Template for Reporting Results of Biomarker Testing of Specimens From Patients With Non-Small Cell Carcinoma of the Lung

Version: 2.0.1.1
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This biomarker template is not required for accreditation purposes but may be used to facilitate compliance with CAP Accreditation Program Requirements

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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 2.0.1.1

- Removed PD-L1 CPS answer report text to PD-L1 IHC question, so that CPS is now visible on the final report and corrected erroneous unit “cells”
- Corrected ERBB2 (HER2) amplification answer grammatical format error
CASE SUMMARY: (Lung Biomarker Reporting Template)
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.

All reported gene sequence variations should be identified following the recommendations of the Human Genome Variation Society (www.hgvs.org/mutnomen/; accessed February 10, 2015).

SPECIMEN

+Adequacy of Sample for Testing
___ Adequate
   ___ Specify Estimated Percent of Tumor Cellularity (area used for testing): _______________ %
___ Suboptimal (explain): _______________
Please refer to original laboratory report for explanation.

+Specimen Type
___ Untreated diagnostic specimen
___ Relapse specimen (after treatment; specify): _______________
# When data is available, specify treatment type. This is most relevant to targeted inhibitors associated with specific genomic changes conferring treatment resistance.

RESULTS

EGFR

+Mutational Analysis
___ No EGFR mutation detected
___ Mutation(s) identified
   ___ EGFR:p.G719X
   ___ EGFR Exon 19 deletion (specify if known): _______________
   ___ EGFR Exon 20 insertion (specify if known): _______________
   ___ EGFR:p.S768I
   ___ EGFR:p.T790M
   ___ EGFR:p.L858R
   ___ EGFR:p.L861Q
   ___ Other (specify): _______________
___ Cannot be determined (explain): _______________

+EGFR L858R by Immunohistochemistry (clone 43B2)
___ Negative
___ Positive
___ Equivocal (explain): _______________

+EGFR Exon 19 Deletion (E746_A750del) (clone 6B6)
___ Negative
___ Positive
___ Equivocal (explain): _______________

+Interpretation (select all that apply)
___ An EGFR mutation is present that is associated with response to EGFR tyrosine kinase inhibitors
An EGFR mutation is present that is associated with resistance to EGFR tyrosine kinase inhibitors
Two EGFR mutations are present, one of which is associated with resistance to EGFR tyrosine kinase inhibitors
EGFR L858R immunohistochemical staining is positive, which is associated with response to EGFR tyrosine kinase inhibitors
EGFR E746_A750del immunohistochemical staining is positive, which is associated with response to EGFR tyrosine kinase inhibitors

**ALK**

**Rearrangement by Molecular Methods**
- No ALK rearrangement detected
- Rearrangement identified
  - EML4-ALK (specify variant type, if known): ________________________
  - KIF5B-ALK
  - KLC1-ALK
  - Other ALK rearrangement (specify if known): _______________________
  - Cannot be determined (explain): ______________________

**Immunohistochemistry**
- Negative
- Positive
- Equivocal (explain): ______________________

**Interpretation (select all that apply)**
- An ALK fusion is identified that is associated with response to ALK tyrosine kinase inhibitors
- ALK immunohistochemical staining is positive which is associated with response to ALK tyrosine kinase inhibitors

**ROS1**

**Rearrangement by Molecular Methods**
- No ROS1 rearrangement detected
- ROS1 rearrangement identified
- Cannot be determined (explain): ______________________

**Immunohistochemistry**
- Negative
- Positive
- Equivocal (explain): ______________________

**Interpretation (select all that apply)**
- A ROS1 fusion is present, which is associated with response to ROS tyrosine kinase inhibitors
- ROS1 immunohistochemical staining is positive, which is associated with response to ROS1 tyrosine kinase inhibitors

**RET**

**Rearrangement by Molecular Methods**
- No RET rearrangement detected
- RET rearrangement identified
- Cannot be determined (explain): ______________________

**Interpretation**
- A RET fusion is present which is associated with response to RET tyrosine kinase inhibitors
- No RET fusions are detected

**KRAS**

**Mutational Analysis**
- No KRAS mutation detected
- Mutation(s) identified
  - KRAS:p.G12C
**KRAS**
- KRAS:p.G12D
- KRAS:p.G12V
- KRAS:p.G12S
- KRAS:p.G12A
- KRAS:p.G12R
- KRAS:p.G13D
- KRAS:p.G13C
- KRAS:p.Q61L
- Other (specify): _________________
- Cannot be determined (explain): _________________

**Interpretation (select all that apply)**
- A KRAS mutation is identified which is associated with resistance to tyrosine kinase inhibitor therapy
- A KRAS mutation is identified which is associated with response to specific inhibitors

**BRAF**

**Mutational Analysis**
- No BRAF mutations detected
- Mutation(s) identified
  - BRAF:p.V600E
  - Other (specify): _________________
- Cannot be determined (explain): _________________

**Interpretation**
- A BRAF mutation is present which is associated with response to BRAF inhibitors
- No BRAF mutations are detected

