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

Version: 2.0.1.0
Protocol Posting Date: November 2021
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*; Frank Schneider, MD; Alexander Baras, MD, PhD; George G. Birdsong, MD; Patrick L. Fitzgibbons, MD, FCAP; Joseph D. Khoury, MD; Raja R. Seethala, MD.

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 2.0.1.0

- Changed Questions for RET and BRAF Interpretation from select all that apply to single select

Replaced by version 2.0.1.1 on September 20, 2023, Obsolete as of June 2024 (8 months after newest release date)

Reporting Template

Protocol Posting Date: November 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.
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
+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

___ 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 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): _____