Head and Neck Biomarker Reporting Template

Version: 2.2.0.0
Protocol Posting Date: September 2023
The use of this protocol is recommended for clinical care purposes but is not required for accreditation purposes.

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With guidance from the CAP Cancer and CAP Pathology Electronic Reporting Committees.
* Denotes primary author.

Accreditation Requirements
Completion of the template is the responsibility of the laboratory performing the biomarker testing and/or providing the interpretation. When both testing and interpretation are performed elsewhere (eg, a reference laboratory), synoptic reporting of the results by the laboratory submitting the tissue for testing is also encouraged to ensure that all information is included in the patient’s medical record and thus readily available to the treating clinical team. This template is not required for accreditation purposes.
Summary of Changes
v2.2.0.0
• Updated "HPV-DNA PCR" and "HPV-E6/E7 mRNA RT-PCR" questions and answer sets
Reporting Template

Protocol Posting Date: September 2023
Select a single response unless otherwise indicated.

CASE SUMMARY: (Head and Neck Biomarker Reporting)

MORPHOLOGIC DIAGNOSIS

+Diagnosis: _________________

RESULTS

Head and Neck Squamous Cell Carcinoma (HNSCC)

Human Papillomavirus (HPV) Testing

+p16 IHC as a Surrogate for Transcriptionally Active High-Risk HPV
  ___ Negative (less than 50% diffuse and moderate-to-strong nuclear and cytoplasmic staining)
  ___ Equivocal (less than 70% but greater than or equal to 50% diffuse and moderate-to-strong
   nuclear and cytoplasmic staining)
  ___ Positive (greater than or equal to 70% diffuse and moderate-to-strong nuclear and cytoplasmic
   staining)
  ___ Other results (including cytology specimens, specify): _________________
  ___ Cannot be determined (explain): _________________

+HPV E6 / E7 mRNA ISH
  ___ Negative (no signal)
  ___ Positive (cytoplasmic and / or nuclear signals)
  +Specify Subtypes (if available): _________________
  ___ Cannot be determined (explain): _________________

+HPV-DNA ISH
  ___ Negative (no nuclear signal)
  ___ Positive (punctate and / or diffuse nuclear staining)
  +Specify Subtypes (if available): _________________
  ___ Cannot be determined (explain): _________________

+HPV-DNA PCR
  ___ Negative
  ___ Positive
  +Specify Subtypes (if available): _________________
  ___ Cannot be determined (explain): _________________

+HPV E6 / E7 mRNA RT-PCR
  ___ Negative
  ___ Positive
  +Specify Subtypes (if available): _________________
  ___ Cannot be determined (explain): _________________

Epstein-Barr Virus (EBV) Testing

+EBV Early mRNA (EBER) ISH
  ___ Negative (no signal)
  ___ Positive (nuclear signal)
  ___ Cannot be determined (explain): _________________
### NUT Midline Carcinoma

**+NUT IHC**  
- Negative (no nuclear staining)  
- Positive (nuclear staining)  
- Cannot be determined (explain): ________________  

**+NUT Rearrangements (by Molecular Methods)**  
- No NUT rearrangement detected  
- NUT rearrangement detected  
  - Specify Fusion Partner (if available): ________________  
  - Cannot be determined (explain): ________________

### Salivary Gland Carcinoma

#### Mucoepidermoid Carcinoma

**+MAML2 Rearrangements (by Molecular Methods)**  
- No MAML2 rearrangement detected  
- MAML2 rearrangement detected  
  - Specify Fusion Partner (if available): ________________  
  - Cannot be determined (explain): ________________

### Adenoid Cystic Carcinoma

**+MYB IHC**  
- Negative (no nuclear staining)  
- Positive (nuclear staining)  
- Cannot be determined (explain): ________________  

**+MYB Rearrangements (by Molecular Methods)**  
- No MYB rearrangement detected  
- MYB rearrangement detected  
  - Specify Fusion Partner (if available): ________________  
  - Cannot be determined (explain): ________________  

**+MYB-L1 IHC**  
- Negative (no nuclear staining)  
- Positive (nuclear staining)  
- Cannot be determined (explain): ________________  

**+MYB-L1 Rearrangements (by Molecular Methods)**  
- No MYB-L1 rearrangement detected  
- MYB-L1 rearrangement detected  
  - Specify Fusion Partner (if available): ________________  
  - Cannot be determined (explain): ________________

### Salivary Duct Carcinoma

**+AR IHC**  
- Negative (no nuclear staining)  
- Positive (nuclear staining)  
- Cannot be determined (explain): ________________  

**+HER2 Immunohistochemistry Interpretation**  
- Negative  
- Equivocal  
- Positive  

**+HER2 Immunohistochemistry Scoring System**  
- Breast  
- Gastric  
- Other (specify): ________________
<table>
<thead>
<tr>
<th><strong>HER2 Immunohistochemistry Score</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1+</td>
<td></td>
</tr>
<tr>
<td>2+</td>
<td></td>
</tr>
<tr>
<td>3+</td>
<td></td>
</tr>
<tr>
<td>Other (specify):</td>
<td></td>
</tr>
</tbody>
</table>

