



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.

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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.

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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): _____

+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: _____

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COMMENTS

Comment(s): _____