MOLECULAR SERVICES

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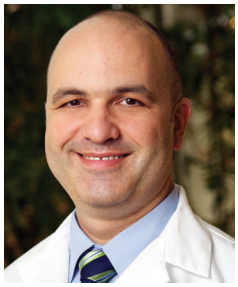
PICTURED ON LEFT IS MARWAN TAYEH, PH.D, CLINICAL ASSISTANT PROFESSOR, PEDIATRICS - GENETICS, ON RIGHT IS TODD ACKLEY, LABORATORY MANAGER

MLabs is a full-service reference laboratory and part of one of the largest health care complexes in the world, Michigan Medicine.

With 30+ years of reference laboratory experience, MLabs' CLIA-certified/CAP accredited molecular laboratories offer state of the art clinical molecular services including testing, analyzing and interpreting complex data sets, issuing informative reports and providing consultations that aid in the delivery of precision medicine. MLab's current molecular test portfolio includes over 100 genetic tests and we are continuously adding new molecular assays. Our highly experienced doctors, medical technologists, and bioinformaticians are dedicated to delivering the highest quality laboratory results to meet the needs of today's patients in a cost effective and personalized manner.

MOLECULAR ONCOLOGY & GENETICS

CONSULTANTS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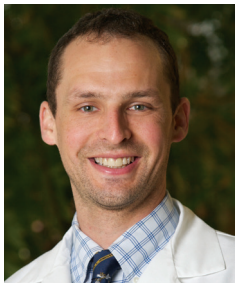
Scott A. Tomlins
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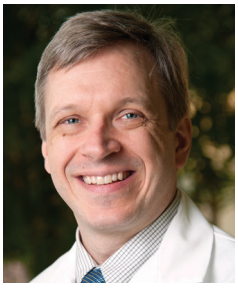
Thomas E. Wilson
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SERVICES

MOLECULAR ONCOLOGY/GENETICS

Performing over 14,000 assays annually with an average turn-around-time of 4.1 days, our Molecular Oncology and Genetics Laboratory specializes in offering cutting-edge molecular tests to aid in cancer diagnosis, selection of therapy, determination of prognosis, and monitoring of residual disease. An expanding menu of tests are offered in disease-specific service lines to provide a comprehensive testing solution for each disease, including colorectal cancer, non-small cell lung cancer, melanoma, gastrointestinal stromal tumor, glioma, sarcoma, myeloproliferative neoplasms, acute myeloid leukemia, lymphoproliferative disorders, and others. The implementation of next generation sequencing technology to many tests and panels now provides the ability to detect mutations with excellent sensitivity and broad coverage while also preserving the ability to test small biopsies and challenging specimens with low neoplastic cell content.

MOLECULAR GENETICS

MLab's Molecular Genetics Laboratory has two ABMGG board certified Geneticists, Marwan Tayeh, PhD; Jeffry Innis, MD, PhD and a board certified Genetic Counselor. Molecular Genetics Laboratory offers comprehensive clinical testing for germline genetic diseases and is committed to assisting clinicians in identifying genetic aberrations to facilitate clinical diagnosis, management, and genetic counseling. Molecular Genetics offers a variety of NGS germline cancer panels including: Breast and Ovarian, Colorectal, Pancreatic, Renal, Endometrial/Uterine, Melanoma, Stomach, Prostate, and Paraganglioma. In addition, the laboratory offers Sanger sequencing for a long list of genes, SNP Chromosomal Microarray, mutation screening for cystic fibrosis, Methylation-Specific PCR for Prader-Willi/Angelman syndrome and Fragile X, MLPA for deletion/duplication detection of BRCA1, BRCA2, TP53, PTEN, MECP2, CFTR, and SMN1 exons 7 and 8 deletions.

TRANSLATIONAL PATHOLOGY

MLabs comprehensively characterize disease using novel bioinformatics approaches and high-throughput technologies. This work facilitates more accurate, early detection methods, assists in the prediction of prognosis, defines disease subtypes, as well as assists in the assessment of treatment efficacy. These efforts could result in the future development of targeted therapies.

Our featured tests include PCA3 (Gen-Probe) test for prostate cancer detection and MiPS (Mi-Prostate Score (MiPS) an early detection test for prostate cancer that combines the amount of serum PSA, with the amounts of two genes in the urine. These two genes, TMPRSS2:ERG and PCA3, are specific for prostate cancer, meaning they are rarely present at high levels in the urine of men without prostate cancer.

