



*Integrated hematopathology analysis
& reporting - SaraPath CompDX*

Working with you to advance patient care.



Why does SaraPath Diagnostics provide CompDX ---- comprehensive hematopathology diagnostics and reports that combine pathology, IHC stains, flow cytometry and cytogenetic studies into one document?

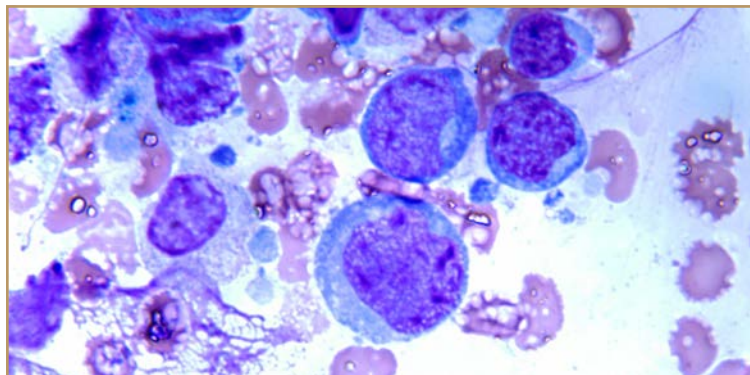
Because we want ordering physicians to have every piece of the diagnostic puzzle.

SaraPath Diagnostics offers full service diagnostic evaluation of blood, bone marrow, lymph nodes and other hematopoietic and lymphoid tissues. Our goal is to provide timely, appropriate, accurate and cost-effective evaluation of each specimen, integrating the various results obtained into a single diagnosis.

Specialty-trained hematopathologists provide continuous consultation services and are available to discuss cases directly with clinicians. Rapid results are provided for immunohistochemical stains, flow cytometry, cytogenetic analyses and other molecular testing. Hematopathology services are available Monday through Friday, including Friday evening, with STAT cases reportable Saturday morning at the ordering physician's request.

Because oncology cases often are complex...

- SaraPath Diagnostics integrates all pathology, flow cytometry and cytogenetic studies into a useful diagnosis tool for the clinician.
- SaraPath ensures ready accessibility of its hematopathologists for pre- or post-analytical consultation with clinicians.
- SaraPath pathologists are an important part of your oncology team to guarantee definitive diagnosis and optimal case management for each patient.
- SaraPath pathologists refer bone marrow specimens (depending on the clinical indications) for cytogenetic analysis, incorporating the results, provided by PhD cytogeneticists, into the comprehensive pathology report.



Comprehensive oncology reports include all pathology, IHC, flow cytometry, cytogenetic and molecular studies.

 **SaraPath CompDX™**



SaraPath Diagnostics FISH Testing Protocols

Fluorescence in situ hybridization (FISH) is a gene mapping technique which can be used on cell nuclei. The method does not require formation of chromosomes, and therefore can be used on non-dividing cells in smear preparations and tissue sections. It can be used to detect numerical chromosome abnormalities, losses and gains of specific genes and chromosomal regions, and translocations. The results help to confirm specific diagnoses and provide prognostic and therapeutic information.

The following FISH panels are available through SaraPath Diagnostics:

Test Name	Locus / Gene	Abnormality ID'd	Significance
CML Panel	9q34/ABL, 9q34/ASS, 22q11.2/BCR	BCR/ABL fusion	Diagnosis of CML
APL Panel (always run STAT)	15q22/PML, 17q21/RARA	PML/RARA fusion	Diagnosis of APL
MDS Panel	5p15.2/DSS721-D5S23, 5q33-q34/CSF1R, 7q11.1-q11.1/CEN 7, 7q31/D7S486, 8p11.1-q11.1/CEN 8, 20q12/D20S108	Chromosomal gains & deletions	Diagnosis of MDS
CLL Panel	11q22.3/ATM, 17p13.1/p53, 12p11.1-q11.1/CEN 12, 13q13/D13S319, 13q34/LAMP1, 11q13/CCND1(BCL1), 14q32/IgH	Deletions of ATM, p53, RB1, LAMP1, Trisomy 12, Bcl1 translocation	Diagnosis of MDS
MM-MGUS Panel	1pter/CEB108/T7, 1qter/1QTEL10, 5p15.2/D5S721-D5S23, 5q33-q34/CSF1R, 3p11.1-11.1/CEN 3, 9p11.1-q11.1/CEN 9, 13q14.3/D13S319, 13q34/LAMP1, 14q32/IgH, 17p13.1/p53	Deletions & translocations	Diagnosis of MDS
MM Panel	4p16.3/FGFR3, 14q32/IgH, 11q13/CCND1(BCL1), 14q32/IgH, 14q32/IgH, 16q23/MAF	Deletions & translocations	Prognostic markers in multiple myeloma
AML Panel	5p15.2/DSS721-DSS23, 5q33-q34/CSF1R, 7q11.1-q11.1/CEN 7, 7q31/D7S486, 8p11.1-q11.1/CEN 8, 11q23/MLL, 8q22/ETO, 21q22/AML1, 15q22/PML, 17q21/RARA, 16q22/CBFB	Deletions, duplications, translocations	Classification, prognostic markers in acute myeloid leukemia (AML)
PDGFRa Panel	4q12/FIP1L1/CHIC2/PDGFR A	Translocations	Confirmation/classification of hypereosinophilic syndromes
NHL Panel	2p23/ALK, 3q27/BCL6, 8q24/MYC, 8p11.1-q11.1/CEN 8, 11q13/CCND1(BCL1), 14q32/IgH, 18q21/BCL2	Translocations	Classification of nonHodgkin lymphoma (NHL)
AML t(8;21) Panel	8q22/ETO, 21q22/AML1	Translocations	Confirmation of AML with t(8;21)
APL t(15;17) Panel	15q22/PML, 17q21/RARA	Translocations	Confirmation of APL with t(15;17)
AML inv(16)/t(16;16) Panel	16q22/CBFB	Translocations	Confirmation of AML with Inv(16) or t(16;16)
MLL Panel	11q23/MLL	Translocations	Confirmation of AML or ALL with MLL translocation
IgH Panel	14q32/IgH	Translocations	Prognostic marker in leukemia and myeloma
ALK Panel	2p23/ALK	Translocations	Confirmation of anaplastic large cell lymphoma (ALK). Prognostic marker in non-small cell lung CA.
MCL Panel	11q13/CCND1(BCL1), 14q32/IgH	Translocations	Confirmation of mantle cell lymphoma (MCL)
FL Panel	14q32/IgH, 18q21/BCL2	Translocations	Confirmation of follicular lymphoma (FL)
Burkitts Panel	8p11.1-q11.1/CEN 8, 8q24/MYC, 14q32/IgH	Translocations	Confirmation of Burkitts lymphoma
MALT1 Panel	18q21/MALT1	Translocations	Identification of translocation involving MALT1, associated with MALT lymphoma
MALT t(11;18) Panel	11q21/AP12, 18q21/MALT1	Translocations	Identification of t(11;18), associated with MALT lymphoma
BCL6 Panel	3q27/BCL6	Translocations	Detection of BCL6 rearrangement, associated with follicular lymphoma
MYC Panel	8q24/MYC	Translocations	Detection of variant translocations involving MYC
UroVysion Panel	3p11.1-q11.1/CEN 3, 7p11.1-q11.1/CEN 7, 17p11.1-q11.1/CEN 17, 9p21/p16	Aneuploidy	Prognostic markers in urothelial carcinoma
Melanoma Panel	6p25/RREB1, 6p11.1-q11.1/CEN 6, 6q23/MYB, 11q13/CCND1(BCL1)	Aneuploidy and deletions	Detection of lesions associated with malignant melanoma
PathVysion Panel	17q11.2-q12/HER2, 17p11.1-q11.1/CEN 17	Amplification of HER2	Prognostic/therapeutic marker in breast carcinoma

SaraPath Diagnostics Testing Protocols

SaraPath CompDX™ is a series of testing options that provides the hematopathologist a broad range of advanced diagnostic technologies based on the medical need.

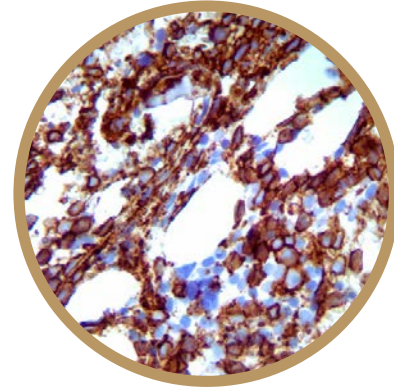
CompDX delivers a higher patient care level, removes unnecessary testing, controls costs and results in a faster diagnosis.

CompDX includes one or more of the following tests:

- Microscopy/Morphology
- Immunohistochemistry (IHC)
- In Situ Hybridization/FISH
- Multi-color Cytometry
- Cell enrichment for FISH and/or molecular analysis
- Cytogenetics
- Qualitative & Quantitative PCR
- Sequencing & Fragment Analysis
- Molecular Genetics

Molecular Services:

- FISH Assays (see separate list)
- JAK2 Mutation analysis
- Quantitative PCR for BCR/ABL



Flow Cytometry is the analysis of biological material by detection of fluorescent-labeled antibodies which are bound to the cells being evaluated. The results provide information involving cell lineage, useful in classification of neoplastic populations, and expression of prognostic markers.

Analysis often is used clinically to help determine a patient's leukemia type or lymphoma and to assess the prognosis. Panels of antibodies, which include acute and chronic leukemias, lymphomas and MDS, are used to evaluate which malignant cell type exists.

Flow Cytometry is quite sensitive and able to detect residual levels of diseases as well as rare cell types. SaraPath Diagnostics evaluates an extensive standard flow panel to detect and classify hematopoietic and lymphoid neoplasms.

