



## 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.

### Authors

Raja R. Seethala, MD\*; Alexander Baras, MD, PhD; Brett W. Baskovich, MD; George G. Birdsong, MD; Patrick L. Fitzgibbons, MD, FCAP; Joseph D. Khoury, MD; Frank Schneider, MD.

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

#### 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):** \_\_\_\_\_
- 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):** \_\_\_\_\_