# Comprehensive Cancer Biomarker Testing Program

As of January 1, 2024

**Version 2324.3** 



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Note: Effective January 1, 2024, all testing indications are funded for the adult and pediatric populations, unless otherwise specified. Central Nervous System (CNS) and Soft Tissue & Bone indications are currently undergoing review and are intended for the adult population.

#### **Adrenal Gland**

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2,	Grand River Hospital
diagnosed tumours with adrenal	MSH6, PMS2	Hamilton Health Sciences/ St. Joseph's
cortical carcinoma.		Healthcare Hamilton
		Health Sciences North
		Hospital for Sick Children (SickKids)
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare

# **Bladder/Urothelial**

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	FGFR2, FGFR3	Hamilton Health Sciences/ St. Joseph's
diagnosed tumours with		Healthcare Hamilton
advanced/metastatic urothelial		Hospital for Sick Children (SickKids)
carcinoma		Kingston Health Sciences Centre
		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2,	Grand River Hospital
diagnosed tumours with upper	MSH6, PMS2	Hamilton Health Sciences/ St. Joseph's
tract (ureter/renal pelvis)		Healthcare Hamilton
urothelial carcinoma.		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		North York General Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare

## **Breast**

Testing Indication	Biomarkers	Testing Sites
Reflex testing on all newly	ER, PR, HER2	Grand River Hospital
diagnosed breast cancers.		Hamilton Health Sciences/ St. Joseph's
		Healthcare Hamilton
		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Mount Sinai Hospital
		North York General Hospital
		Royal Victoria Regional Health Centre
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Thunder Bay Regional Health Sciences
		Centre
		Trillium Health Partners - Credit Valley Site
		Unity Health – St. Michael's Hospital
		University Health Network
		William Osler Health System
		Windsor Regional Hospital

Testing Indication	Biomarkers	Testing Sites
Reflex testing on all newly	ER	Grand River Hospital
diagnosed ductal carcinoma in		Hamilton Health Sciences/ St. Joseph's
situ (DCIS)		Healthcare Hamilton
,		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Mount Sinai Hospital
		North York General Hospital
		Royal Victoria Regional Health Centre
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Thunder Bay Regional Health Sciences
		Centre
		Trillium Health Partners - Credit Valley Site
		Unity Health – St. Michael's Hospital
		University Health Network
		William Osler Health System
		Windsor Regional Hospital
Testing on advanced/metastatic	ESR1, PIK3CA	Hamilton Health Sciences/ St. Joseph's
breast cancer where directed		Healthcare Hamilton
therapy is being considered		Kingston Health Sciences Centre
		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System
Testing on locally recurrent	PD-L1	Hamilton Health Sciences/ St. Joseph's
unresectable or metastatic triple		Healthcare Hamilton
negative breast cancer (TNBC)		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System

Testing Indication	Biomarkers	Testing Sites
Testing on HER2 negative,	Ki-67	Grand River Hospital
hormone receptor positive, node		Hamilton Health Sciences/ St. Joseph's
positive, early breast cancer at		Healthcare Hamilton
high risk of disease recurrence		Health Sciences North
where Ki-67 directed therapy is		Kingston Health Sciences Centre
being considered		Lakeridge Health
being considered		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System

# **Central Nervous System (CNS)**

Note: CNS indications are currently undergoing review and are intended for the adult population.

## **Ependymomas**

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	H3 K27me3, EZHIP,	Hospital for Sick Children (SickKids)
diagnosed adult cases of	chrom 1q gain,	
Ependymoma (infratentorial)	chrom 6q loss	
Reflex testing on newly	ZFTA, YAP1,	Trillium Health Partners - Credit Valley Site
diagnosed adult cases of	CDK2NA	
Ependymoma (supratentorial)		
Testing to support newly	MYCN	London Health Sciences Centre
diagnosed adult cases of	amplification	Trillium Health Partners - Credit Valley Site
Ependymoma (spinal cord)		

