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Biomarkers - MD Anderson Approved

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The Molecular Testing Evaluation Committee (MTEC) is responsible for the review and approval of requests for biomarker testing based on evaluating published data and determining if there is sufficient scientific and clinical interest for their use in standard care of patients at MD Anderson. The committee reports up to Medical Practice and the Executive Committee for the Medical Staff. Biomarkers approved by MTEC and available through Pathology and Laboratory Medicine using CLIA-compliant molecular diagnostic tests that satisfy the institutionally defined criteria are included in this document.

The following exception criteria must be met for orders which are not included in this document; additionally, the request must be approved by the internal MDACC Single Use Order Set Committee.

Exception criteria:
- The test is clinically justifiable: Molecular test results will guide treatment decisions, and the results will identify treatment selection among currently available therapies.
- The patient is appropriate for such therapies: The patient has a performance status of ECOG of 0 or 1 and is expected to live for at least three months.
- The patient has locally advanced or metastatic disease not appropriate for other therapies.
### Biomarkers - MD Anderson Approved

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<table>
<thead>
<tr>
<th>DISEASE SITE</th>
<th>CELL TYPE</th>
<th>FISH</th>
<th>IMMUNOHISTOCHEMISTRY</th>
<th>MOLECULAR</th>
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<tr>
<td>Brain/Neuro-Oncology</td>
<td>Glioma</td>
<td>1p/19q co-deletion</td>
<td>EGFR, PTEN, BRAF V600E</td>
<td>MGMT promoter methylation, IDH1 mutation, IDH2 mutation, PIK3CA mutation, BRAF mutation, PTEN mutation, EGFR mutation, CTNNB1, PDGFR, MET, FGFR, TP53, CDKN2A, NF1</td>
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<td>MYC</td>
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<tr>
<td>Breast</td>
<td>All invasive Cancer types</td>
<td>HER2/neu²</td>
<td>ER²,2, PR², Ki-67 (MIB-1) labeling index², HER2/neu²</td>
<td>ESR1, FGFR1, MammaPrint, Oncotype DX, PIK3CA, TP53</td>
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1 For DCIS specimens, ER and PR should be performed on the final surgical specimen and not the core biopsy since there may be invasive cancer in the surgical specimen in which case all biomarkers should be done on the invasive cancer (ER, PR, HER2/neu, Ki-67). If no invasive cancer seen, then ER and PR should be preformed on the DCIS specimen.

2 For metastatic breast cancer cases, ER, PR, HER2/neu and Ki-67 should be obtained if ordered by the requesting physician as clinically indicated.

3 HER2/neu by FISH will only be performed if a 2+ or greater result is obtained by HER2/neu IHC, or in select 1+ IHC results as judged by the pathologist on the case, or if requested by the ordering or treating physicians as clinically indicated.
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<tr>
<th>DISEASE SITE</th>
<th>CELL TYPE</th>
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<td>Follicular Thyroid Carcinoma / Hurthle Cell (oxyphilic) Thyroid Carcinoma</td>
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<td>Colorectal Adenocarcinoma</td>
<td>• HER2/neu</td>
<td>• Immunohistochemistry for DNA mismatch repair enzymes (MLH1, MSH2, MSH6, PMS2) Note: MLH1 promoter hypermethylation analysis and BRAF mutation analysis will also be performed if immunohistochemistry shows loss of MLH1 and if sufficient tumor DNA is available for analysis.</td>
<td>• MLH1 promoter hypermethylation analysis and BRAF mutation analysis (only if immunohistochemistry for DNA mismatch repair enzymes has already been performed and shows loss of MLH1)</td>
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<td>• BRAF V600E</td>
<td>• KIT mutation</td>
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<td>• iNOS</td>
<td>• NRAS mutation</td>
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<td>• PD-L1 28-8</td>
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<td>• PD-L1 28-8</td>
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<td></td>
<td>• BRAF mutation</td>
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<td>• NRAS mutation</td>
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<td>• PD-L1 28-8</td>
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<td>• BRAF mutation</td>
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<td>• PD-L1 28-8</td>
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<td>• BRAF mutation</td>
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<td>• PD-L1 28-8</td>
<td>• 15-gene signature</td>
<td>• GNAQ</td>
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<td>• Monosomy 3</td>
<td>• GNA11</td>
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<td>• BRAF mutation</td>
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<td>Sarcoma</td>
<td>Neuroblastoma</td>
<td>MYCN (N-MYC)</td>
<td>• GNAQ mutation</td>
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<td>Desmoid Fibromatosis</td>
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<td>PD-L1</td>
<td>• KIT mutation</td>
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<td>Gastrointestinal Stromal Tumor</td>
<td>PD-L1</td>
<td>• PDGFRA mutation</td>
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# Biomarkers - MD Anderson Approved

