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 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 (e.g., 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): ____________________