



## Head and Neck Biomarker Reporting Template

**Version:** 2.3.0.0

**Protocol Posting Date:** April 2026

The use of this protocol is recommended for clinical care purposes but is not required for accreditation purposes.

### **Version Contributors**

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### **Glossary:**

**Author:** Expert who is designated by the chair of the Cancer Committee.

**Expert Panel Contributors:** Includes members of other CAP committees or external subject matter experts who contribute to the current version of the protocol.

### **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 (e.g., 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 2.3.0.0**

- Removal of HPV-DNA ISH and HER2 Immunohistochemistry Interpretation questions
- Addition of defined score definitions for HER2 (by Immunohistochemistry)
- Addition of 4B5, A0485, and CB11 antibodies for HER2 Immunohistochemistry
- Removal of HER2 Immunohistochemistry Interpretation question
- Section heading change from “SMARCB1 (INI-1) and SMARCA4 (BRG-1) Deficient Sinonasal Carcinoma / Rhabdoid Tumor / Teratocarcinosarcoma” to “SWI / SNF Complex Deficient Sinonasal Carcinoma / Teratocarcinosarcoma”
- Minor typographical changes to questions and answers

**Reporting Template**

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**Protocol Posting Date:** April 2026

**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)**

*For PD-L1 testing, please refer to the General IHC Quantitative Biomarkers protocol.*

**Human Papillomavirus (HPV) Testing**

**+p16 IHC as a Surrogate for Transcriptionally Active High-Risk HPV**

- Negative (less than 50% moderate-to-strong nuclear and cytoplasmic staining)
- Equivocal (less than 70% but greater than or equal to 50% moderate-to-strong nuclear and cytoplasmic staining)
- Positive (greater than or equal to 70% moderate-to-strong nuclear and cytoplasmic staining)
- Other (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 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 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 Scoring System**

- Breast scoring system  
 Gastric / gastroesophageal junction scoring system (Rüschoff / Hofmann method)  
 Other (specify): \_\_\_\_\_

**+HER2 (by immunohistochemistry)**

- Negative (score 0)  
 Negative (score 1+)  
 Equivocal (score 2+)  
 Positive (score 3+)  
 Other (specify): \_\_\_\_\_  
 Cannot be determined (explain): \_\_\_\_\_

**+Specify Percentage of Cells with Uniform Intense Complete Membrane Staining:**  
 \_\_\_\_\_ %

**+HER2 Immunohistochemistry Antibody**

- 4B5  
 HercepTest  
 A0485  
 SP3  
 CB11  
 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)  
 Other (specify): \_\_\_\_\_  
 Cannot be determined (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): \_\_\_\_\_

**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**

**SWI / SNF Complex Deficient Sinonasal Carcinoma / Teratocarcinosarcoma**

**+IN1 IHC**

- Retained nuclear staining (negative for deletion / alteration)
- Loss of nuclear staining (positive for deletion / alteration)
- Cannot be determined (explain): \_\_\_\_\_

**+BRG1 IHC**

- Retained 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**

- Retained cytoplasmic staining (negative for deletion / alteration)
- Loss of cytoplasmic staining (positive for deletion / alteration)
- Cannot be determined (explain): \_\_\_\_\_

**Other Markers**

**+Specify Other Marker(s) and Result(s) (repeat up to 10x, as needed):** \_\_\_\_\_

**COMMENTS**

**Comment(s):** \_\_\_\_\_