

ASCO/CAP Guideline Recommendations for ER/PgR Testing in Breast Cancer

Reporting Elements for IHC:

When reviewing ER/PgR test assessments it is important to know whether the testing laboratory is CAP-accredited or whether it meets the accreditation and proficiency testing requirements set out by the ASCO/CAP guideline on ER/PgR testing. Each ER/PgR status report should report the following elements:

Standard Reporting Elements for IHC*

- Patient identification information
- Physician identification
- Date of service
- Specimen site and type
- Specimen identification (case and block number)
- Specimen fixative type
- Cold ischemia time (time from removal to fixation)
- Duration of fixation
- Staining method utilized
- Primary antibody and vendor
- Assay details and other reagents/vendors
- References supporting validation of assay (note: most commonly, these will be published studies performed by others which the testing laboratory is emulating)
- Status of FDA approval
- Controls (high protein expression, low-level protein expression, negative protein expression, internal elements [ideally from normal breast tissue included with sample])
- Adequacy of sample for evaluation
- Results

*If a FDA-approved method is used, it should be noted. If the FDA-approved method has been modified, a statement in the report should be included indicating what modifications were made and that the changes have been validated. If the test is not FDA-approved or an FDA-approved test has been modified, a clear statement must be made that the laboratory reporting results takes responsibility for test performance.