**Specify Percentage of Cells with Uniform Intense Complete Membrane Staining:**  

<table>
<thead>
<tr>
<th><strong>HER2 Immunohistochemistry Antibody</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HercepTest</td>
<td></td>
</tr>
<tr>
<td>4B5</td>
<td></td>
</tr>
<tr>
<td>SP3</td>
<td></td>
</tr>
<tr>
<td>Other (specify):</td>
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</table>

**HER2 Immunohistochemistry Assay Information**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Food and Drug Administration (FDA) cleared test / vendor (specify):</td>
<td></td>
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<tr>
<td>Laboratory-developed test</td>
<td></td>
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</tbody>
</table>

**HER2 by in situ Hybridization**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Negative (not amplified)</td>
<td></td>
</tr>
<tr>
<td>Positive (amplified)</td>
<td></td>
</tr>
<tr>
<td>Cannot be determined (indeterminate) (explain):</td>
<td></td>
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</tbody>
</table>

**Aneusomy (as defined by vendor kit used)**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Not identified</td>
<td></td>
</tr>
<tr>
<td>Present (explain):</td>
<td></td>
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</table>

**Heterogeneous Signals**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Not identified</td>
<td></td>
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<tr>
<td>Present</td>
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</tbody>
</table>

**Specify Percentage of Cells with Amplified HER2 Signals:**  

<table>
<thead>
<tr>
<th><strong>Carcinoma ex Pleomorphic Adenoma / Pleomorphic Adenoma</strong></th>
<th></th>
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</table>

**PLAG1 IHC**

<table>
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<tbody>
<tr>
<td>Negative (no nuclear staining)</td>
<td></td>
</tr>
<tr>
<td>Positive (nuclear staining)</td>
<td></td>
</tr>
<tr>
<td>Cannot be determined (explain):</td>
<td></td>
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</tbody>
</table>

**PLAG1 Rearrangements (by Molecular Methods)**

<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td>No PLAG1 rearrangement detected</td>
<td></td>
</tr>
<tr>
<td>PLAG1 rearrangement detected</td>
<td></td>
</tr>
</tbody>
</table>

**Specify Fusion Partner (if available):**  

| Cannot be determined (explain): |  |

**HMGA2 IHC**

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Negative (no nuclear staining)</td>
<td></td>
</tr>
<tr>
<td>Positive (nuclear staining)</td>
<td></td>
</tr>
<tr>
<td>Cannot be determined (explain):</td>
<td></td>
</tr>
</tbody>
</table>

**HMGA2 Rearrangements (by Molecular Methods)**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>No HMGA2 rearrangement detected</td>
<td></td>
</tr>
<tr>
<td>HMGA2 rearrangement detected</td>
<td></td>
</tr>
</tbody>
</table>

**Specify Fusion Partner (if available):**  

| Cannot be determined (explain): |  |
(Mammary Analogue) Secretory Carcinoma
+ETV6 Rearrangements (by Molecular Methods)
___ No ETV6 rearrangement detected
___ ETV6 rearrangement detected
  +Specify Fusion Partner (if available): ___________________
  ___ Cannot be determined (explain): ___________________
+NTRK Rearrangements (by Molecular Methods)
___ NTRK rearrangement detected
  +NTRK Type
    ___ NTRK1
    ___ NTRK2
    ___ NTRK3
  +Specify Fusion Partner (if available): ___________________
  ___ No NTRK rearrangement detected
  ___ Cannot be determined (explain): ___________________

(Hyalinizing) Clear Cell Carcinoma
+EWSR1 Rearrangements (by Molecular Methods)
___ No EWSR1 rearrangement detected
___ EWSR1 rearrangement detected
  +Specify Fusion Partner (if available): ___________________
  ___ Cannot be determined (explain): ___________________

Sinonasal Malignancies
SMARCB1 (INI-1) and SMARCA4 (BRG-1) Deficient Sinonasal Carcinoma / Rhabdoid Tumor / Teratocarcinosarcoma
+INI1 IHC
___ Intact nuclear staining (negative for deletion / alteration)
___ Loss of nuclear staining (positive for deletion / alteration)
___ Cannot be determined (explain): ___________________
+BRG1 IHC
___ Intact nuclear staining (negative for deletion / alteration)
___ Loss of nuclear staining (positive for deletion / alteration)
___ Cannot be determined (explain): ___________________

Biphenotypic Sinonasal Sarcoma
+PAX Rearrangements (by Molecular Methods)
___ PAX rearrangement detected
  +PAX Type
    ___ PAX3
    ___ PAX7
  +Specify Fusion Partner (if available): ___________________
  ___ No PAX rearrangement detected
  ___ Cannot be determined (explain): ___________________

Paraganglioma
+SDHB IHC
___ Intact cytoplasmic staining
___ Loss of cytoplasmic staining
___ Cannot be determined (explain): ___________________

Other Markers (repeat up to 10X, as needed)
+Specify Other Marker and Results: ___________________
COMMENTS

Comment(s): _________________