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

Version: 2.0.1.1
Protocol Posting Date: September 2023
This biomarker template is not required for accreditation purposes but may be used to facilitate compliance with CAP Accreditation Program Requirements

Authors
Brett W. Baskovich, MD*; Patrick L. Fitzgibbons, MD, FCAP; George G. Birdsong, MD; Joseph D. Khoury, MD; Raja R. Seethala, MD; Frank Schneider, MD; Alexander Baras, MD, PhD.
With guidance from the CAP Cancer and CAP Pathology Electronic Reporting Committees.
* Denotes primary author.

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

Reporting Template

Protocol Posting Date: September 2023

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.

Gene names should follow recommendations of The Human Genome Organisation (HUGO) Nomenclature Committee (www.genenames.org; accessed February 10, 2015).

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): _____

+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
___ 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

___ 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
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): _____