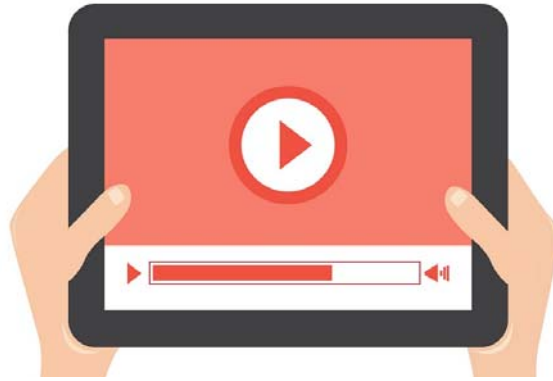


## BREAST SSDI

PRESENTED BY  
LORI SOMERS, RN

IOWA CANCER  
REGISTRY



SHRI VIDEO TRAINING SERIES  
2018-2020 DX  
RECORDED 12/2020

1

1

## 00480: Breast

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- Chapter 48 in AJCC [updated pdf]
- 21 Required SSDI's, current version 1.7
- Don't panic!

2

2

## Update

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SSDI & Grade Manual <https://apps.naacr.org/ssdi/list/>

Version 1.7 Change Log

<https://www.naacr.org/SSDI/Change-Log.pdf?v=1603216378>

3

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## v1.7 Updates Related to Breast

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### •Rounding Rules

- **Exceptions:** HER2 ISH Single Probe Copy Number; HER2 ISH Dual Probe Copy Number; HER2 ISH Dual Probe Ratio
  - Example: HER2 ISH DP Copy Number 6.78. Per note 8, ignore hundredth decimal. **Do NOT round**. Code 6.7
  - Note: ER/PR % pos do not have decimal points, so anything with decimal point will have to be rounded. Example 78.6 round up to 79% and code 079. If value 99.5% to 99.9% round up to 100% and code 100.

4

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## v1.7 Updates Related to Breast

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### Recording Lab Values when “less than” or “greater than” are used.

- Record value as one less than stated when value is stated “less than X”
- Record value as one more than stated when value is stated “more than X”
- It may refer to a whole number (1) or a decimal (0.1) depending on code structure of field

#### Examples:

Ki-67 reported as >20%. Code 20.1 [decimal code structure]

ER % Pos stated as <60%. Code 059 [without decimals]

PR % Pos stated as >75%. Code 076 [without decimals]

5

5

## v1.7 Updates Related to Breast

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### Timing for Recording Lab Tests

- Before any cancer-directed treatment is given (neoadjuvant therapy or surgical)
- No earlier than approx. 3 mos before dx
- If multiple tests are available, record the highest value

6

6

Do not use results from  
any of the multigene tests  
(oncotype dx,  
mammaprint)

## ER/PR data items

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#3827/3915	}	• ER/PR Summary
#3826/3914	}	• ER/PR % pos or range
#3828/3916	}	• ER/PR Total Allred Score

7

7

## 3827/3915: ER/PR Summary

---

Note 1: Physician statement of ER/PR summary can be used if no other info.

Note 2: Result of ER/PR performed on primary breast tissue.

Note 3: Results from nodal or metastatic tissue may be used ONLY when no evid pri tumor.

Note 4: If invasive and insitu results, ignore the insitu results. Code the invasive results.

- If ER/PR pos on insitu; neg on invasive, code ER/PR as negative (code 0)
- If ER/PR only done on insitu component and not on invasive component, code ER/PR as unknown (code 9)

8

8

## 3827/3915: ER/PR Summary

Note 5: **Single tumor** with multiple biopsies and/or resection with different results

- Use highest (pos versus neg)

Note 6: **Multiple tumors** with different results, code from largest tumor size (clin or path) but not specimen size.

Note 7: Neoadjuvant therapy given, record results prior to neoadjuvant therapy. If no results pre-treatment, report findings from post-treatment specimens.

Note 8: Do not record the results of multigene testing (Oncotype Dx or mammaprint)

9

9

## 3827/3915 ER/PR Summary

Code	Description
0	ER or PR Negative (0.0% or less than 1%)
1	ER or PR Positive
7	Test ordered, results not in chart
9	Not documented in medical record Cannot be determined (indeterminate) ER or PR summary status not assessed or unknown if assessed

10

10

## 3826/3914 ER/PR % Pos or Range

Note 1: Physician statement of ER/PR % pos or range can be used

Note 2: Code using same report as ER/PR Summary [3827/3915]

Note 3: If ER/PR is neg, or percentage <1%, code 000

Note 4: Actual ER/PR (1-100%) takes priority over range codes

Note 5: ER/PR is pos but % unknown, code XX7

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## 3826/3914 ER/PR % Positive or Range

