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

Version: 1.1.0.1
Protocol Posting Date: September 2023
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 1.1.0.1

- 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”
- Updated “Specify Biomarker” question response from core (required) to optional, and added “Other (specify)” answer
Reporting Template
Protocol Posting Date: September 2023
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): _________________ %
+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: _________________

PD-L1 IHC 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
+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 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
___ Other (specify): _________________
___ 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): __________________