MAYO CLINIC LABORATORIES

Test Definition: ERPR

Estrogen/Progesterone Receptor, Semi-Quantitative Immunohistochemistry, Manual

Overview

Useful For

Guiding decisions on hormonal therapy in patients with breast carcinomas

This test is **not useful for** cases of lobular carcinoma in situ.

Method Name

Semi-Quantitative Immunohistochemistry

NY State Available

Yes

Specimen

Specimen Type

Special

Ordering Guidance

This test is for prognostic purposes only.

For diagnostic purposes, order PATHC / Pathology Consultation and then request the stains.

Estrogen/progesterone receptor testing is not appropriate and not performed for cases of lobular carcinoma in situ.

Shipping Instructions

Attach the green pathology address label included in the kit to the outside of the transport container.

Necessary Information

1. **Include accompanying pathology report stating the final diagnosis**. If not available, a preliminary diagnosis is acceptable.

2. Information regarding fixative used, time to fixation, and duration of fixation is required. The following questions, as stated on the order form or presented electronically, must be answered:

a. "Was specimen fixed in 10% neutral buffered formalin within 1 hour from surgical collection time? Yes, No, or Unknown."

b. "Has specimen been fixed in 10% neutral buffered formalin for 6 to 72 hours? Yes, No, or Unknown."

c. "Was tissue decalcified? Yes, No, or Unknown."

d. "Tumor type? Primary breast carcinoma, metastatic breast carcinoma, or non-breast tumor."

e. "Tumor classification? Invasive breast carcinoma, ductal carcinoma in situ, metastatic breast carcinoma,

micro-invasive breast carcinoma, solid/intracystic papillary carcinoma, or non-breast tumor."

Specimen Required

Supplies: Pathology Packaging Kit (T554)
Specimen Type: Breast carcinoma
Preferred: A paraffin-embedded tissue block containing in-situ, invasive or metastatic breast carcinoma tissue that has been fixed in 10% neutral buffered formalin within 1 hour from surgical collection time and for a total of 6 to 72 hours and shipped at ambient temperature
Acceptable: 3 unstained sections, containing carcinoma, on charged slides cut at 4 microns <1 month ago and shipped at ambient temperature
Collection Instructions: Submit paraffin-embedded carcinoma tissue

Specimen Type: Non-breast carcinoma
Preferred: A paraffin-embedded tissue block containing carcinoma tissue that has been fixed in 10% neutral buffered formalin and shipped at ambient temperature
Acceptable: 3 unstained sections, containing carcinoma, on charged slides cut at 4 microns <1 month ago and shipped at ambient temperature
Collection Instructions: Submit paraffin-embedded carcinoma tissue

Additional Information:
1. According to the American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines, estrogen/progesterone receptor protein immunohistochemical test results are only valid for nondecalcified, paraffin-embedded specimens fixed in 10% neutral buffered formalin within 1 hour from surgical collection time and for a total time of 6 to 72 hours. Delay to fixation, under- or overfixation may affect these results.
2. Paraffin blocks will be returned with final report.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Oncology Test Request (T729)
-Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763)

Reject Due To

Broken or cracked unstained slides	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Special	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information

The steroid hormone receptors, estrogen receptor (ER) and progesterone receptor (PR), are commonly used in the management of women with breast cancer. ER and PR status provide an indication of prognosis and of the potential benefit from hormonal therapy. Generally, ER/PR-positive tumors are more likely to respond to endocrine therapy and have a better prognosis, stage-for-stage, than receptor-negative tumors.

While the test can be performed on any formalin-fixed, paraffin-embedded tissue, it is infrequently used for non-breast cancer specimens.

Reference Values

Negative: <1% reactive cells
Positive: > or =1% reactive cells

Interpretation

Immunoperoxidase-stained slides are examined microscopically by the consulting anatomic pathologist and interpreted as negative (<1% reactive cells), or positive. The percent of reactive cells is provided in the report.

Cautions

The performance and quality of immunohistochemical (IHC) stains for formalin-fixed, paraffin-embedded tissue depends critically on proper fixation of tissue specimens. IHC staining of steroid hormone receptors is especially sensitive to fixation conditions (see Specimen Required for specific handling instructions).

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Clinical Reference

1. Hammond ME, Hayes DF, Dowsett M, et al: American Society of Clinical Oncology/College of American Pathologists guideline recommendations for immunohistochemical testing of estrogen and progesterone receptors in breast cancer. Arch Pathol Lab Med. 2010 Jun;134(6):907-22. doi: 10.1043/1543-2165-134.6.907. Erratum in: Arch Pathol Lab Med. 2010 Aug;134(8):1101
2. Allison KH, Hammond MEH, Dowsett M, et al: Estrogen and progesterone receptor testing in breast cancer: ASCO/CAP Guideline Update. J Clin Oncol. 2020 Apr 20;38(12):1346-1366. doi: 10.1200/JCO.19.02309

Performance

Method Description

Immunoperoxidase staining and detection of estrogen receptor (ER) and progesterone receptor (PR) are performed in formalin-fixed, paraffin-embedded tissue sections using a proprietary kit detection system. The 4-micron tissue sections

are deparaffinized, subjected to heat-induced antigen retrieval, and then sequentially incubated with antireceptor monoclonal antibodies (ER clone SP1 and PR clone 1E2) and followed by a proprietary kit detection system. The chromogen, diaminobenzidine, is subsequently applied to the section to produce a brown nuclear precipitate in cells expressing receptors. Sections are lightly counterstained with hematoxylin. Stained slides are examined microscopically by the consulting anatomic pathologist and interpreted as negative (<1% reactive cells), or positive with one of the following ranges: (1%-10% reactive cells), (11%-20% reactive cells), (21%-30% reactive cells), (31%-40% reactive cells), (41%-50% reactive cells), (51%-60% reactive cells), (61%-70% reactive cells), (71%-80% reactive cells), (81%-90% reactive cells), or (91%-100% reactive cells).(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
4 to 6 days

Specimen Retention Time
1 week after results are reported. Materials made at Mayo Clinic may be retained at Mayo Clinic indefinitely.

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
88360 x 2

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value

ERPR	ER/PR Semi Quant IHC Manual	10480-2

Result ID	Test Result Name	Result LOINC® Value
MA002	Fixed in 10% NB formalin w/in 1 hr	8100-0
MA003	Fixed in 10% NB formalin 6-72 hrs	8100-0
MA004	Tumor type	44638-5
MA005	Tumor classification	21918-8
70965	Interpretation	50595-8
70966	Participated in the Interpretation	No LOINC Needed
70967	Report electronically signed by	19139-5
70969	Material Received	81178-6
71620	Disclaimer	62364-5
71834	Case Number	80398-1
MA044	Tissue was decalcified	8100-0