Head and Neck Biomarker Reporting Template

Version: 2.0.0.1
Protocol Posting Date: November 2021
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.
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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

v 2.0.0.1
- The CAP made no changes to Cancer Protocol content. We updated metadata only for the electronic Cancer Checklists (eCC), requiring a version number change for the Word and PDF Cancer Protocols.
Reporting Template

Protocol Posting Date: November 2021
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 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 (no signal)
   ____ Positive (cytoplasmic and/or nuclear signals)
   +Specify Subtypes (if available): _________________
   ____ Cannot be determined (explain): _________________

+HPV E6/E7 mRNA RT-PCR
   ____ Negative (no signal)
   ____ Positive (cytoplasmic and/or nuclear signals)
   +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): ___________________

+HER2 Immunohistochemistry Score
___ 0
___ 1+
___ 2+
___ 3+
___ Other (specify): ___________________

+Specify Percentage of Cells with Uniform Intense Complete Membrane Staining: __________________ %

+HER2 Immunohistochemistry Antibody
___ HercepTest
___ 4B5
___ SP3
___ Other (specify): ___________________

+HER2 Immunohistochemistry Assay Information
___ Food and Drug Administration (FDA) cleared test / vendor (specify): ___________________
___ Laboratory-developed test

+HER2 by in situ Hybridization
___ Negative (not amplified)
___ Positive (amplified)
___ Cannot be determined (indeterminate) (explain): ___________________

+Aneusomy (as defined by vendor kit used)
___ Not identified
___ Present (explain): ___________________

+Heterogeneous Signals
___ Not identified
___ Present
Specify Percentage of Cells with Amplified HER2 Signals: _________________ %

Carcinoma ex Pleomorphic Adenoma / Pleomorphic Adenoma
+PLAG1 IHC
___ Negative (no nuclear staining)
___ Positive (nuclear staining)
___ Cannot be determined (explain): _________________

+PLAG1 Rearrangements (by Molecular Methods)
___ No PLAG1 rearrangement detected
___ PLAG1 rearrangement detected
___ Specify Fusion Partner (if available): _________________
___ Cannot be determined (explain): _________________

+HMGA2 IHC
___ Negative (no nuclear staining)
___ Positive (nuclear staining)
___ Cannot be determined (explain): _________________

+HMGA2 Rearrangements (by Molecular Methods)
___ No HMGA2 rearrangement detected
___ HMGA2 rearrangement detected
___ 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): _________________
___ 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): _________________