



SCOPE OF ACCREDITATION TO ISO 15189:2012

MOLECULAR PATHOLOGY LABORATORY NETWORK, INC.
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CLINICAL

Valid To: May 31, 2021

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, Bone Marrow (BM) clot, Peripheral Blood (PB), Formalin fixed paraffin embedded (FFPE) tissues, Pathology Materials, Fine Needle Aspirations (FNA), Fresh Tissues, Amniotic Fluid, Cerebrospinal Fluid (CSF), Cervical Swabs, Urethral Swabs, and Urine.**

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
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 clot, PB
		Image analysis	Aperio system	FFPE tissues
		Immunohistochemistry antibodies/markers	Automated immunohistochemistry staining	FFPE tissues
		Special stains	Manual histochemistry staining	FFPE tissues
		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
Pathology				
	Histopathology – Immunostains			
		Epstein Barr Virus Early RNA	Automated chromogenic in-situ hybridization staining	FFPE tissues
		Kappa Immunoglobulin Light Chains	Automated chromogenic in-situ hybridization staining	FFPE tissues

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Histopathology – Immunostains (cont.)			
		Lambda Immunoglobulin Light Chains	Automated chromogenic in-situ hybridization staining	FFPE tissues
		34BE12 (CK HMW)	Immunohistochemistry staining	FFPE tissues
		Alk-1 (CD246)	Immunohistochemistry staining	FFPE tissues
		Androgen Receptor	Immunohistochemistry staining	FFPE tissues
		Annexin A1	Immunohistochemistry staining	FFPE tissues
		Bcl-2	Immunohistochemistry staining	FFPE tissues
		Bcl-6	Immunohistochemistry staining	FFPE tissues
		BerEP4	Immunohistochemistry staining	FFPE tissues
		BRAF	Immunohistochemistry staining	FFPE tissues
		CA 19.9	Immunochemistry staining	FFPE Tissues
		Caldesmon	Immunohistochemistry staining	FFPE tissues
		Calretinin	Immunohistochemistry staining	FFPE tissues
		Cam 5.2 (CK7/CK8)	Immunohistochemistry staining	FFPE tissues
		CD10	Immunohistochemistry staining	FFPE tissues
		CD103	Immunohistochemistry staining	FFPE tissues
		CD117	Immunohistochemistry staining	FFPE tissues
		CD138	Immunohistochemistry staining	FFPE tissues
		CD15	Immunohistochemistry staining	FFPE tissues
		CD163	Immunohistochemistry staining	FFPE tissues
		CD1a	Immunohistochemistry staining	FFPE tissues
		CD2	Immunohistochemistry staining	FFPE tissues



Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Histopathology – Immunostains (cont.)			
		CD19	Immunohistochemistry staining	FFPE tissues
		CD20	Immunohistochemistry staining	FFPE tissues
		CD22	Immunohistochemistry staining	FFPE tissues
		CD23	Immunohistochemistry staining	FFPE tissues
		CD25	Immunohistochemistry staining	FFPE tissues
		CD3	Immunohistochemistry staining	FFPE tissues
		CD30	Immunohistochemistry staining	FFPE tissues
		CD31	Immunohistochemistry staining	FFPE tissues
		CD34	Immunohistochemistry staining	FFPE tissues
		CD4	Immunohistochemistry staining	FFPE tissues
		CD42b	Immunohistochemistry staining	FFPE tissues
		CD43	Immunohistochemistry staining	FFPE tissues
		CD45	Immunohistochemistry staining	FFPE tissues
		CD45RO	Immunohistochemistry staining	FFPE tissues
		CD5	Immunohistochemistry staining	FFPE tissues
		CD56	Immunohistochemistry staining	FFPE tissues
		CD57	Immunohistochemistry staining	FFPE tissues
		CD61	Immunohistochemistry staining	FFPE tissues
		CD68	Immunohistochemistry staining	FFPE tissues
		CD7	Immunohistochemistry staining	FFPE tissues
		CD79a	Immunohistochemistry staining	FFPE tissues
		CD8	Immunohistochemistry staining	FFPE tissues
		CD99	Immunohistochemistry staining	FFPE tissues
		CDK4	Immunohistochemistry staining	FFPE tissues

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Histopathology – Immunostains (cont.)			
		CDX 2	Immunohistochemistry staining	FFPE tissues
		CEA	Immunohistochemistry staining	FFPE tissues
		Chromogranin	Immunohistochemistry staining	FFPE tissues
		CK 5/6	Immunohistochemistry staining	FFPE tissues
		CK 8/18	Immunohistochemistry staining	FFPE tissues
		CK20	Immunohistochemistry staining	FFPE tissues
		CK7	Immunohistochemistry staining	FFPE tissues
		CMV	Immunohistochemistry staining	FFPE tissues
		c-MYC	Immunohistochemistry staining	FFPE tissues
		Cyclin D1	Immunohistochemistry staining	FFPE tissues
		Cytokeratin AE1/AE3	Immunohistochemistry staining	FFPE tissues
		D2-40 Podoplanin	Immunohistochemistry staining	FFPE tissues
		Desmin	Immunohistochemistry staining	FFPE tissues
		DOG1	Immunohistochemistry staining	FFPE tissues
		E-cadherin	Immunohistochemistry staining	FFPE tissues
		EGFR	Immunohistochemistry staining	FFPE tissues
		EMA	Immunohistochemistry staining	FFPE tissues
		ER	Immunohistochemistry staining	FFPE tissues
		ERA	Immunohistochemistry staining	FFPE tissues
		Factor XIIIa	Immunohistochemistry staining	FFPE tissues
		GCDFP-15(BRST2)	Immunohistochemistry staining	FFPE tissues
		Glycophorin A	Immunohistochemistry staining	FFPE tissues
		Granzyme B	Immunohistochemistry staining	FFPE tissues

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Histopathology – Immunostains (cont.)			
		H. Pylori	Immunohistochemistry staining	FFPE tissues
		Hep-Par-1(HSA)	Immunohistochemistry staining	FFPE tissues
		HER2 (Ventana)	Immunohistochemistry staining	FFPE tissues
		HMB45	Immunohistochemistry staining	FFPE tissues
		HSV 1&2	Immunohistochemistry staining	FFPE tissues
		Human Herpesvirus type 8	Immunohistochemistry staining	FFPE tissues
		Kappa ISH	Immunohistochemistry staining	FFPE tissues
		Ki-67	Immunohistochemistry staining	FFPE tissues
		Lambda ISH	Immunohistochemistry staining	FFPE tissues
		Mammaglobin	Immunohistochemistry staining	FFPE tissues
		MDM2	Immunohistochemistry staining	FFPE tissues
		Melan A (Mart1)	Immunohistochemistry staining	FFPE tissues
		MLH-1	Immunohistochemistry staining	FFPE tissues
		MSH2	Immunohistochemistry staining	FFPE tissues
		MSH6	Immunohistochemistry staining	FFPE tissues
		MUC-1	Immunohistochemistry staining	FFPE tissues
		Multiple Myeloma Oncogene 1	Immunohistochemistry staining	FFPE tissues
		Myeloperoxidase	Immunohistochemistry staining	FFPE tissues
		Napasin A	Immunohistochemistry staining	FFPE tissues
		NSE	Immunohistochemistry staining	FFPE tissues
		p16ink4a	Immunohistochemistry staining	FFPE tissues
		P504S	Immunohistochemistry staining	FFPE tissues
		p-53	Immunohistochemistry staining	FFPE tissues
		P57 Kip2	Immunohistochemistry staining	FFPE tissues

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Histopathology – Immunostains (cont.)			
		p-63 (nuclear stain)	Immunohistochemistry staining	FFPE tissues
		Pax-5	Immunohistochemistry staining	FFPE tissues
		Pax-8	Immunochemistry Staining	FFPE tissues
		PD-1	Immunochemistry Staining	FFPE tissues
		PD-L1	Immunochemistry Staining	FFPE tissues
		PMS2	Immunohistochemistry staining	FFPE tissues
		PR	Immunohistochemistry staining	FFPE tissues
		Protein Kinase B	Immunohistochemistry staining	FFPE tissues
		PSA	Immunohistochemistry staining	FFPE tissues
		PSAP	Immunohistochemistry staining	FFPE tissues
		RCC	Immunohistochemistry staining	FFPE tissues
		S-100	Immunohistochemistry staining	FFPE tissues
		SMA	Immunohistochemistry staining	FFPE tissues
		Smooth Muscle Myosin	Immunohistochemistry staining	FFPE tissues
		SOX-11	Immunohistochemistry staining	FFPE tissues
		Synaptophysin	Immunohistochemistry staining	FFPE tissues
		TdT	Immunohistochemistry staining	FFPE tissues
		TTF-1	Immunohistochemistry staining	FFPE tissues
		Tyrosinase	Immunohistochemistry staining	FFPE tissues
		Vimentin	Immunohistochemistry staining	FFPE tissues
		VonWillebrand (F-8)	Immunohistochemistry staining	FFPE tissues
		Wilms Tumor	Immunohistochemistry staining	FFPE tissues

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Molecular Pathology			
		Acute Lymphoblastic Leukemia Adult Panel [t(9;22), t(12;21), MLL]	FISH	PB, BM aspirate, FNA, Fresh tissue
		ALK 2p23 rearrangement Anaplastic Large Cell Lymphoma	FISH	FNA, FFPE
		AML1/ETO t(8;21)	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/ABL1 t(9;22)	FISH	PB, BM aspirate, FNA, Fresh tissue
		Burkitt / Diffuse Large "double hit" B-cell Lymphoma Panel [C-MYC, BCL2, BCL6]	FISH	PB, BM aspirate, FNA, FFPE, Fresh tissue
		Bladder Cancer +3,+7,+17,9p21	FISH	Urine, Bladder washings
		CBFB t(16;16), inv(16)	FISH	PB, BM aspirate, FNA, Fresh tissue
		C MYC 8q24 rearrangement	FISH	PB, BM aspirate, FNA, FFPE, Fresh tissue
		Chronic Lymphocytic Leukemia (CLL) Panel [MYB (6q23), ATM (11q22.3), +12, DLEU1 (13q14.3), TP53 (17p13)]	FISH	PB, BM aspirate, FNA, Fresh tissue
		Deletion 7q22 [D7S796, D7S658]/7q31.2 [D7S486]	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
		EGR1 5q deletion, monosomy 5	FISH	PB, BM aspirate, FNA, Fresh tissue

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Molecular Pathology (cont.)			
		Eosinophilia FISH Panel [FIPIL1/PDGFRa, PDGFRβ]	FISH	PB, BM aspirate, FNA, Fresh tissue
		FGFR	RT-PCR	FFPE
		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 14q32 rearrangement	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, FNA, FFPE, Fresh tissue
		IGH/MYC CEP 8, t(8;14)	FISH	PB, BM aspirate, FNA, Fresh tissue
		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
		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

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Molecular Pathology (cont.)			
		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
		BCR/ABL qRT PCR, Major p210 and Minor p190 Mutations, Minimal Residual Disease	qRT-PCR	PB, BM aspirate
		EGFR Mutation Analysis	Qiagen theascreen EGFR RGQ PCR Kit	FFPE, FNA
		JAK2 V617F Mutation Analysis	PCR	PB, BM aspirate
Pathology				
	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
		JAK2 exon12	Next Generation Sequencing (LDT)	PB, BM aspirate

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Genomics (cont.)			
		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
		Solid Tumor 8 Gene NGS	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
Pathology				
	Infectious Disease			
		Chlamydia Trachomatis, Qualitative	Hologic Aptima COMBO® 2 TMA	ThinPrep, SurePath, Cervical swab, Urethral Swab, Urine
		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, 18/45 genotype assay	ThinPrep, SurePath
		Human Papillomavirus High Risk	Hologic Aptima HPV	ThinPrep, SurePath
		Human Papillomavirus High Risk Panel plus Genotype	PCR by Roche cobas 4800	SurePath
		Neisseria Gonorrhoeae Qualitative	Hologic Aptima COMBO® 2 TMA	ThinPrep, SurePath, cervical swab, urethral swab, urine
		Trichomonas Vaginalis	Hologic Aptima Aptima® Trichomonas Vaginalis	ThinPrep, swab, urine

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
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
		Chromosome Analysis Products of Conception	Culture / G-banding	POC, skin biopsy
		Chromosome Analysis Solid Tumor	Culture / G-banding	Fresh tissue/tumor
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 and PB Smear
		Flow Cytometry Leukemia / Myeloma / Lymphoma	Flow Cytometry	PB, BM aspirate, BM core biopsy, fresh tissue, body fluids, FNA, CSF
		LAD (Leukocyte Adhesion Deficiency)	Flow Cytometry	PB, BM aspirate
		Paroxymal Nocturnal Hemoglobinuria - High Sensitivity (FLAER, CD14, CD24, CD59)	Flow Cytometry	PB, BM aspirate



***ISO 15189:2012
Internationally-Recognized
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 ISO-ILAC-IAF Communiqué dated January 2015*).

Presented this 8th day of July 2019.

A blue ink signature of the Vice President, Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3765.01
Valid to May 31, 2021



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



Raising the Bar in Laboratory Quality