Code	Description
000	ER negative, or stated as less than 1%
001-100	1-100 percent
R10	Stated as 1-10%
R20	Stated as 11-20%
R30	Stated as 21-30%
R40	Stated as 31-40%
R50	Stated as 41-50%
R60	Stated as 51-60%
R70	Stated as 61-70%
R80	Stated as 71-80%
R90	Stated as 81-90%
R99	Stated as 91-100%
XX7	Test done, results not in chart
XX8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX8 will result in an edit error.)
XX9	Not documented in medical record ER (Estrogen Receptor) Percent Positive or Range not assessed or unknown if assessed

12

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## Clarifications

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- ❑ If ER/PR is stated as “negative”
  - ❑ Percent Positive/Range is assigned 000 [can mean either 0% or <1%]
  - ❑ Allred score is X9\*\*.
  - ❑ Exception: If Allred score is listed in path report, code the Allred score listed.
- ❑ If ER/PR is stated as 0% and intensity is not listed
  - ❑ Percent Positive/Range is assigned 000
  - ❑ Allred score is 0. (Assume intensity score is none.)
- ❑ If ER/PR is stated as 0% and intensity listed
  - ❑ Percent Positive/Range is assigned 000
  - ❑ Use intensity to calculate Allred score

\*\*To calculate the Allred score you need **both** the percent positive and the intensity. As a negative result can have a proportion score of 0 or 1, you would not be able to calculate an Allred score, therefore Allred would be coded to X9.

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## 3828/3916 ER/PR Total Allred Score

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Note 1: Physician statement of ER/PR Allred score can be used

Note 2: Code this data item using same report as ER/PR Summary [3827/3915]

Note 3: Allred system looks at what % of cells test positive for hormone receptors along with how well the receptors show up after staining (intensity). Combine info to score the sample from 0 to 8.

- Do not calculate Allred score unless **both** components are available
- See the ALLRED Score for ER/PR eval in SSDI manual [pg 174]

Note 4: If ER/PR test performed, but Allred score is not documented or cannot be calculated, code X9

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## 3828/3916 ER/PR Total Allred Score

Allred score combines % pos cells (proportion score) and intensity score. Added together for final Allred score. Possible values (00-08).

Proportion Score	Positive Cells, %
0	0
1	<1
2	1 to 10
3	11 to 33
4	34 to 66
5	≥67

Intensity	Intensity Score
None	0
Weak	1
Intermediate/Moderate	2
Strong	3

Tables only found in SSDI Manual, pg 174  
<https://www.naaccr.org/SSDI/SSDI-Manual.pdf?v=1544714242>

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## 3828/3916 ER/PR Allred Score

Code	Description
00	Total ER Allred score of 0
01	Total ER Allred score of 1
02	Total ER Allred score of 2
03	Total ER Allred score of 3
04	Total ER Allred score of 4
05	Total ER Allred score of 5
06	Total ER Allred score of 6
07	Total ER Allred score of 7
08	Total ER Allred score of 8
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record ER (Estrogen Receptor) Total Allred Score not assessed, or unknown if assessed

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## Pop Quiz

8/26/2020 Addendum:  
 ER positive (Allred score = 8 of 8)  
 PR positive (Allred score = 8 of 8)  
 HER2 by IHC neg  
 Ki-67 5%  
 HER by FISH not done.

Field	Code
ER Summary	
ER % Pos	
ER Allred Score	
PR Summary	
PR % Positive	
PR Allred Score	

17

17

## Calculate Allred Score for ER/PR

Quiz 1: Labs: 6-22-20 **ERA: Positive 100%. PRA: Positive 100%**. Her-2/Neu: Weakly positive. Her-2/Fish: Negative, ratio: 1.2 Number of observers: 1 (single). Her-2 copy number: Less than 4 signals per cell. Ki-67: under 10%.

Field	Code
ER Allred Score {5+?}	
PR Allred Score {5+?}	

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## Calculate Allred Score for ER/PR

Quiz 2: Labs: 6-7-20 **ER pos, <95%, strong intensity. PR neg.** HER2 IHC 2+/equivocal. FISH pos, avg HER2 signals/nucleus 5.4, avg CEN 17 signals/nucleus 1.7, HER2/CEN 17 ratio 3.2. Ki-67 not done.

Field	Code
ER Summary	
ER % Pos {less than 95%}	
ER Allred Score {5+3}	
PR Summary	
PR % Positive {see note 3}	
PR Allred Score {?+?}	

19

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## Calculate Allred Score for ER/PR

Quiz 3: Labs: 1-24-20 **ER pos, 95%, 3+/strong intensity. PR pos, 90%, 2+/moderate to strong intensity.**

HER2 IHC 2+/equivocal. FISH: Avg HER2 signals/nucleus 2.5. Avg CEN17 signals/nucleus 2.0. HER2/CEN17 signal ration 1.3. Number of observers 1. Results show no evid of HER2 amplification and a HER2/CEN17 ratio of <2.0 /w an avg HER2 copy number of <4.0 signals per cell, this is a neg result.