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<table>
<thead>
<tr>
<th>DISEASE SITE</th>
<th>CELL TYPE</th>
<th>FISH</th>
<th>IMMUNOHISTOCHEMISTRY</th>
<th>MOLECULAR</th>
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<td>Non Small Cell Lung Carcinoma</td>
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<td>ROS1 rearrangement</td>
<td>MET</td>
<td>KRAS mutation</td>
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<td>MET</td>
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<td>RET</td>
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<td>EGFR Targeted Therapy Resistance Mutation (T790M, C7975 only)</td>
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<td>Breast, Gastric Profile</td>
<td>HER2/neu</td>
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<td>EGFR mutation</td>
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<td>Lung Profile</td>
<td>ALK rearrangement</td>
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<tr>
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<td>Small Bowel, Colon Profile</td>
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<td>KRAS mutation</td>
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<table>
<thead>
<tr>
<th>DISEASE SITE</th>
<th>DIAGNOSIS</th>
<th>CYTOGENETICS</th>
<th>MOLECULAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukemia</td>
<td>ALL - New Patient Work-up for all patients</td>
<td>● Conventional chromosome analysis</td>
<td>● ABL1 gene mutation (kinase domain) qualitative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>● FISH - t(9;22) BCR/ABL1</td>
<td>● ABL1 gene mutation p.T315I quantitative</td>
</tr>
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<td>● FISH - MYC (8q24)</td>
<td>● TP53 mutation</td>
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<td>● JAK2 mutation</td>
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<td>● KRAS mutation</td>
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<td></td>
<td></td>
<td></td>
<td>● NRAS mutation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>● NOTCH1 Exons 26, 27, 34</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>● FBXW7</td>
</tr>
<tr>
<td></td>
<td>ALL - Peripheral Blood (Similar to Marrow)</td>
<td>FISH - MYC</td>
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<td>ALL - T Lineage</td>
<td>Conventional chromosome analysis</td>
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<td>ALL – Philadelphia Negative</td>
<td>Conventional chromosome analysis</td>
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<td>ALL – Philadelphia Positive</td>
<td>Conventional chromosome analysis</td>
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<td>● TCRB clonality</td>
<td>● ABL1 gene mutation (kinase domain) qualitative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>● TCRG clonality</td>
<td>● ABL1 gene mutation p.T315I quantitative</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>● TP53 mutation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>● JAK2 mutation</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>● KRAS mutation</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>● NRAS mutation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>● NOTCH1 Exons 26, 27, 34</td>
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<td>● FBXW7</td>
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<td>ALL - Relapsed</td>
<td>● Conventional chromosome analysis</td>
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</tr>
<tr>
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<td>● FISH - t(9;22) BCR/ABL1</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>● Ph-Like ALL Fusion Multiplex Panel (ABL1, JAK2, Kinase: ABL2, PDGFRB, CSF1R, TYK2, NTRK3)</td>
</tr>
</tbody>
</table>

