



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.

Authors

Alexander Baras, MD, PhD*; Brett W. Baskovich, MD; Andrew M. Bellizzi, MD; Patrick L. Fitzgibbons, MD, FCAP; George G. Birdsong, MD; Joseph D. Khoury, MD; Raja R. Seethala, MD; Frank Schneider, MD.

With guidance from the CAP Cancer and CAP Pathology Electronic Reporting Committees.

* Denotes primary author.

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): _____