# **High-Grade Gliomas**

Testing Indication	Biomarkers	Testing Sites
Reflex testing should be performed on tumours from newly diagnosed adult patients with astrocytic and oligodendroglial tumours, including glioblastomas (all diffuse high-grade gliomas Stage III and IV).  Additional testing as needed to confirm diagnosis and subtype	ATRX, IDH R132H, p53	<ul> <li>London Health Sciences Centre</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>Unity Health – St. Michael's Hospital</li> <li>University Health Network</li> </ul>
1p/19q, CDKN2A testing should be performed on patients who test positive for an IDH1 mutation.  For IDH wild-type patients diagnosed with Grade II and III tumours, sequencing should be performed.	1p/19q, CDKN2A  IDH, TERT, EGFR, +7/-10	<ul> <li>London Health Sciences Centre</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>Unity Health – St. Michael's Hospital</li> <li>University Health Network</li> <li>London Health Sciences Centre</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>Unity Health – St. Michael's Hospital</li> <li>University Health Network</li> </ul>
MGMT testing should be performed on all Grade IV patients > 55, all Grade III patients > 55 and IDH wild-type Grade III patients ≤ 55.	MGMT Promoter Methylation	<ul> <li>London Health Sciences Centre</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>Unity Health – St. Michael's Hospital</li> <li>University Health Network</li> </ul>
H3-K27M testing should be performed on patients diagnosed with a glioma tumour in the midline location.	H3-K27M	<ul> <li>London Health Sciences Centre</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>Unity Health – St. Michael's Hospital</li> <li>University Health Network</li> </ul>

## Medulloblastomas

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	CTNNB1,	Hospital for Sick Children (SickKids)
diagnosed adult cases of	INI1/SMARCB1,	
medulloblastoma.	FLNA, p53*,	
	Nanostring/	
	Methylation for	
	subtyping	
*TP53 testing should be	TP53 SNV	Hospital for Sick Children (SickKids)
performed on patients with an		
abnormal p53 IHC result.		

# Cervix

<b>Testing Indication</b>	Biomarkers	Testing Sites
Newly diagnosed cases of cervical	HPV	Hamilton Health Sciences/ St. Joseph's
carcinoma where HPV status		Healthcare Hamilton
cannot be determined from		Health Sciences North
histology/p16 staining.		Markham Stouffville Hospital
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners – Credit Valley Site
		University Health Network
		William Osler Health System
Testing on cases of persistent,	PD-L1	Hamilton Health Sciences/ St. Joseph's
recurrent, or metastatic cervical		Healthcare Hamilton
cancer where PD-L1 directed		London Health Sciences Centre
therapy is being considered.		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare

# Colorectal

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly diagnosed tumours with invasive colorectal cancer.	MLH1, MSH2, MSH6, PMS2	<ul> <li>Grand River Hospital</li> <li>Hamilton Health Sciences/ St. Joseph's Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Kingston General Hospital</li> <li>Lakeridge Health</li> <li>London Health Sciences Centre</li> <li>Markham Stouffville Hospital</li> <li>Mount Sinai Hospital</li> <li>North York General Hospital</li> <li>Royal Victoria Regional Health Centre</li> <li>Southlake Regional Health Centre</li> <li>Southlake Regional Health Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>Unity Health - St. Michael's Hospital</li> <li>University Health Network</li> <li>William Osler Health System</li> <li>Dynacare</li> </ul>
BRAF testing should be performed for colorectal cancer cases with abnormal MLH1 results.	BRAF	<ul> <li>LifeLabs</li> <li>Health Sciences North</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>Dynacare</li> <li>LifeLabs</li> </ul>

# **Colorectal and Small Bowel**

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	BRAF, KRAS, NRAS,	Hamilton Health Sciences/ St. Joseph's
diagnosed cases of	PIK3CA	Healthcare
advanced*/metastatic colorectal		Health Sciences North
or small bowel carcinoma.		<ul> <li>Hospital for Sick Children (SickKids)</li> </ul>
		Kingston Health Sciences Centre
*For biomarker testing purposes,		London Health Sciences Centre
advanced is considered		Mount Sinai Hospital
CRC/Small Bowel tumours Stage		Sunnybrook Health Sciences Centre
III and above		The Ottawa Hospital
in and above		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System
		LifeLabs

# **Endometrium**

Testing Indication	Biomarkers	Testing Sites
Serous (high grade/advanced)	HER2	Hamilton Health Sciences/ St. Joseph's
endometrial carcinoma where		Healthcare Hamilton
HER2 directed therapy is being		Health Sciences North
considered.		Kingston Health Sciences Centre
		<ul> <li>London Health Sciences Centre</li> </ul>
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly diagnosed tumours with invasive endometrial carcinoma when needed to establish subtype.	p53, ER, PR	<ul> <li>Hamilton Health Sciences/ St. Joseph's Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Kingston Health Sciences Centre</li> <li>Lakeridge Health</li> <li>London Health Sciences Centre</li> <li>Markham Stouffville Hospital</li> <li>Mount Sinai Hospital</li> <li>North Bay Regional Health Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>Unity Health - St. Michael's Hospital</li> <li>University Health Network</li> </ul>
		<ul><li>William Osler Health System</li><li>Dynacare</li><li>LifeLabs</li></ul>
Reflex testing on newly diagnosed tumours with invasive endometrial carcinoma.	CTNNB1, KRAS, PIK3CA, POLE, PTEN, TP53	<ul> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> <li>LifeLabs</li> </ul>

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2, MSH6,	Grand River Hospital
diagnosed tumours with invasive	PMS2	Hamilton Health Sciences/ St. Joseph's
endometrial cancer.		Healthcare Hamilton
		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		Royal Victoria Regional Health Centre
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare
		LifeLabs

# **Head and Neck**

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	PD-L1	Hamilton Health Sciences/ St. Joseph's
diagnosed tumours with		Healthcare Hamilton
metastatic, unresectable		<ul> <li>Health Sciences North</li> </ul>
recurrent head and neck		Kingston Health Sciences Centre
squamous cell carcinoma.		<ul> <li>London Health Sciences Centre</li> </ul>
squamous cen carementa.		Mount Sinai Hospital
		<ul> <li>Sunnybrook Health Sciences Centre</li> </ul>
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		<ul> <li>University Health Network</li> </ul>
		William Osler Health System
		• Dynacare

Testing Indication	Biomarkers	Testing Sites
Testing to support diagnosis of nasopharyngeal carcinoma (newly diagnosed or suspected nasopharyngeal carcinoma).	EBER	<ul> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> </ul>
		<ul> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Markham Stouffville Hospital</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>Unity Health - St. Michael's Hospital</li> <li>University Health Network</li> </ul>
Newly diagnosed cases of squamous cell carcinoma where HPV status cannot be determined from histology/p16 staining.	HPV	<ul> <li>William Osler Health System</li> <li>Health Sciences North</li> <li>Markham Stouffville Hospital</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners – Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> </ul>
Testing on all sinonasal carcinoma where HPV and EBV have been excluded	SMARCA4, SMARCB1	<ul> <li>Hospital for Sick Children (SickKids)</li> <li>London Health Sciences Centre</li> <li>Mount Sinai Hospital</li> <li>William Osler Health System</li> </ul>
Testing on all sinonasal carcinoma where HPV and EBV have been excluded, and with retained/equivocal SMARC immunohistochemistry test results.	DEK::AFF2, EWSR1::FLI, EGFR, IDH2, NUTM1, PAX3, PAX7	<ul> <li>Hospital for Sick Children (SickKids)</li> <li>Mount Sinai Hospital</li> <li>University Health Network</li> </ul>

# Hematology

# **Acute Lymphoblastic Leukemia (ALL)**

Testing Indication	Biomarkers	Testing Sites
Rapid Workup of select biomarkers to guide early management decisions in cases of ALL	BCR::ABL1	<ul> <li>Children's Hospital of Eastern Ontario</li> <li>Hamilton Health Sciences/ St. Joseph's Healthcare Hamilton</li> <li>Health Sciences North</li> </ul>
OT NEE		<ul> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> </ul>
Cytogenetic analysis (Karyotyping) for all new diagnoses of ALL in line with established criteria	Please refer to 2016 Pathology Recommendations for Complex Malignant Hematology*	<ul> <li>Children's Hospital of Eastern Ontario</li> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> </ul>
FISH analysis in cases of ALL where karyotyping is insufficient or criteria for additional testing is met	Please refer to 2016 Pathology Recommendations for Complex Malignant Hematology*	<ul> <li>Children's Hospital of Eastern Ontario</li> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> </ul>

Testing Indication	Biomarkers	Testing Sites
Minimal Residual Disease (MRD)	Please refer to 2016	Hamilton Health Sciences/ St. Joseph's
Testing in ALL	Pathology	Healthcare Hamilton
	Recommendations	Health Sciences North
	for Complex	Hospital for Sick Children (SickKids)
	Malignant	Kingston Health Sciences Centre
	Hematology*	London Health Sciences Centre
	Tiematology	Trillium Health Partners - Credit Valley Site
		University Health Network

<sup>\*</sup>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/43061

# Acute Myeloid Leukemia (AML) / Acute Promyelocytic Leukemia (APL)

Testing Indication	Riomarkors	Tasting Sites
Testing Indication  Repeat FLT3 testing on cases of relapsed or refractory acute myeloid leukemia where therapy with Gilteritinib is being considered.	Biomarkers FLT3 (ITD)	<ul> <li>Testing Sites</li> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>The Ottawa Hospital</li> </ul>
Rapid Workup of select biomarkers to guide early management decisions in cases of AML/APL	PML::RARA, BCR::ABL1, FLT3 (ITD/TKD), NPM1	<ul> <li>University Health Network</li> <li>Children's Hospital of Eastern Ontario</li> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> </ul>
Cytogenetic analysis (Karyotyping) for all new diagnoses of AML/APL in line with established criteria	Please refer to 2016 Pathology Recommendations for Complex Malignant Hematology*	<ul> <li>Children's Hospital of Eastern Ontario</li> <li>Hamilton Health Sciences/ St. Joseph's Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>North York General Hospital</li> <li>London Health Sciences Centre</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> </ul>

Testing Indication	Biomarkers	Testing Sites
FISH analysis in cases of AML/APL where karyotyping is insufficient or criteria for additional testing is met	Please refer to 2016 Pathology Recommendations for Complex Malignant Hematology*	<ul> <li>Children's Hospital of Eastern Ontario</li> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> </ul>
Evaluation of Genomic Biomarkers in cases of AML/APL for diagnostic sub-classification, prognosis or therapeutic guidance	Please refer to 2016 Pathology Recommendations for Complex Malignant Hematology*	<ul> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> </ul>
Minimal Residual Disease (MRD) Testing in AML/APL	Please refer to 2016 Pathology Recommendations for Complex Malignant Hematology*	<ul> <li>Hamilton Health Sciences/ St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> </ul>

<sup>\*</sup>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/43061

# Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)

Testing Indication	Biomarkers	Testing Sites
Testing on cases of previously	Chromosome 17p	Health Sciences North
untreated CLL/SLL where therapy	deletion, TP53	University Health Network
is being considered.	mutation,	
	Unmutated	
	immunoglobulin	
	heavy chain variable	
	region (IgHV)	

# Myelodysplastic Syndromes (MDS), Myeloproliferative Neoplasms (MPN) and Myelodysplastic/Myeloproliferative Neoplasms (MDS/MPN)

Testing Indication	Biomarkers	Testing Sites
Cytogenetic analysis (karyotyping) for all new diagnoses of MDS, MPN or MDS/MPN in line with established criteria.  FISH analysis in cases of MDS, MPN or MDS/MPN where	Please refer to 2024 Consensus Diagnostic and Prognostic Testing Recommendations for MDS, MPN and MDS/MPN*  Please refer to 2024 Consensus Diagnostic	<ul> <li>Children's Hospital of Eastern Ontario</li> <li>Hamilton Health Sciences/St. Joseph's         Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>Children's Hospital of Eastern Ontario</li> <li>Hamilton Health Sciences/St. Joseph's         Healthcare Hamilton</li> </ul>
karyotyping is insufficient or criteria for additional testing is met.	and Prognostic Testing Recommendations for MDS, MPN and MDS/MPN*	<ul> <li>Health Sciences North</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> </ul>
Evaluation of genomic biomarkers in cases of MDS, MPN or MDS/MPN for diagnostic subclassification, prognosis or therapeutic guidance.	Please refer to 2024 Consensus Diagnostic and Prognostic Testing Recommendations for MDS, MPN and MDS/MPN*	<ul> <li>Hamilton Health Sciences/St. Joseph's Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>Trillium Health Partners – Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> </ul>

<sup>\*</sup>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/75246

# Hepatobiliary

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2, MSH6,	Grand River Hospital
diagnosed tumours with invasive	PMS2	Hamilton Health Sciences/ St. Joseph's
biliary / gallbladder		Healthcare Hamilton
adenocarcinoma		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		North York General Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare
Testing on previously treated,	FGFR2	Hamilton Health Sciences/ St. Joseph's
unresectable locally advanced or		Healthcare Hamilton
metastatic cholangiocarcinoma		Hospital for Sick Children (SickKids)
(CCA) where FGFR2 directed		London Health Sciences Centre
therapy is being considered		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System

# Lung (Non-Small Cell Lung Cancer (NSCLC))

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	PD-L1, ALK, EGFR,	Hamilton Health Sciences/ St. Joseph's
diagnosed cases of NSCLC	ROS1, BRAF, MET	Healthcare Hamilton
(adenocarcinoma/non-squamous).	(Met skipping), RET, FGFR1, HER2 (ERBB2), KRAS, PIK3CA, NTRK1, NTRK2, NTRK3  Optional For 23/24: NRG1, TP53, STK11, KEAP1	<ul> <li>Health Sciences North</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> </ul>

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	PD-L1	Hamilton Health Sciences/ St. Joseph's
diagnosed cases of NSCLC		Healthcare Hamilton
(squamous).		Health Sciences North
, ,		Kingston Health Sciences Centre
		London Health Sciences Centre
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System
Testing on previously diagnosed	Acquired EGFR T790M	Hamilton Health Sciences/ St. Joseph's
cases of locally advanced or		Healthcare Hamilton
metastatic NSCLC that has		Health Sciences North
progressed on or after EGFR TKI		Kingston Health Sciences Centre
therapy.		London Health Sciences Centre
therapy.		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System

# Melanoma

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	BRAF, KIT, NRAS	Hamilton Health Sciences/ St. Joseph's
diagnosed cases of		Healthcare Hamilton
advanced*/metastatic		Health Sciences North
melanoma.		<ul> <li>Hospital for Sick Children (SickKids)</li> </ul>
		<ul> <li>Kingston Health Sciences Centre</li> </ul>
*For biomarker testing purposes,		<ul> <li>London Health Sciences Centre</li> </ul>
advanced is considered any		Mount Sinai Hospital
melanoma >2mm in depth (pT3)		Sunnybrook Health Sciences Centre
melanoma v zmm m depen (p 13)		The Ottawa Hospital
		<ul> <li>Trillium Health Partners - Credit Valley Site</li> </ul>
		University Health Network
		William Osler Health System
		• LifeLabs

# **Multiple Disease Sites**

#### Mismatch Repair (MMR) / MLH1 Promoter Methylation Testing

MMR testing is available for the following disease sites (please refer to each section for specific testing indications):

- Adrenal Gland
- Colorectal
- Endometrium
- Esophagus
- Gallbladder
- Gastric
- Small Bowel
- Ocular
- Ovary
- Pancreas
- Skin
- Ureter

Testing Indication	Biomarkers	Testing Sites
Promoter Methylation testing should be performed for all MMR cases with abnormal MLH1 results*.	MLH1 Promoter Methylation	<ul> <li>Health Sciences North</li> <li>Kingston Health Sciences</li> <li>London Health Sciences Centre</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> </ul>
*For CRC Promoter Methylation testing should be performed only on BRAF wild-type cases.		<ul> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>LifeLabs</li> </ul>

#### **NTRK Testing**

Disease Site	<b>Testing Indication</b>	Testing Sites
Multiple disease sites¹  Screening by IHC, followed by confirmatory testing if a variant is identified²   Multiple disease sites¹  Screening by IHC, followed by confirmatory testing if a variant is identified²	Testing on advanced/metastatic solid tumour cancers³ where NTRK directed therapy is being considered.  Biomarkers: NTRK1, NTRK2, NTRK3 (Pan-TRK)  Confirmatory testing for cases positive for NTRK by IHC.  Biomarkers: NTRK1, NTRK2, NTRK3 (fusions)	<ul> <li>Hamilton Health Sciences/ St. Joseph's Healthcare Hamilton</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>University Health Network</li> <li>William Osler Health System</li> <li>Hamilton Health Sciences/ St. Joseph's Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> </ul>
<ul> <li>The following disease sites should be tested by fusion analysis only:         <ul> <li>Soft tissue sarcoma</li> <li>Salivary carcinoma</li> <li>Primary Central Nervous System (CNS) tumours</li> <li>Secretory breast cancer</li> <li>Mammary analogue secretory carcinoma</li> </ul> </li> </ul>	Testing on advanced/metastatic solid tumour cancers³ where NTRK directed therapy is being considered.  Biomarkers: NTRK1, NTRK2, NTRK3 (fusions)	<ul> <li>Hamilton Health Sciences/ St. Joseph's Healthcare Hamilton</li> <li>Health Sciences North</li> <li>Hospital for Sick Children (SickKids)</li> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners – Credit Valley Site</li> <li>University Health Network</li> <li>William Osler Health System</li> </ul>

<sup>&</sup>lt;sup>1</sup> NTRK testing is incorporated into existing panel testing at diagnosis for the following: Non-Small Cell Lung Cancer (NSCLC), Thyroid Cancer.

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<sup>&</sup>lt;sup>3</sup> Where surgical resection is likely to result in severe morbidity, and, have no satisfactory treatment options.

# Paragangliomas

Testing Indication	Biomarkers	Testing Sites
Reflex testing for all newly	SDHB	London Health Sciences Centre
diagnosed paragangliomas (to		Mount Sinai Hospital
inform need for germline testing)		Sunnybrook Health Sciences Centre
G,		University Health Network
		William Osler Health System

# **Pharmacogenomic Testing**

Testing Indication	Biomarkers	Testing Sites
Testing where treatment with fluoropyrimidines is being considered	DPYD Genotyping:	<ul> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>North York General Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> <li>Dynacare</li> </ul>

# Ocular

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2, MSH6,	Grand River Hospital
diagnosed sebaceous tumours.	PMS2	Hamilton Health Sciences/ St. Joseph's
		Healthcare Hamilton
		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare
Reflex testing on newly	GNAQ, GNA11	Hamilton Health Sciences/ St. Joseph's
diagnosed tumours with uveal		Healthcare Hamilton
melanoma.		Hospital for Sick Children (SickKids)
		Kingston Health Sciences Centre
		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		Trillium Health Partners - Credit Valley Site
		The Ottawa Hospital
		University Health Network
		William Osler Health System
		Dynacare
Testing on newly diagnosed cases	HLA-A*02:01	Hamilton Health Sciences/ St. Joseph's
of unresectable or metastatic		Healthcare Hamilton
uveal melanoma		London Health Sciences Centre
		The Ottawa Hospital
		University Health Network

# Ovary

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2, MSH6,	Grand River Hospital
diagnosed epithelial and low	PMS2	Hamilton Health Sciences/ St. Joseph's
malignant potential ovarian		Healthcare Hamilton
tumours.		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		Royal Victoria Regional Health Centre
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare
Reflex testing for the diagnosis of	p53, WT1	Hamilton Health Sciences/ St. Joseph's
serous tumours (epithelial		Healthcare
ovarian, fallopian tube,		Health Sciences North
peritoneal cancers) when needed		Kingston Health Sciences Centre
to establish histologic subtype.		Lakeridge Health
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		North Bay Regional Health Centre
		North York General Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare

Testing Indication	Biomarkers	Testing Sites
Reflex testing to confirm or	SMARCA4	Hamilton Health Sciences/ St. Joseph's
exclude small cell carcinoma of		Healthcare
the ovary, hypercalcemic type		Health Sciences North
(SCCOHT).		Hospital for Sick Children (SickKids)
		Kingston Health Sciences
		London Health Sciences Centre
		Mount Sinai Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System
Testing to support diagnosis of	FOXL2, DICER1	Hamilton Health Sciences/ St. Joseph's
sex-cord stromal tumours.		Healthcare
		Hospital for Sick Children (SickKids)
		Kingston Health Sciences
		London Health Sciences Centre
		Mount Sinai Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
Reflex testing on newly	BRCA1, BRCA2	Hamilton Health Sciences/ St. Joseph's
diagnosed tumours with high		Healthcare Hamilton
grade epithelial ovarian, fallopian		Hospital for Sick Children (SickKids)
tube, or primary peritoneal		Kingston Health Sciences
cancer.		London Health Sciences Centre
cancer.		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System

# **Pancreas**

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2, MSH6,	Grand River Hospital
diagnosed tumours with invasive	PMS2	Hamilton Health Sciences/ St. Joseph's
carcinoma of the pancreas.		Healthcare Hamilton
		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		North York General Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare

# Penile

Testing Indication	Biomarkers	Testing Sites
Newly diagnosed cases of penile	HPV	Hamilton Health Sciences/ St. Joseph's
carcinoma where HPV status		Healthcare Hamilton
cannot be determined from		Health Sciences North
histology/p16 staining.		Markham Stouffville Hospital
3,7,1		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		Trillium Health Partners – Credit Valley Site
		The Ottawa Hospital
		University Health Network
		William Osler Health System

# Prostate

Testing Indication	Biomarkers	Testing Sites
Testing on newly diagnosed	ATM, BRCA1, BRCA2,	Hamilton Health Sciences/ St. Joseph's
tumours with advanced/	PALB2	Healthcare Hamilton
metastatic prostate carcinoma.	AR	Kingston Health Sciences Centre
		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		University Health Network
		William Osler Health System

# Skin

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2, MSH6,	Grand River Hospital
diagnosed sebaceous neoplasms.	PMS2	Hamilton Health Sciences/ St. Joseph's
		Healthcare Hamilton
		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare
		LifeLabs

## **Small Bowel**

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2, MSH6,	Grand River Hospital
diagnosed tumours with	PMS2	Hamilton Health Sciences/ St. Joseph's
advanced/metastatic small bowel		Healthcare Hamilton
carcinoma.		Health Sciences North
		Kingston Health Sciences Centre
		Lakeridge Health
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
		Dynacare
		LifeLabs

#### **Soft Tissue and Bone**

Note: Soft Tissue & Bone indications are currently undergoing review and are intended for the adult population.

Testing Indication	Biomarkers	Testing Sites
Secondary review - Review of	Please refer to 2023	Hamilton Health Sciences/ St. Joseph's
tumour by a subspecialist	Pathology	Healthcare Hamilton
Pathologist for classification	Recommendations	Mount Sinai Hospital
	for Mesenchymal	The Ottawa Hospital
	Tumours of Soft	
	Tissue and Bone*	
Immunohistochemical evaluation,	Please refer to 2023	Hamilton Health Sciences/ St. Joseph's
where indicated, to assess line of	Pathology	Healthcare Hamilton
differentiation for classification	Recommendations	London Health Sciences Centre
	for Mesenchymal	Mount Sinai Hospital
	Tumours of Soft	The Ottawa Hospital
	Tissue and Bone*	

Testing Indication	Biomarkers	Testing Sites
Molecular interrogation, where	Please refer to 2023	Mount Sinai Hospital
indicated, for classification,	Pathology	The Ottawa Hospital
prognostic and/or therapeutic	Recommendations	
purposes.	for Mesenchymal	
	Tumours of Soft	
When applicable more than one	Tissue and Bone*	
type of molecular assay may be		
included (e.g. RNA, DNA, or		
methylation-based assay)		
Assessment of gene amplification	Please refer to 2023	Hamilton Health Sciences/ St. Joseph's
(e.g. MDM2, CDK4, BCOR); FISH,	Pathology	Healthcare Hamilton
array, and/or NGS methods	Recommendations	London Health Sciences Centre
acceptable	for Mesenchymal	Mount Sinai Hospital
	Tumours of Soft	The Ottawa Hospital
	Tissue and Bone*	
Reflex testing on newly diagnosed	BRAF, KIT, PDGFRA	Hamilton Health Sciences/ St. Joseph's
CD117 (cKIT) positive		Healthcare Hamilton
Gastrointestinal Stromal Tumours	Optional For 23/24:	Hospital for Sick Children (SickKids)
(GIST)	SDH, NF1, NTRK	London Health Sciences Centre
	(fusion), FGFR	Mount Sinai Hospital
	(fusion)	Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners – Credit Valley Site
		University Health Network
CDUB testing on CICT for a service	CDUD	William Osler Health System
SDHB testing on GIST for negative	SDHB	<ul><li>Hospital for Sick Children (SickKids)</li><li>London Health Sciences Centre</li></ul>
molecular results		<ul><li>London Health Sciences Centre</li><li>Mount Sinai Hospital</li></ul>
		Sunnybrook Health Sciences Centre
		Suffrybrook fleatur sciences Centre

<sup>\*</sup> https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/73926

# Stomach

Testing Indication	Biomarkers	Testing Sites
Testing on newly diagnosed	EBER	Hamilton Health Sciences/ St. Joseph's
gastric tumours when EBV		Healthcare Hamilton
associated adenocarcinoma is		Health Sciences North
being considered.		Hospital for Sick Children (SickKids)
		Kingston Health Sciences Centre
		London Health Sciences Centre
		Markham Stouffville Hospital
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Trillium Health Partners - Credit Valley Site
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System

# Stomach/Esophagus

Testing Indication	Biomarkers	Testing Sites
Reflex testing on newly	MLH1, MSH2, MSH6,	Hamilton Health Sciences/ St. Joseph's
diagnosed invasive	PMS2	Healthcare Hamilton
gastroesophageal	HER2	Health Sciences North
adenocarcinomas.		Kingston Health Sciences Centre
		London Health Sciences Centre
		Mount Sinai Hospital
		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System
Reflex testing on newly	PD-L1	Kingston Health Sciences Centre
diagnosed invasive		London Health Sciences Centre
gastroesophageal		Mount Sinai Hospital
adenocarcinomas.		Sunnybrook Health Sciences Centre
		The Ottawa Hospital
		Unity Health - St. Michael's Hospital
		University Health Network
		William Osler Health System

# **Thyroid**

Testing Indication	Biomarkers	Testing Sites
Testing on all metastatic thyroid cancer, including sporadic medullary and radio-iodine refractory well differentiated thyroid cancer.	BRAF, HRAS, NRAS, NTRK3, PPARG, RET, KRAS	<ul> <li>Kingston Health Sciences Centre</li> <li>London Health Sciences Centre</li> <li>Mount Sinai Hospital</li> <li>Sunnybrook Health Sciences Centre</li> <li>The Ottawa Hospital</li> <li>Trillium Health Partners - Credit Valley Site</li> <li>University Health Network</li> </ul>
		William Osler Health System

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