SELECT TEST MENU

Molecular Oncology

ACUTE MYELOID LEUKEMIA

NPM1 Mutation (PCR)
FLT3 Mutation (PCR)
CEPBA Mutation (Sanger)
IDH1 and IDH2 Mutation (Sanger)
KIT D816V Mutation (PCR)
KIT Mutation for AML - Exons 8, 17 (Sanger)
PML/RARA t(15;17) Translocation Qualitative (PCR)

MYELOPROLIFERATIVE NEOPLASMS

JAK2 V617F Mutation (PCR)
JAK2 Exon 12 Mutation (PCR)
CALR Mutation (PCR)
MPL Mutation (PCR)
KIT D816V Mutation (PCR)
BCR/ABL1 Analysis, Quantitative (PCR)
BCR/ABL1 Kinase Domain Mutation (Sanger)

LYMPHOPROLIFERATIVE DISORDERS

B Cell Clonality (PCR) (IGK & IGH Gene Rearrangement)
B Cell Clonality (PCR) (IGK Gene Rearrangement)
B Cell Clonality (PCR) (IGH Gene Rearrangement)
T Cell Clonality (PCR) (TRG & TRB Gene Rearrangement)
T Cell Clonality (PCR) (TRG Gene Rearrangement)
T Cell Clonality (PCR) (TRB Gene Rearrangement)
IGH/BCL2 t(14;18) Translocation (PCR)
IGH/BCL2 t(14;18) Translocation (FISH)
BCL6 (3q27) Rearrangement (FISH)
MYC (8q24) Rearrangement (FISH)
MALT1 (18q21) Rearrangement (FISH)
MYD88 (L265P) Mutation (PCR)
BRAF V600E/V600K Mutations (PCR)

COLORECTAL AND ENDOMETRIAL CANCER

Colorectal Cancer (NGS) Panel*
Germline MLH1 Promoter Methylation (PCR)
KRAS Mutation (NGS)
MLH1 Promoter Methylation (PCR)
NRAS Mutation (NGS)
BRAF V600E/V600K Mutations (PCR)
Microsatellite Instability Analysis (PCR)
UGT1A1 Promoter Genotyping (PCR)
Circulating Tumor Cells (CellSearch)

GASTROINTESTINAL STROMAL TUMOR

KIT Mutation - Exons 9,11,13,17 (Sanger)
PDGFRA Mutation for GIST (Sanger)

GENITOURINARY TUMOR

BRAF (7q34) Rearrangement (FISH)
ERG Rearrangement (FISH)
TFE3 (Xp11,2) Rearrangement (FISH) for Renal Cell CA & Other Tumors
TFEB (6p21) Rearrangement (FISH) for Renal Cell Carcinoma

GLIOMA

BRAF (7q34) Rearrangement (FISH)
IDH1 and IDH2 Mutations (Sanger)
1p/19q Deletion (FISH)
BRAF V600E/V600K Mutations (PCR)
MGMT Promoter Methylation (PCR)
TERT Promoter Mutation (PCR)

LUNG CANCER

Lung Cancer (NGS) Panel*
EGFR Mutation (NGS)
BRAF V600E/V600K Mutations (PCR)
KRAS Mutation (NGS)
ALK Rearrangement for NSCLC (FISH)
ROS1(6q22) Rearrangement (FISH)
RET (10q11) Rearrangement (FISH)
PD-L1 (IHC)
MET Amplification (FISH)

MELANOMA

Melanoma (NGS) Panel*
BRAF (7q34) Rearrangement (FISH)
BRAF V600E/V600K Mutations (PCR)
KIT Mutation for Melanoma - Exons 11,13,17 (Sanger)
NRAS Mutation (NGS)
Chromosomal (Microarray) for Melanoma
Multiprobe (FISH) for Melanoma
TERT Promoter Mutation (PCR)

PROSTATE CANCER

Prostate Cancer Antigen 3 (PCA3)
MiPS (Mi-Prostate Score)

SARCOMA

SYT/SSX Translocation (PCR)
PAX/FOXO1 Translocation (PCR)
EWSR1/WT1 Translocation (PCR)
EWSR1/ATF1 Translocation (PCR)
EWSR1/FLI1 & EWSR1/ERG Translocation (PCR)
EWSR1 (22q12) Rearrangement (FISH)
MDMD2 Amplification (FISH)
CIC (19q13) Rearrangement (FISH)

THYROID CANCER

BRAF V600 E/V600K Mutations (PCR)
BRAF (7q34) Rearrangement (FISH)
TERT Promoter Mutation (PCR)

MISCELLANEOUS

Solid Tumor (NGS) Panel*
Biliary Tract Malignancy (FISH)
Bone Marrow Transplant Engraftment Analysis (PCR)
Circulating Tumor Cells for Breast, Colorectal and Prostate Cancer
HER2 (FISH)
UGT1A1 Promoter Genotyping (PCR)
UroVysion™ (FISH) (Bladder Cancer)

*NGS Panels include: mutations (35 genes), amplification (19 genes) and gene fusion (21 genes)

TEST LISTING CONTINUED ON BACK

SELECT TEST MENU CONTINUED

Genetics (Germline)