**ALL** = acute lymphocytic/lymphoblastic leukemia  
**AML/MDS** = acute myelogenous leukemia/myelodysplasic syndrome  

Approved by the Executive Committee of the Medical Staff on 2/27/2018

Department of Clinical Effectiveness V4
### Leukemia – continued

<table>
<thead>
<tr>
<th>DISEASE SITE</th>
<th>DIAGNOSIS</th>
<th>CYTOGENETICS</th>
<th>MOLECULAR</th>
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<tbody>
<tr>
<td>Leukemia – continued</td>
<td>AML/MDS</td>
<td>Conventional chromosome analysis</td>
<td>FLT3, ASXL1, IDH1, CEBPA, DNMT3A, JAK2, aCGH panel (chr 5, 7, 8, 17, 20)</td>
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<tr>
<td>APL</td>
<td>Conventional chromosome analysis</td>
<td>t(15;17) PML/RARA</td>
<td>FLT3, KIT (exon 17), KRAS, MPL, NPM1, NRAS, RUNX1, U2AF1, SRSF2, ZRSR2</td>
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<tr>
<td>APL – Peripheral Blood</td>
<td>FISH – PML/RARA t(15;17)</td>
<td>t(15;17) PML/RARA</td>
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<tr>
<td>Aplastic Anemia</td>
<td>Conventional chromosome analysis</td>
<td>TCRB clonality (TCR-BETA chain gene)</td>
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<tr>
<td>Burkitt Leukemia</td>
<td>Conventional chromosome analysis, FISH - MYC</td>
<td>IGH clonality, TP53</td>
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<tr>
<td>Burkitt Leukemia Peripheral Blood</td>
<td>FISH - MYC</td>
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<tr>
<td>CLL - Peripheral Blood with or without Bone Marrow</td>
<td>Conventional chromosome analysis, FISH – CLL Panel</td>
<td>Somatic Hypermutation, Mutation Analysis for (EndCLL Assay V1): ATM, BTK, PLCG2, TP53, BIRC3, NOTCH1, SF3B1, IGH Clonality, aCGH panel (chr 5, 7, 8, 17, 20)</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- APL = acute promyelocytic leukemia
- CLL = chronic lymphoblastic leukemia

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<table>
<thead>
<tr>
<th>DISEASE SITE</th>
<th>DIAGNOSIS</th>
<th>CYTOGENETICS</th>
<th>MOLECULAR</th>
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</thead>
<tbody>
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<td>CML</td>
<td>Hairy Cell Leukemia</td>
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<td>ABL1 gene mutation (kinase domain) quantitative</td>
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<td>FISH – BCR/ABL1 t(9;22)</td>
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<td>CMML</td>
<td>Conventional chromosome analysis</td>
<td>ABL1 gene mutation (kinase domain) qualitative</td>
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<td>FISH – BCR/ABL1 t(9;22)</td>
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<td>CML – Blast Phase</td>
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<td>HES, Mastocytosis</td>
<td>Conventional chromosome analysis</td>
<td>FIP1L1/PDGFRA (Hypereosinophilic Syndrome)</td>
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<tr>
<td>MPN</td>
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</table>

**MOLECULAR BIOMARKERS**

- ABL1 kinase domain mutation
- ABL1 p.T315I mutation (quantitative)
- ASXL1 mutation
- CALR mutation
- CSF3R mutation
- EZH2 mutation
- JAK2 exon 12 mutation
- JAK2 v617F mutation
- KIT mutation
- MPL mutation
- TET2 mutation
- TP53 mutation
- FIP1L1-PDGFR fusion
- t(9;22) BCR-ABL1 quantitative PCR

CML = chronic myeloid leukemia  
HES = hypereosinophilic syndrome  
CMML = chronic myelomonocytic leukemia  
MPN = myeloproliferative neoplasms

