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
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
___ 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): _____