AUTISM SPECTRUM DISORDERS/ INTELLECTUAL DISABILITY

Chromosomal Microarray Analysis
Fragile X Syndrome Mutation
Prader-Willi /Angelman Syndrome
CDKL5 Gene Sequencing
GDI1 Gene Sequencing
MBD5 Gene Sequencing
MEF2C Gene Sequencing
NLGN3 Gene Sequencing
NLGN4X Gene Sequencing
SHANK2 Gene Sequencing
SHANK3 Gene Sequencing
SLC9A6 Gene Sequencing
TCF4 Gene Sequencing
UBE3A Gene Sequencing

MECP2 (RETT SYNDROME)

MECP2 Gene Sequencing
MECP2 Deletion/Duplication
MECP2 Targeted Sequencing Familial

PTEN HARMARTOMA TUMOR SYNDROME

PTEN Gene Sequencing
PTEN Deletion/Duplication
PTEN Targeted Sequencing Familial

BREAST AND OVARIAN CANCER

BRCA1 and BRCA2 Gene Sequencing
BRCA1 and BRCA2 Targeted Sequencing, Familial
BRCA1 and BRCA2 Deletion/Duplication
BRCA Ashkenazi Jewish Founder Mutations
BRCA Mutation Panel
Hereditary Breast and Ovarian Cancer (HBOC) Comprehensive Germline NGS Panel
Hereditary Breast and Ovarian Cancer (HBOC) High-Moderate Risk Germline NGS Panel
PTEN Gene Sequencing
PTEN Deletion/Duplication
TP53 Gene Sequencing
TP53 Deletion/Duplication

COLORECTAL CANCER

Colorectal Cancer Germline NGS Panel
MSH2 Gene Sequencing

CYSTIC FIBROSIS

Cystic Fibrosis Carrier Screening
Cystic Fibrosis Full Gene Sequencing
Cystic Fibrosis Deletion/Duplication
Cystic Fibrosis Diagnostic Mutation Detection
Cystic Fibrosis Targeted Sequencing Familial

HEARING LOSS

GJB2 (Connexin 26) Mutation Analysis
GJB2 (Connexin 26) Targeted Sequencing Familial
GJB6 (Connexin 30) Deletion Analysis
WFS1 (Wolfram Syndrome) Gene Sequencing

NOONAN SYNDROME

PTPN11 Gene Sequencing
KRAS Gene Sequencing
RAF1 Gene Sequencing
SOS1 Gene Sequencing

FRAGILE X SYNDROME

Fragile X Syndrome Mutation Detection

LI-FRAUMENI SYNDROME

TP53 Gene Sequencing
TP53 Deletion/Duplication

NEUROFIBROMATOSIS

NF1 Gene Sequencing

SPINAL MUSCULAR ATROPHY

SNM1 and SNM2 Deletion/Duplication

MISCELLANEOUS

Apolipoprotein E Genotyping
Factor V Leiden Mutation
Hereditary Hemochromatosis Mutation
Prothrombin 20210 Mutation

CANCER GERMLINE NGS PANELS (63 GENES)

Colorectal Cancer Germline NGS Panel
19 Genes: MLH1, MSH2, MSH6, MUTYH, PMS2, EPCAM, APC, TP53, PTEN, STK11, SMAD4, BMPR1A, CDH1, CHEK2, GREM1, POLD1, POLE, ATM, AXIN2

Endometrial/Uterine Cancer Germline NGS Panel
13 Genes: BRCA1, BRAC2, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, TP53, STK11, POLD1

Hereditary Breast and Ovarian Cancer Comprehensive Germline NGS Panel
21 Genes: ATM, BARD1, BRAC1, BRAC2, BRIP1, CDH1, STK11, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, TP53, FANCC, XRCC2

Hereditary Breast and Ovarian Cancer High-Moderate Risk Germline NGS Panel
9 Genes: ATM, BRAC1, BRAC2, BRIP1, CDH1, CHEK2, PALB2, PTEN, TP53

Melanoma Cancer Germline NGS Panel
6 Genes: BRCA1, BRCA2, CDKN2A, CDK4, TP53, PTEN

Neurofibromatosis Germline NGS Panel
3 Genes: NF1, NF2, SPRED1

Pancreatic Cancer Germline NGS Panel
18 Genes: APC, ATM, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53, CDK4, BMPR1A, SMAD4, VHL, XRCC2

Paraganglioma Cancer Germline NGS Panel
12 Genes: SDHAF2, MAX, TMEM127, FH, MEN1, NF1, RET, VHL, SDHB, SDHC, SDHD, SDHA

Prostate Cancer Germline NGS Panel
6 Genes: BRCA1, BRCA2, CHEK2, HOXB13, NBN, TP53

Renal Cancer Germline NGS Panel
19 Genes: VHL, PMS2, PTEN, TP53, EPCAM, FH, FLCN, MET, MLH1, MSH2, MSH6, SDHB, SDHC, SDHD, SDHA, BAP1, TSC1, TSC2, MITF

Stomach Cancer Germline NGS Panel
11 Genes: MLH1, MSH2, MSH6, EPCAM, PMS2, APC, TP53, STK11, CDH1, BMPR1A, SMAD4

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN