Tissue, Swab, CSF, Cervical Cells, ThinPrep, SurePath, Amniotic Fluid
		Human Papillomavirus Genotyping	Hologic Aptima HPV 16, n 18/45 Genotype Assay	ThinPrep, SurePath
		Human Papillomavirus High Risk	Hologic Aptima HPV	ThinPrep, SurePath
		<i>Neisseria gonorrhoeae</i> , Qualitative	Hologic Aptima COMBO [®] 2 TMA	ThinPrep, SurePath, Cervical Swab, Urethral Swab, U
		SARS-CoV-2	Aptima TMA	Nasopharyngeal, Nasal, and Oropharyngeal Swabs
		<i>Trichomonas vaginalis</i>	Hologic Aptima [®] Trichomonas vaginalis	ThinPrep, Swab, U

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Cytogenetics				
	Cytogenetics			
		Chromosome Analysis, Bone Marrow	Culture / G-banding	BM Aspirate
		Chromosome Analysis, Leukemic (Oncology)	Culture / G-banding	PB
		Chromosome Analysis, Lymphoma (Lymph Node)	Culture / G-banding	Fresh Tissue, Tumor
		Chromosome Analysis, Peripheral Blood (Constitutional)	Culture / G-banding	PB
Hematology				
	Hematology			
		Bronchoalveolar Lavage (CD3, CD4, CD8, CD16, CD45, CD4:CD8 Ratio)	Flow Cytometry	Bronchoalveolar Lavage
		Flow Cytometry and Morphology	Flow Cytometry & PB Slide Review	PB, PB Smear
		Flow Cytometry Leukemia / Myeloma / Lymphoma	Flow Cytometry	PB, BM Aspirate, BM Core Biopsy, Fresh Tissue, BF, FNA, CSF
		Paroxysmal Nocturnal Hemoglobinuria - High Sensitivity (FLAER, CD14, CD24, CD59)	Flow Cytometry	PB, BM Aspirate



Accredited Laboratory

A2LA has accredited

MOLECULAR PATHOLOGY LABORATORY NETWORK, INC.

Maryville, TN

for technical competence in the field of

Clinical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO 15189:2012 *Medical laboratories – Requirements for quality and competence*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint IAF-ILAC-ISO Communiqué dated January 2015).



Presented this 9th day of August 2021.

A blue ink signature of a person, likely the Vice President of Accreditation Services, written over a horizontal line.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3765.01
Valid to May 31, 2023

For the tests to which this accreditation applies, please refer to the laboratory's Clinical Scope of Accreditation.