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

Version: 2.0.0.0
Protocol Posting Date: June 2021
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 2.0.0.0

- Complete Reformatting
Reporting Template

Protocol Posting Date: June 2021
Select a single response unless otherwise indicated.

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
___ Estimated % Tumor Cellularity (area used for testing): _________________ %
___ Suboptimal (explain): _________________

+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): ______________________

**+ALK 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): ______________________

**+ROS1 by 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 (select all that apply)**
- 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: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 (select all that apply)**
- 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 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
   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): _________________