Field	Code
ER Summary	
ER % Pos	
ER Allred Score {5+3}	
PR Summary	
PR % Positive	
PR Allred Score {5+3}	

20

20

## ER & PR

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- ✓ ER Summary
- ✓ ER % Positive
- ✓ ER Allred Score



- ✓ PR Summary
- ✓ PR % Positive
- ✓ PR Allred Score

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## Other References

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CAnswer Forum: Good reference for SSDI questions

<http://cancerbulletin.facs.org/forums/> create account

NAACCR Breast Webinar from 10/2019 updated with v1.7 SSDI Manual –

- request from Bobbi [bobbi-matt@uiowa.edu](mailto:bobbi-matt@uiowa.edu) or
- Lori [lori-somers@uiowa.edu](mailto:lori-somers@uiowa.edu)

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## HER2 data items

Record HER2 results from IHC or ISH tests only.

HER2 Overall Summary	9	Yes	NAACCR #3855
HER2 IHC Summary	8	No	NAACCR #3850
HER2 ISH Summary	8	No	NAACCR #3854
HER2 ISH DP Ratio	XX.8	No	NAACCR #3852
HER2 ISH DP Copy No	XX.8	No	NAACCR #3851
HER2 ISH SP Copy No	XX.8	No	NAACCR #3853

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## Breast: HER2

- Human Epidermal Growth Factor receptor 2 -> HER2
  - HER2 protein -> ERBB2
  - HER2 gene -> ERBB2 gene
- 15-20% Breast cancers have an overexpression of HER2
- Worse prognosis in **both** node negative/positive patients
- Determines eligibility for anti-HER2 therapy, Herceptin

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## 3855 HER2 Overall Summary

Note 1: Physician statement can be used to code HER2 overall summary if no other info.

Note 2: Results of HER2 test performed on primary breast tissue [not from lymph node]

Note 3: Results from nodal or metastatic tissue may **only** be used when no evid of primary tumor.

**Note 4: If invasive and insitu: Ignore in situ results.**

- ✓ HER2 pos on in situ and HER2 neg on invasive, code HER2 as neg (code 0)
- ✓ HER2 only done on in situ but both in situ and invasive present, code unknown (code 9)

**Note 5: Single tumor, multiple biopsies with different HER2 results, code highest (positive vs neg)**

**Note 6: Multiple tumors, different HER2 results, code from largest tumor (not largest specimen)**

Note 7: Neoadjuvant therapy given, code HER2 prior to neoadj therapy

Note 8: Do not record multigene test in this field [no Oncotype Dx]

Note 9: HER2 not routinely done on pure insitu tumors

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## 3855 HER2 Overall Summary

Code	Description
0	HER2 negative; equivocal
1	HER2 positive
7	Test ordered, results not in chart
9	Not documented in medical record Cannot be determined (indeterminate) HER2 Overall Summary status not assessed or unknown if assessed

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## 3850 HER2 by IHC Summary

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Note 1: Physician statement of HER2 IHC Summary can be used

Note 2: HER2 IHC test performed on primary breast tissue

Note 3: Results from nodal or metastatic tissue may be used ONLY when no evid primary tumor

Note 4: Ignore in situ results

Note 5: **SINGLE** tumor, multiple biopsies and/or resection with different HER2 IHC results, use highest or positive result.

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## 3850 HER2 by IHC Summary

---

Note 6: **MULTIPLE** tumors, different HER2 IHC results, code from largest tumor size (not specimen size)

Note 7: Neoadjuvant therapy, record assay prior to neoadjuvant therapy. If none, code from post-treatment specimens

Note 8: A 2+ (equivocal) finding by IHC should result in add'l testing with ISH (FISH, CISH, SISH) to determine gene copy number



Note 9: An IHC test identifies protein expressed by gene (ERBB2). And ISH test identifies the number of copies of the gene (ERBB2) itself.

Note 10: HER2 not routinely done on pure in situ tumors; however if you have HER2 on in situ tumor only, code it. Otherwise code 9.

