



**CMS Measure ID/CMS QCDR ID: CAP 14**

**Measure Title:** Appropriate Formalin Fixation Time (6 – 72 hours) of Breast Cancer Specimens to Ensure Accurate Ancillary Testing Results

Measure Specifications

<p><b>Measure Description</b></p>	<p>Percentage of breast cancer specimens (cytology, biopsy and/or resection) in which the total fixation time in formalin is between 6-72 hours.</p> <p>INSTRUCTIONS: This measure is to be reported each time a breast cancer specimen is processed during the performance period. This measure may be submitted by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.</p>
<p><b>Denominator Statement</b></p>	<p>All breast cancer specimens (cytology, biopsy, and/or resection).</p> <p>CPT®: 88305, 88307, 88309, 88173</p> <p><b>AND</b></p> <p>ICD10:</p> <ul style="list-style-type: none"> <li>• C50.011: Malignant neoplasm of nipple and areola, right female breast</li> <li>• C50.012: Malignant neoplasm of nipple and areola, left female breast</li> <li>• C50.019: Malignant neoplasm of nipple and areola, unspecified female breast</li> <li>• C50.021: Malignant neoplasm of nipple and areola, right male breast</li> <li>• C50.022: Malignant neoplasm of nipple and areola, left male breast</li> <li>• C50.029: Malignant neoplasm of nipple and areola, unspecified male breast</li> <li>• C50.111: Malignant neoplasm of central portion of right female breast</li> <li>• C50.112: Malignant neoplasm of central portion of left female breast</li> <li>• C50.119: Malignant neoplasm of central portion of unspecified female breast</li> <li>• C50.121: Malignant neoplasm of central portion of right male breast</li> <li>• C50.122: Malignant neoplasm of central portion of left male breast</li> <li>• C50.129: Malignant neoplasm of central portion of unspecified male breast</li> <li>• C50.211: Malignant neoplasm of upper-inner quadrant of right female breast</li> <li>• C50.212: Malignant neoplasm of upper-inner quadrant of left female breast</li> <li>• C50.219: Malignant neoplasm of upper-inner quadrant of unspecified female breast</li> <li>• C50.221: Malignant neoplasm of upper-inner quadrant of right male breast</li> <li>• C50.222: Malignant neoplasm of upper-inner quadrant of left male breast</li> <li>• C50.229: Malignant neoplasm of upper-inner quadrant of unspecified male breast</li> <li>• C50.311: Malignant neoplasm of lower-inner quadrant of right female</li> </ul>



	<p>breast</p> <ul style="list-style-type: none"><li>• C50.312: Malignant neoplasm of lower-inner quadrant of left female breast</li><li>• C50.319: Malignant neoplasm of lower-inner quadrant of unspecified female breast</li><li>• C50.321: Malignant neoplasm of lower-inner quadrant of right male breast</li><li>• C50.322: Malignant neoplasm of lower-inner quadrant of left male breast</li><li>• C50.329: Malignant neoplasm of lower-inner quadrant of unspecified male breast</li><li>• C50.411: Malignant neoplasm of upper-outer quadrant of right female breast</li><li>• C50.412: Malignant neoplasm of upper-outer quadrant of left female breast</li><li>• C50.419: Malignant neoplasm of upper-outer quadrant of unspecified female breast</li><li>• C50.421: Malignant neoplasm of upper-outer quadrant of right male breast</li><li>• C50.422: Malignant neoplasm of upper-outer quadrant of left male breast</li><li>• C50.429: Malignant neoplasm of upper-outer quadrant of unspecified male breast</li><li>• C50.511: Malignant neoplasm of lower-outer quadrant of right female breast</li><li>• C50.512: Malignant neoplasm of lower-outer quadrant of left female breast</li><li>• C50.519: Malignant neoplasm of lower-outer quadrant of unspecified female breast</li><li>• C50.521: Malignant neoplasm of lower-outer quadrant of right male breast</li><li>• C50.522: Malignant neoplasm of lower-outer quadrant of left male breast</li><li>• C50.529: Malignant neoplasm of lower-outer quadrant of unspecified male breast</li><li>• C50.611: Malignant neoplasm of axillary tail of right female breast</li><li>• C50.612: Malignant neoplasm of axillary tail of left female breast</li><li>• C50.619: Malignant neoplasm of axillary tail of unspecified female breast</li><li>• C50.621: Malignant neoplasm of axillary tail of right male breast</li><li>• C50.622: Malignant neoplasm of axillary tail of left male breast</li><li>• C50.629: Malignant neoplasm of axillary tail of unspecified male breast</li><li>• C50.811: Malignant neoplasm of overlapping sites of right female breast</li><li>• C50.812: Malignant neoplasm of overlapping sites of left female breast</li></ul>
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	<ul style="list-style-type: none"> <li>• C50.819: Malignant neoplasm of overlapping sites of unspecified female breast</li> <li>• C50.821: Malignant neoplasm of overlapping sites of right male breast</li> <li>• C50.822: Malignant neoplasm of overlapping sites of left male breast</li> <li>• C50.829: Malignant neoplasm of overlapping sites of unspecified male breast</li> <li>• C50.911: Malignant neoplasm of unspecified site of right female breast</li> <li>• C50.912: Malignant neoplasm of unspecified site of left female breast</li> <li>• C50.919: Malignant neoplasm of unspecified site of unspecified female breast</li> <li>• C50.921: Malignant neoplasm of unspecified site of right male breast</li> <li>• C50.922: Malignant neoplasm of unspecified site of left male breast</li> <li>• C50.929: Malignant neoplasm of unspecified site of unspecified male breast</li> </ul>
<b>Denominator Exclusions</b>	Specimen is from site other than the breast (i.e., metastatic)
<b>Denominator Exceptions</b>	Documentation of reason(s) for specimen not needing formalin fixation (e.g., re-excision without residual tumor, non-carcinomas)
<b>Numerator Statement</b>	Breast cancer specimens (cytology, biopsy and/or resection) in which the total fixation time in formalin is between 6-72 hours.
<b>Numerator Exclusions</b>	None
<b>Measure Information</b>	
<b>NQS Domain</b>	Effective Clinical Care
<b>Meaningful Measures Area(s)</b>	Make Care Affordable: Appropriate Use of Healthcare
<b>Meaningful Measure Rationale</b>	<p>The most recent ASCO/CAP Guidelines related to HER2 testing in breast cancer recommendations, cytologic, biopsy and resection specimens should be placed in formalin in a timely fashion (within 1 hour) and should be fixed in 10% neutral buffered formalin for 6 to 72 hours. Subsequently, routine processing, as well as staining or probing, are then performed according to standardized analytically validated protocols (1).</p> <p>Breast specimens that will be subject to ER/PgR and HER2 testing should be fixed in neutral buffered formalin for a minimum of six hours and a maximum of 72 hours. This fixation time begins when the specimen is initially placed in formalin (not when the specimen is sectioned during gross examination) and ends when the cassettes are no longer in formalin. For specimens fixed longer than 72 hours for HER2 or ER and PgR in which negative test results are obtained, the report should state that prolonged fixation could be a</p>