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<table>
<thead>
<tr>
<th>DISEASE SITE</th>
<th>DIAGNOSIS</th>
<th>CYTOGENETICS</th>
<th>MOLECULAR</th>
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<td>Leukemia – continued</td>
<td>Leukemia</td>
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<td>Leukemia – continued</td>
<td>MF - Peripheral Blood</td>
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<td>JAK2, MPL, MPL, JAK2, BCR/ABL1, E2A/PBX1, IL2RB, TET2</td>
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<td>Leukemia – continued</td>
<td>PV, ET, MF</td>
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<td>Leukemia – continued</td>
<td>T Cell Disorders - Peripheral Blood</td>
<td>EBV</td>
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<td>T Cell Disorders</td>
<td>Conventional chromosome analysis</td>
<td>TCRB clonality, TCRG clonality</td>
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<td>T-Prolymphocytic Leukemia (T-PLL)</td>
<td>FISH - 14q32</td>
<td>IL2RG, JAK1, JAK3, STAT3, STAT5B</td>
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<td>Leukemia – continued</td>
<td>T-Large Granular Lymphocytic Leukemia (T-LGL)</td>
<td>Conventional chromosome analysis</td>
<td>STAT3, STAT5B</td>
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MF = Mycosis fungoides  PV = Polycythemia Vera  ET = Essential thrombocytopenia
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<td>Burkit Lymphoma</td>
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<td>• TP53</td>
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<td>Burkit Lymphoma Peripheral Blood</td>
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<td>Diffuse Large B-Cell Lymphoma</td>
<td>FISH - MYC</td>
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<td>Mantle Cell Lymphoma</td>
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<td>Plasma Cell Myeloma</td>
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<td>• MYD88 (codon 265)</td>
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<td>• CARD11</td>
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<td>• NOTCH1 – Exons 26, 27, 34</td>
<td>• CD79A</td>
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<td>• MYD88 (codon 265)</td>
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<td>• FGFR3 mutation</td>
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<td>Waldenstrom’s Macroglobulinemia</td>
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<td>• CXCR4</td>
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</table>

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Brain/Neuro-Oncology

Diffuse Glioma

FISH/1p19q:

Immunohistochemistry/BRAF:

Immunohistochemistry/EGFR528:

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**Brain/Neuro-Oncology – continued**

**Diffuse Glioma**

**Molecular/IDH1/IDH2:**

Capper, D., Sahm, F., Hartmann, C., et al. (2010). Application of mutant IDH1 antibody to differentiate diffuse glioma from nonneoplastic central nervous system lesions and therapy-induced changes. *American Journal of Surgical Pathology, 34*(8), 1199-1204. doi: http://dx.doi.org/10.1097/PAS.0b013e3181e7740d.


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**SUGGESTED READINGS - continued**

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**Continued on next page**
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**SUGGESTED READINGS - continued**

### Diffuse Glioma

**Molecular/IDH1/Multigene predictor:**


**Molecular/PIK3CA:**


**Immunohistochemistry/PTEN:**


**Molecular/CIMP:**


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*Continued on next page*
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**SUGGESTED READINGS - continued**

**Low Grade Glioma**

**Molecular/BRAF:**


**Molecular/MGMT:**


**FISH/1p/19q:**


Continued on next page
Breast

SUGGESTED READINGS - continued

Immunohistochemistry/ER and Immunohistochemistry/PR:


Immunohistochemistry/Ki67:

Immunohistochemistry/HER2/NEU and Immunohistochemistry/FISH/HER2/NEU:


Breast - continued

Molecular/ESR1:

Molecular/FGFR1:

SUGGESTED READINGS - continued

Continued on next page
Molecular/MammaPrint:


Molecular/Oncotype:


Molecular/PIK3CA:


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SUGGESTED READINGS - continued

Breast – continued

Molecular/TP53:

Endocrine

Adrenocortical Neoplasm

Immunohistochemistry/Ki67:

Medullary Thyroid Carcinoma

Molecular/RET mutation status:

Molecular/HHRAS KRAS & NRAS mutation status:
Sherman et al. (2013). Demonstrating patients with somatic RAS or RET mutation in MTC have better response to TKI therapy with cabozantinib than those lacking mutations.
ASCO presentation #6000.
**SUGGESTED READINGS - continued**

### Endocrine – continued

**Papillary, Follicular, Anaplastic Thyroid Carcinoma**

**Molecular/BRAF:**

CMS SUPERSEDED Local Coverage Determination (LCD):

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35396&ContrId=338&ver=20&ContrVer=1&Keyword=biomarker&SearchType=O&PolicyType=Both&ArticleType=SAD%7cEd&Cntctr=338*1&Date=&KeyWordLookUp=Doc&SearchType=Advanced&CoverageSelection=Both&kt=1&bc=1AABABAAAAAAAS%3d%3d


**Molecular/KRAS NRAS:**


CMS SUPERSEDED Local Coverage Determination (LCD):

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35396&ContrId=338&ver=20&ContrVer=1&Keyword=biomarker&SearchType=O&PolicyType=Both&ArticleType=SAD%7cEd&Cntctr=338*1&Date=&KeyWordLookUp=Doc&SearchType=Advanced&CoverageSelection=Both&kt=1&bc=1AABABAAAAAAAAS%3d%3d

**Molecular/PIK3CA:**


Continued on next page
SUGGESTED READINGS - continued

**Endocrine – continued**

**Papillary, Follicular, Anaplastic Thyroid Carcinoma**

**Immunohistochemistry/PTEN:**

**Parathyroid Carcinoma**

**Immunohistochemistry/Ki67:**

**Pituitary Neoplasm**

**Immunohistochemistry/Ki67:**

**Immunohistochemistry/p53:**

Continued on next page
Gastrointestinal

Stomach and Esophagogastric Junction Adenocarcinoma

Immunohistochemistry/HER2/neu and FISH/HER2/neu:

Small Intestinal Adenocarcinoma

Immunohistochemistry/DNA mismatch repair enzymes and Molecular/MSI PCR, MLH1 promoter methylation, KRAS, BRAF:
Small bowel and appendiceal adenocarcinoma may be treated with systemic chemotherapy according to the NCCN Guidelines for Colon Cancer. NCCN Guidelines, Version 3.2013, Colon Cancer, Page COL-1.

Colorectal Adenocarcinoma

Immunohistochemistry/IHC mmr enzymes and Colorectal Adenocarcinoma/Molecular/MSI PCR:
The panel recommends that MMR protein testing be performed for all patients younger than 50 years old with colon cancer, based on an increased likelihood of Lynch syndrome in this population. MMR testing should also be considered for all patients with stage II disease, because stage II MSH-H patients may have a good prognosis and do not benefit from 5-FU adjuvant therapy. NCCN Guidelines, Version 3.2013, Colon Cancer, Page COL-A 4 of 5.

Suggested Readings - continued
SUGGESTED READINGS - continued

Gastrointestinal - continued

Colorectal Adenocarcinoma

**Molecular/KRAS:**

**Molecular/BRAF:**

**Carcinoma of the Anal Canal**

**Immunohistochemistry/p16:**

**Immunohistochemistry/HPV:**

Continued on next page
**SUGGESTED READINGS - continued**

**Gastrointestinal - continued**

**Neuroendocrine**

**Immunohistochemistry/TTF:**


**Immunohistochemistry/CDX2:**


**Immunohistochemistry/Ki67:**


**Molecular/18Q LOH:**


*Continued on next page*
SUGGESTED READINGS - continued

Gastrointestinal – continued

Neuroendocrine

MGMT Methylation:

Immunohistochemistry/DAXX, ATRX:

DAXX, ATRX, MEN1, PTEN, PIK3CA, TSC2:

Immunohistochemistry/MEN1:

Molecular/PTEN, TSC2:


Pseudomyxoma Peritonei

Molecular/IKRAS:

Continued on next page
SUGGESTED READINGS - continued

Genitourinary/Urology

Hepatic Adenoma

Molecular/Beta Catenin:

Prostate

Immunochemistry/PSA:

Immunochemistry/PAP:

Immunochemistry/CgA:

Molecular/BR1, TP53, PTEN, AR:

Molecular/BR1, TP53, AR:

Molecular/BR1, TP53:

Use of platinum-based chemotherapy in aggressive variant prostate carcinomas:

Continued on next page
**Genitourinary/Urology - continued**

**Testicular, Suspected Testicular**

**Immunohistochemistry/hCG and AFP:**

**Upper Urinary Tract and Renal Pelvis Urothelial Carcinoma**

**FISH/HER2/neu:**


DOI - 10.1038/ncpuro0318.

**Immunohistochemistry and Molecular/MSI panel and MLH1 promoter methylation assay and PCR based MSI testing:**


DOI - 10.1097/01.mp.0000024263.25043.0C


**Continued on next page**
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Gynecology

Ovarian and Uterine

FISH/Her2/neu:


AID – 10.1111/j.1525-1438.2007.00946.x [doi]


SUGGESTED READINGS - continued

Continued on next page
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Gynecology – continued

SUGGESTED READINGS - continued

Ovarian and Uterine

Immunohistochemistry/Her2/neu:


Continued on next page
Gynecology - continued

Ovarian and Uterine

**Immunohistochemistry/HPV:**


**Immunohistochemistry/MSI:**


Murphy, M. A., & Wentzensen, N. (2011). Frequency of mismatch repair deficiency in ovarian cancer: a systematic review This article is a US Government work and, as such, is in the public domain of the United States of America. *International Journal of Cancer*, 129(8), 1914-1922. doi: http://dx.doi.org/10.1002/ijc.25835.


**SUGGESTED READINGS - continued**

Continued on next page
Ovarian and Uterine

Immunohistochemistry/PTEN:


**Gynecology - continued**

**Ovarian and Uterine**

**Molecular/BRAF:**


**Continued on next page**
SUGGESTED READINGS - continued

Gynecology - continued

Ovarian and Uterine

Molecular/KRAS:


Continued on next page
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**Gynecology - continued**

**SUGGESTED READINGS - continued**

**Ovarian and Uterine**

**Molecular/MLH1 promoter methylation:**


Continued on next page
**SUGGESTED READINGS - continued**

**Ovarian and Uterine**

Molecular/MSI PCR:


Continued on next page
SUGGESTED READINGS - continued

Gynecology - continued

Ovarian and Uterine

Molecular/PI3K AKT:
SUGGESTED READINGS - continued

**Gynecology - continued**

**Ovarian and Uterine**

**Molecular/PTEN:**


*continued on next page*
SUGGESTED READINGS - continued

Head and Neck

Oropharynx/Nasopharynx/Oral Cavity

HPV and P16:

Nasopharynx Cancer and Salivary Cancer

EBV and erB-2 and HER2/neu:

Salivary Cancer

c-kit and EGFR and Androgen Receptor:
SUGGESTED READINGS - continued

Leukemia

ALL

Cytogenetics/Multiplex PCR (all subtypes):

Molecular-Genetics (Overview):

Molecular-Genetics (Philadelphia negative - all types):

Molecular-Genetics (Philadelphia negative B-lineage):

Burkitt subtype (c-myc):

Philadelphia positive subtype (BCR-ABL) - Overlap CML:

Philadelphia positive subtype (Mutations) - Overlap CML:

Continued on next page
SUGGESTED READINGS - continued

Leukemia – continued

ALL
IgH/TCR (all subtypes):

TP53 Mutations:
Chiaretti S, Brugnoletti F, Tavolaro, S et al. TP53 mutations are frequent in adult acute lymphoblastic leukemia cases negative for recurrent fusion genes and correlate with poor response to induction therapy. Haematologica 2013 May;98(5):e59-61

NOTCH1 and FBXW7:

Continued on next page
SUGGESTED READINGS - continued

AML/MDS

Molecular RUNX1:

Molecular SF3B1, SRSF2, U2AF1, ZRSR2:

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SUGGESTED READINGS - continued

AML/MDS

Molecular SF3B1:


AML/MDS/CMMML/Aplastic Anemia

Cytogenetics:


AML/MDS/CMMML/Aplastic Anemia

Molecular/FLT3:


Continued on next page
Leukemia – continued

**Molecular/FLT3:**


**Molecular/DNMT3:**


**KIT:**


**IDH1/IDH2:**


SUGGESTED READINGS - continued

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2010

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SUGGESTED READINGS - continued

Luekemia – continued

AML/MDS/CMML/Aplastic Anemia

RAS:

CEBPA:

NPM1:

Continued on next page
Leukemia – continued

AML/MDS/CMMML/Aplastic Anemia

JAK2/MPL:

Additional CMML:


APL

Cytogenetics/FISH:


FLT3:


SUGGESTED READINGS - continued
SUGGESTED READINGS - continued

APL

KIT:


IDH1/IDH2:

RAS:

NPM1:
Blood or bone marrow can be used for any of these tests. There are leukemia cells sampled by blood draw or bone marrow aspirate.

**CLL**

**Metaphase karyotype:**


**FISH for 11q del, 17p del, +12, 13q del:**


**IGHV mutation status:**


**TP53 sequencing and ATM sequencing, TP53, BIRC3, BTK, NOTCH1, PLCG2, SF3B1:**


Continued on next page
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Leukemia – continued

SUGGESTED READINGS - continued

CLL

**TP53 sequencing and ATM sequencing, TP53, BIRC3, BTK, NOTCH1, PLCG2, SF3B1:**


Continued on next page
SUGGESTED READINGS - continued

Leukemia – continued

CLL

TP53 sequencing and ATM sequencing, TP53, BIRC3, BTK, NOTCH1, PLCG2, SF3B1:


CML


Hairy Cell Leukemia


HES, Mastocytosis, MF, PV, ET


Continued on next page
SUGGESTED READINGS - continued

**Leukemia – continued**

**T-Cell Disorders**

TCRB clonality, TCRG clonality, FISH - 14q32:


**Large Granular Lymphocytic Leukemia (T-LGL)**

Somatic STAT3:


**Prolymphocytic Leukemia (T-PLL)**

JAK1, JAK3, STAT5B, IL2RG:


**Lymphoma**

**Diffuse Large B-Cell Lymphoma**


**Mantle Cell**

NOTCH1:


TP5:


Continued on next page
SUGGESTED READINGS - continued

**Melanoma**


Ekmeckioğlu S, Ellerhorst JA, Prieto VG, Johnson MM, Broemeling LD, Grimm EA. Tumor iNOS predicts poor survival for stage III melanoma patients. *Int J Cancer*. 2006 Aug 1;51(4):861-6


**Myeloma**

**Plasma Cell**


Continued on next page
SUGGESTED READINGS - continued

Sarcoma

Neuroblastoma

FISH/NMYC:

Desmoid fibromatosis

Molecular/CTNNBI:

Gastrointestinal stromal tumor


Thoracic

Non Small Cell Lung Cancer

Immunohistochemistry/PD-L1 22C3:


Non Small Cell Lung Cancer

Molecular/EGFR:


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SUGGESTED READINGS - continued

Thoracic – continued

Non Small Cell Lung Cancer

Molecular/EGFR:


Molecular/KRAS:


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SUGGESTED READINGS - continued

Non Small Cell Lung Cancer

Molecular/BRAF V600E:


Molecular/ELM4-ALK:


Molecular/BRAF V600E:


Continued on next page
Thoracic – continued

Non Small Cell Lung Cancer

FISH/ROS1:


FISH/Non Small Cell Lung Cancer/BRAF:
This practice consensus document was reviewed in conjunction with disease site representatives listed below. It was approved by the Molecular Testing Evaluation Committee (MTEC) at the University of Texas MD Anderson Cancer Center. The information is updated at least every two years or as new evidence emerges and is presented to MTEC for review and approval.

**DEVELOPMENT CREDITS**

This practice consensus document was reviewed in conjunction with disease site representatives listed below. It was approved by the Molecular Testing Evaluation Committee (MTEC) at the University of Texas MD Anderson Cancer Center. The information is updated at least every two years or as new evidence emerges and is presented to MTEC for review and approval.

**MTEC Members, 2015:**

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Disease Site</th>
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</thead>
<tbody>
<tr>
<td>MTEC Co-Chair, Clinical Research</td>
<td>Aman U. Buzdar, MD</td>
<td>Brain - W.K. Alfred Yung, MD</td>
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<tr>
<td>MTEC Co-Chair, Pathology/Laboratory Medicine</td>
<td>Stanley R. Hamilton, MD</td>
<td>Breast – Debu Tripathy, MD</td>
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<td>Bioinformatics and Computational Biology</td>
<td>Keith A. Baggery, PhD</td>
<td>Endocrine – Steven I. Sherman, MD</td>
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<tr>
<td>Pathology</td>
<td>Russell Broadus, MD, PhD</td>
<td>GI – Stanley R. Hamilton, MD</td>
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<td>Cancer Prevention</td>
<td>Ernest Hawk, MD</td>
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<td>Infectious Diseases</td>
<td>Dimitrios P. Kontoyiannis, MD</td>
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<td>Neema Navai, MD</td>
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<td>Leukemia – William G. Wierda, MD</td>
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<td>Unknown Primary</td>
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<td>Melanoma</td>
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**Clinical Effectiveness Development Team:**

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<tr>
<th>Name</th>
<th>Department</th>
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<td>Olga Fleckenstein</td>
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<td>Pauline Koinis, BSMT</td>
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