Template for Reporting Results of Quantitative IHC Biomarker Testing of Specimens From Patients With Carcinoma

Version: 1.1.0.0  
Protocol Posting Date: November 2021
The use of this protocol is recommended for clinical care purposes but is not required for accreditation purposes.

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With guidance from the CAP Cancer and CAP Pathology Electronic Reporting Committees.  
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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. At this point, the breast biomarker template should be used for ER, PR, Ki67, and HER2 reporting. The purpose of this template is to support a generic and extensible reporting framework for various IHC based biomarkers.

Summary of Changes

v 1.1.0.0

- Added accreditation requirements statement
- Reordering of the biomarkers
- Added Controls questions for HER2 and Ki-67
- Addition of a generic repeating section for reporting additional biomarkers
Reporting Template

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

CASE SUMMARY: (Quantitative IHC Biomarker Reporting)

SPECIMEN INFORMATION

+Case Identifier: _________________
+Block Designation: _________________
+Anatomic Site: _________________
+Diagnosis: _________________

+Biomarker(s) Assessed (select all that apply)

___ PD-L1 IHC

PD-L1 IHC Results
+Interpretation
  ___ Positive
  ___ Negative
  ___ Cannot be determined (indeterminate)
+Percentage of Tumor Cells with Staining (TPS): _________________ %
+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: _________________

PD-L1 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: _________________
MMR IHC

MMR IHC Results

+Interpretation

___ No loss of nuclear expression of MMR proteins
___ Loss of nuclear expression of MLH1 and PMS2
___ Loss of nuclear expression of MSH2 and MSH6
___ Loss of nuclear expression of only PMS2 or MSH6
___ Other (specify): __________________
___ Cannot be determined (indeterminate)

+Comments: __________________

MMR Staining

+Nuclear MLH1 staining

___ Intact
___ Loss
___ Other (specify): __________________

+Nuclear PMS2 staining

___ Intact
___ Loss
___ Other (specify): __________________

+Nuclear MSH2 staining

___ Intact
___ Loss
___ Other (specify): __________________

+Nuclear MSH6 staining

___ Intact
___ Loss
___ Other (specify): __________________

MMR IHC Methods

+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: __________________
HER2 IHC

HER2 IHC Results
+Interpretation
  ___ Positive
  ___ Negative
  ___ Equivocal
  ___ Cannot be determined (indeterminate)

+Scoring System
  ___ Breast
  ___ Gastric
  ___ Other (specify): ________________

+Score
  ___ 0
  ___ 1+
  ___ 2+
  ___ 3+
  ___ Other (specify): ________________

+Specify Percentage of Cells with Uniform Intense Complete Membrane Staining:
  ____________________ %

+Comments: ____________________

HER2 IHC Methods
+Antibody
  ___ HercepTest
  ___ 4B5
  ___ SP3
  ___ Other (specify): ________________

+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: ________________
Estrogen Receptor IHC

Estrogen Receptor IHC Results

+ Interpretation
  ___ Positive
  ___ Negative
  ___ Cannot be determined (indeterminate)

+ Specify Tumor Cell Percent Positive: _____________ %

+ Tumor Cell Staining Intensity
  ___ Strong
  ___ Moderate
  ___ Weak
  ___ Other (specify): _________________

+ Comments: _________________

Estrogen Receptor IHC Methods

+ Antibody
  ___ SP1
  ___ 6F11
  ___ 1D5
  ___ 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: _________________
Progesterone Receptor IHC

**Progesterone Receptor IHC Results**

**Interpretation**

- **Positive**
- **Negative**
- **Cannot be determined (indeterminate)**

**Specify Tumor Cell Percent Positive:** _________________%

**Tumor Cell Staining Intensity**

- **Strong**
- **Moderate**
- **Weak**
- **Other (specify):** _________________

**Comments:** __________________

**Progesterone Receptor IHC Methods**

**Antibody**

- **1E2**
- **636**
- **SP2**
- **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:** _________________
Ki-67 IHC

**Ki-67 IHC Results**

+ Specify Tumor Cell Percent Positive: ____________________%

+ Comments: ____________________

**Ki-67 IHC Methods**

+ Antibody
  ___ MIB1
  ___ Other (specify): ____________________

+ Controls
  ___ External controls available, expected immunoreactivity
  ___ External controls available; no immunoreactivity in expected cells

+ Assay Information (eg., Laboratory-developed Test): ____________________

+ Specify Quantitative Imaging Analytics Performed: ____________________
Other Biomarker(s) (may repeat for up to 10 biomarkers)

Specify Biomarker : ________________

Results

+Interpretation
___ Positive
___ Negative
___ Cannot be determined (indeterminate)

+Tumor Cell Staining Intensity : ________________ %

+Comments : ________________

Methods

+Specify Antibody : ________________

+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 : ________________

COMMENTS

Comment(s) : ________________