	<p>possible cause for the negative result, and alternative testing methods should be considered (e.g. FISH for HER2; gene expression assay for ER). For HER2 testing, labs should also consider confirming by FISH any specimen fixed longer than 72 hours that is not Score 3 by IHC (1).</p> <p>While formalin penetrates tissues at the rate of about 1mm/hour, penetration is not the same as fixation and the biochemical cross-linking that represents formalin fixation requires more time. Published studies have documented that a minimum of 6-8 hours formalin fixation is needed to obtain consistent IHC assay results for ER; fixation for less than this time has been shown to cause false negative ER staining. Because of the adverse effects of under fixation, which cannot be overcome by antigen retrieval, testing on specimens fixed for less than 6 hours is no longer acceptable (1).</p> <p>The data from studies suggest that formalin fixation for up to 72 hours does not appear to have any impact on ER, PgR and HER2 reactivity and therefore is an acceptable upper limit of time in routine clinical practice. The immunoreactivity of breast prognostic markers testing for ER, PgR and HER2 may be reduced by very long, extended formalin over-fixation that is not clinically relevant (1, 2).</p> <ol style="list-style-type: none"> <li>1. Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Arch Pathol Lab Med. 31:3997 -4014, 2013).</li> <li>2. Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. Journal of Clinical Oncology 36, no. 20 (July 10 2018) 2105-2122.</li> </ol>
<b>Measure Type</b>	Process
<b>Data Source</b>	Laboratory Information System and pathology reports
<b>Summary of Performance Gap Evidence</b>	<p>A survey was conducted to reassess the ongoing efforts of laboratories to comply with ASCO/CAP HER2 testing Guidelines. The 2011 survey results show that less than half of laboratories are including the exact specimen fixation time in their reports (37.9% [353 of 931] in 2011). At the same time, laboratories fail to report any information on fixation time 16.8% [156 of 931] of cases. Laboratories are also expected to develop policies and procedures to prevent prolonged fixation. Most laboratories (63.5%; 593 of 934) now process and embed tissue on weekends to ensure appropriate fixation time. Other laboratories (21.1%; 197 of 934) have employed different modifications; only 15.4% [144 of 934] of laboratories have no special policies for such specimens.</p> <ol style="list-style-type: none"> <li>1. Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update Recommendations for Human Epidermal Growth Factor Receptor 2</li> </ol>



	Testing in Breast Cancer. Arch Pathol Lab Med. 31:3997 -4014, 2013)
<b>Measure Owner</b>	College of American Pathologists
<b>NQF ID</b>	N/A
<b>Number of Performance Rates</b>	1
<b>Overall Performance Rate</b>	1st Performance Rate
<b>High-priority</b>	No
<b>Improvement Notation</b>	Inverse Measure: No <b>Proportional Measure: Yes (Higher score indicates better quality)</b> Continuous Variable Measure: No Ratio Measure: No Risk-adjusted: No
<b>Specialty</b>	Pathology
<b>Current Clinical Guideline the Measure is Derived From</b>	Optimal tissue handling requirements: Time from tissue acquisition to fixation should be as short as possible; samples for HER2 testing are fixed in 10% neutral buffered formalin for 6-72 hours; cytology specimens must be fixed in formalin. (Strong recommendation) 1. Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Arch Pathol Lab Med. 31:3997 -4014, 2013)



Measure Flow



Data Completeness =			
Denominator Exceptions + Performance Met + Performance Not Met	100 + 500 + 100	=	88%
Eligible Population	800		
Performance Rate =			
Performance Met	500	=	72%
Data completeness Numerator - Denominator Exceptions	800 - 100		

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