**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.*

*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 (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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**