**ERBB2**

**Mutational Analysis**
- No ERBB2 mutations detected
- Mutation(s) identified
  - ERBB2:p.S310F
  - ERBB2:p.L755S
  - ERBB2:p.Y772_A775dup insertion
  - Other (specify): _________________
- Cannot be determined (explain): _________________

**Copy Number Analysis**
- No ERBB2 (HER2) amplification detected
- ERBB2 (HER2) amplification identified
  - Specify Copy Number: _________________
  - Specify Ratio to Centromere 17: _________________
- Cannot be determined (explain): _________________

**HER2 immunohistochemistry**
- Negative (0-1)
- Equivocal (2+)
- Positive (3+)
- Cannot be determined (explain): _________________

**Interpretation (select all that apply)**
- An ERBB2 (HER2) mutation is present which is associated with response to anti-HER2 therapy
- ERBB2 (HER2) amplification is present which is associated with response to anti-HER2 therapy
- HER2 is positive by immunohistochemistry (3+) which is associated with response to anti-HER2 therapy
**MET**

**Mutational Analysis**
- No MET mutation detected
- Mutation(s) identified
  - MET:p.D963_splice mutation
  - MET:p.D1010N
  - MET:p.D1010_splice mutation
  - MET exon 14 deletion
  - Other (specify): __________________________
- Cannot be determined (explain): ______________________

**Copy Number Analysis**
- No MET amplification detected
- MET amplification identified
  - Specify Copy Number: __________________________
  - Specify Ratio to Centromere 7: ___________________
- Cannot be determined (explain): _____________________

**Interpretation (select all that apply)**
- A MET alteration is present which is associated with response to MET tyrosine kinase inhibitors
- MET amplification is present which is associated with response to MET tyrosine kinase inhibitors

**NTRK**

**Rearrangement by Molecular Methods**
- No NTRK rearrangement detected
- NTRK rearrangement identified (specify if known): ______________________
- Cannot be determined (explain): __________________________

**NTRK by immunohistochemistry**
- Negative
- Positive
- Equivocal

**Interpretation (select all that apply)**
- An NTRK fusion is present which is associated with response to NTRK inhibitors
- NTRK immunohistochemical staining is present. Fusion testing by NGS or FISH will be performed
- NTRK immunohistochemical staining is present but fusion testing is negative. This is not associated with response to NTRK inhibitors

**Mismatch Repair**

**Immunohistochemistry (IHC) Testing for Mismatch Repair (MMR) Proteins (select all that apply)**
- MLH1
  - **MLH1 Result**
    - Intact nuclear expression
    - Loss of nuclear expression
    - Cannot be determined (explain): ______________________
- MSH2
  - **MSH2 Result**
    - Intact nuclear expression
    - Loss of nuclear expression
    - Cannot be determined (explain): ______________________
- MSH6
  - **MSH6 Result**
    - Intact nuclear expression
    - Loss of nuclear expression
Cannot be determined (explain): _________________

PMS2 Result

Intact nuclear expression
Loss of nuclear expression
Cannot be determined (explain): _________________

Background nonneoplastic tissue / internal control with intact nuclear expression

Microsatellite Instability (MSI)

MSI-Stable (MSS)
MSI-Low (MSI-L)
MSI-High (MSI-H)
Cannot be determined: _________________

Interpretation (select all that apply)

The case is MSI-H which is associated with response to immune checkpoint inhibitors
The case is mismatch repair deficient which is associated with response to immune checkpoint inhibitors

Tumor Mutational Burden

Specify Tumor Mutational Burden: _________________

Tumor Mutational Burden Level

Low
High
Equivocal
Cannot be determined (explain): _________________

Interpretation

The case is TMB-high which is associated with response to immune checkpoint inhibitors
The case is TMB-low; this finding is not associated with response to immune checkpoint inhibitors

PD-L1 IHC

PD-L1 IHC Interpretation

Positive
Negative
Cannot be determined (indeterminate)

Specify Percentage of Tumor Cells with Staining (TPS): _________________ %

Combined Number of Tumor and Immune Cells with Staining per 100 Tumor Cells (CPS):

Specify Percentage of Tumor-associated Immune Cells with Staining: _________________ %

Specify Percentage of Tumor Area Occupied by Tumor-associated Immune Cells:
_________________ %

Comments: _________________

Methods

Antibody

22C3
SP142
SP263
28-8
Other (specify): _________________

Controls (select all that apply)

Internal control cells present; expected immunoreactivity
Internal control cells present; no immunoreactivity of either tumor cells or internal controls
External controls available, expected immunoreactivity
External controls available; no immunoreactivity in expected cells
+Assay Information
___ Food and Drug Administration (FDA) cleared test / vendor (specify): ____________________
___ Laboratory-developed test
+Specify Quantitative Imaging Analytics Performed: ____________________

Other Markers Tested (repeat as needed)
+Specify Other Marker and Results: ____________________

COMMENTS

Comment(s): ____________________