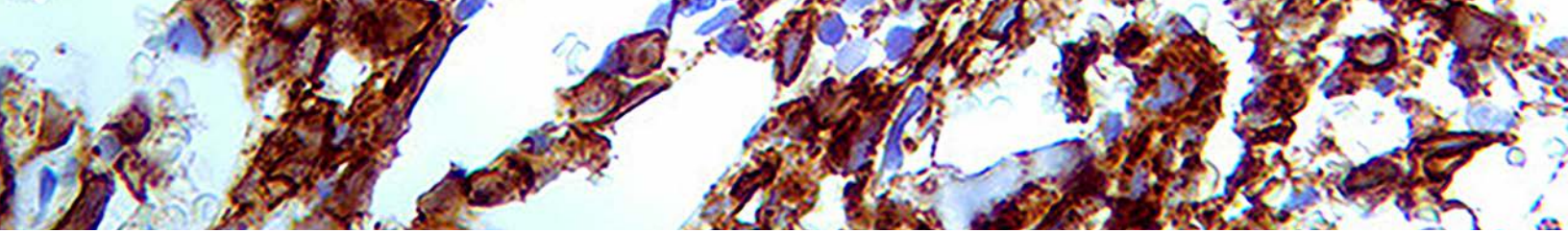
Depending on the specific situation and initial results, the following additional panels are available to the pathologists:

- Monocyte antigen expression (for AML)
- TdT expression (for acute lymphoblastic leukemia)
- Hairy cell leukemia
- Plasma cell clonality
- Paroxysmal Nocturnal Hemoglobinuria (PNH)
- T-cell clonality

Immunohistochemistry (IHC) is a testing method used to analyze and identify cell types based on antibodies binding to cells' specific components. In cases where there may be difficulty determining the cell type from which a tumor originates, IHC can identify a cell's distinctive markers on its surface. Additionally, IHC can determine the difference between a malignant and benign tumor and can assist with the patient's prognosis by diagnosing the cancer type.

IHC requires a tissue sample from a biopsy. The sample will carry characteristic markers on the cell surface from the tumor cells in question. These markers are utilized to identify the specific type of tumor cell. Antibodies against these antigens are added to the sample tissue and bind to the specific antigens. The bound antibodies will have labels that chemically react to render them visible by a microscope.

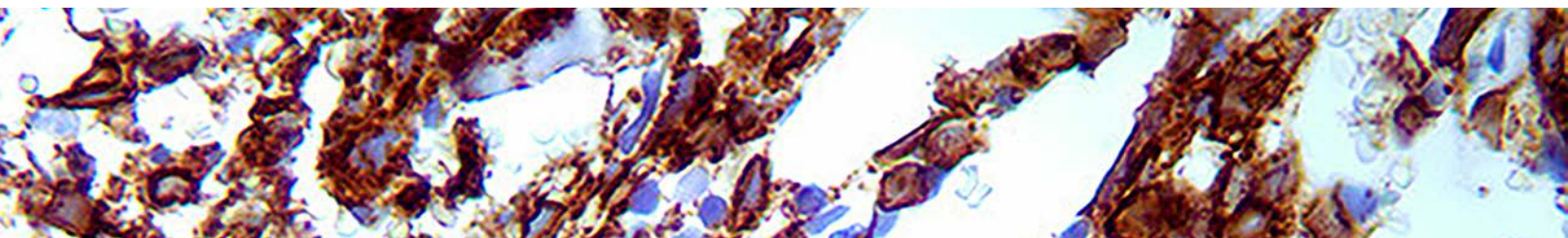
This process allows the pathologist to assess cell maturity, origin, malignancy, specific proteins, hormone receptors, etc. The pathologists use this information to confirm the diagnosis and classify the tumor and, in some applications, provide prognostic and therapeutic indicators.



Definitive diagnoses, cutting-edge technology, and skilled judgment...

SaraPath Advantages

- Experienced, specialty-trained hematopathologists available around-the-clock to support the ordering physician.
- Cutting-edge diagnostic capabilities such as immunohistochemistry, flow cytometry, cytogenetics and molecular assays to support the skilled judgment of SaraPath hematopathologists.
- Appropriate and thoughtful ordering of tests, working in concert with ordering oncologists and hematologists.
- Consolidated reports that combine all studies into a single, easy-to-read document with digital images.
- Fast turn-around time, with many non-complex hematopathology reports available within one day of specimen receipt.
- Most up-to-date CAP and AJCC cancer staging guidelines used, to provide definitive diagnoses and clear, concise reporting.
- Insurance contracts with all major providers, enabling SaraPath clients to consolidate AP testing and streamline ordering practices.
- Full range of IT connectivity solutions to facilitate convenient order entry and reliable result reporting.
- CAP accredited laboratory, proud of its multi-year deficiency-free inspections that support quality patient care.
- Organization-wide service culture to meet and exceed the expectations of valued clients.
- Highly trusted, physician-owned anatomic pathology laboratory that has been delivering reliable, responsive, and individualized AP testing services for physicians since 1975.



*Know the whole picture. SaraPath Diagnostics.
Working with you to advance patient care.*

