Head and Neck Biomarker Reporting Template

Version: 2.0.0.0
Protocol Posting Date: June 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 2.0.0.0

- Complete Reformatting

Reporting Template

Protocol Posting Date: June 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): _____