



SCOPE OF ACCREDITATION TO ISO 15189:2012

MOLECULAR PATHOLOGY LABORATORY NETWORK, INC.
 250 East Broadway Avenue
 Maryville, TN 37804
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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.) | | | |
| | | ALK 2p23 Rearrangement Anaplastic Large Cell Lymphoma | FISH | FNA, FFPE |
| | | Androgen Receptor | Immunohistochemistry Staining | 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 |
| | | BOB1 | 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|------------------|--|--------------|-------------------------------|-------------|
| Pathology | | | | |
| | Histopathology – Immunostains (cont.) | | | |
| | | CD20 | Immunohistochemistry Staining | FFPE |
| | | 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|------------------|--|------------------------------|--|-------------|
| Pathology | | | | |
| | Histopathology – Immunostains (cont.) | | | |
| | | CD8 | Immunohistochemistry Staining | FFPE |
| | | 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|------------------|--|------------------------------------|--|-------------|
| Pathology | | | | |
| | Histopathology – Immunostains (cont.) | | | |
| | | ER | Immunohistochemistry Staining | FFPE |
| | | ERA | Immunohistochemistry Staining | FFPE |
| | | Factor XIIIa | Immunohistochemistry Staining | FFPE |
| | | 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|------------------|--|-----------------------------|-------------------------------|-------------|
| Pathology | | | | |
| | Histopathology – Immunostains (cont.) | | | |
| | | MUC-1 | Immunohistochemistry Staining | FFPE |
| | | Multiple Myeloma Oncogene 1 | Immunohistochemistry Staining | FFPE |
| | | Myeloperoxidase | Immunohistochemistry Staining | FFPE |
| | | Napasin A | Immunohistochemistry Staining | FFPE |
| | | NSE | Immunohistochemistry Staining | FFPE |
| | | OCT2 | 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 |
| | | PAN-TRK | 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|------------------|--|--|-------------------------------|--|
| Pathology | | | | |
| | Histopathology – Immunostains (cont.) | | | |
| | | SOX-11 | Immunohistochemistry Staining | FFPE |
| | | Synaptophysin | Immunohistochemistry Staining | FFPE |
| | | TdT | Immunohistochemistry Staining | FFPE |
| | | TTF-1 | Immunohistochemistry Staining | FFPE |
| | | 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|------------------|------------------------------------|--|-------------------------------------|--|
| Pathology | | | | |
| | Molecular Pathology (cont.) | | | |
| | | 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 |
| | | 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/PDGFR4 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|------------------|------------------------------------|--|----------------------------------|--------------------------------------|
| Pathology | | | | |
| | Molecular Pathology (cont.) | | | |
| | | 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 |
| | | 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|------------------|---------------------------|---|---|--|
| Pathology | | | | |
| | Genomics (cont.) | | | |
| | | IDH1/IDH2 Mutational Analysis | Next Generation Sequencing (LDT) | FFPE, PB, BM Aspirate |
| | | IgVH Somatic Hypermutation | Next Generation Sequencing (LDT) | PB, BM Aspirate |
| | | 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 |

| Specialty | Sub Specialty | Test/Analyte | Method(s) | Matrix(ces) |
|---------------------|-----------------------------------|--|---|---|
| Pathology | | | | |
| | Infectious Disease (cont.) | | | |
| | | SARS-CoV-2 | Aptima TMA | Nasopharyngeal, Nasal, and Oropharyngeal Swabs |
| | | <i>Trichomonas vaginalis</i> | Hologic Aptima® <i>Trichomonas vaginalis</i> | ThinPrep, Swab, U |
| 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.