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## 3850: HER2 IHC Summary

Code	Description
0	Negative (Score 0)
1	Negative (Score 1+)
Code	Description
2	Equivocal (Score 2+) Stated as equivocal  If borderline or indeterminate, an ISH (FISH) will be performed
3	Positive (Score 3+) Stated as positive  If positive, an ISH (FISH) will be performed
4	Stated as negative, but score not stated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined (indeterminate) HER2 IHC Summary not assessed or unknown if assessed

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## 3854 Breast: HER2 ISH

In Situ Hybridization -> ISH

➤ FISH (Fluorescence) -> CISH (Chromogenic) -> SISH (Silver)

- Single Probe assay (1 SSDI)
  - Determine the number of HER2 gene copies present
    - No Ratio {hint}
- Dual Probe assays (2 SSDI's)
  - Include a chromosome enumeration probe (CEP17) (D17Z1)
    - HER2/CEP17 Ratio
    - HER2 copy number

SINGLE PROBE  
Look for terms:  
copy number  
mean signals per  
cell  
DO NOT calculate  
copy number

DUAL PROBE  
Look for terms:  
CEP17  
ratio  
DO NOT calculate  
copy number

30

30

## 3854 HER2 ISH Summary

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Code	Description
0	Negative [not amplified]
2	Equivocal
3	Positive [amplified]
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Results cannot be determined (indeterminate) HER2 ISH Summary not assessed or unknown if assessed

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## 3852 ISH Dual Probe Ratio

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Note 1: Physician Statement of HER2 DP ratio can be used

Note 2: Dual probe results for both HER2 and CEP17 (control). HER2/CEP17 ratio will be reported. Record ratio in this field.

Note 3: **REGISTRARS ARE NOT TO CALCULATE THE RATIO**

Note 4: A HER2 finding of equivocal, 2+ by IHC should result in add'l testing with ISH to determine gene copy number.

Note 5: Any type of ISH (FISH, CISH, SISH) can be used. Use same report as HER2 ISH Summary field. (3854)

Note 6: May also be called ERBB2 (standard symbol for gene)

Note 7: **DO NOT ROUND**. If test presented to hundredth decimal, ignore and do not round.

- Example: Reported as 1.99, record as 1.9.

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## 3852: HER2 ISH Dual Probe Ratio

Code	Description
0.0-99.9	Ratio of 0.0 to 99.9
XX.2	Less than 2.0
XX.3	Greater than or equal to 2.0
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Results cannot be determined (indeterminate) Dual probe test not done, only single probe test performed HER2 ISH dual probe ratio not assessed or unknown if assessed

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## 3851: HER2 ISH Dual Probe Copy Number

Code	Description
0.0-99.9	Reported HER2 copy number of 0.0-99.9
XX.1	Reported HER2 copy number of 100 or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Cannot be determined (indeterminate) HER2 ISH Dual Probe Copy Number not assessed or unknown if assessed

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SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: EQUIVOCAL, INDETERMINATE. HER2 gene copy between 4 & 6 with HER2/CEP17 ratio <2.

HER2/CEP17 RATIO: 4.26 / 3.13 = 1.36

**Dual Probe Ratio 1.3**

HER-2/neu SISH HER-2neu gene (Inform HER2 DNA probe) Number of tumor cell nuclei counted: 120

Number of Her-2/neu gene copies: 511

Mean HER-2/neu gene copy number: 4.26

**Dual Probe HER2 Copy Number 4.2**

CEP-17 (Inform Chromosome 17 probe)

Number of cell nuclei counted: 60

Number of CEP-17 gene copies: 188

Mean CEP-17 gene copies/nucl: 3.13

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## 3853: HER2 ISH Single Probe Copy Number

Code	Description
0.0-99.9	Reported HER2 copy number of 0.0-99.9
XX.1	Reported HER2 copy number of 100 or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Cannot be determined (indeterminate) Single probe test not done, only dual probe test performed HER2 ISH Single Probe Copy Number not assessed or unknown if assessed

- Ignore the hundredth decimal – Do **NOT** round
- Don't use results from Oncotype Dx – MammaPrint – endoPredict – PAM

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SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION  
 INTERPRETATION: POSITIVE (>6 gene copies) HER-2/neu  
 gene amplification.

HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)

HER-2neu gene (Inform HER2 DNA probe)

Number of tumor cell nuclei counted: 60

Number of Her-2/neu gene copies: 418

Mean HER-2/neu gene copy number: 6.9

Single Probe Copy  
 Number: 6.9

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### HER2 FISH Report

#### Her-2/neu

Probe Manufacturer: PathVision Assay (Abbott)

<b>Final Her-2/CEP-17 Ratio:</b>	<b>1.35</b>	<b>Negative for Amplification of Her2/neu</b>
KARYOTYPE: nuc ish 17cen(D17Z1x2.1),17q11.2(HER-2x2.8)[115]		
<b>Number of targets examined:</b>		<b>115</b>
<b>Total HER-2/neu:</b>		<b>323</b>
<b>Total CEP-17:</b>		<b>239</b>
<b>Average Her-2/neu signals per cell:</b>		<b>2.8</b>
<b>Average Cep-17 signals per cell:</b>		<b>2.1</b>
<b>Final Her-2/CEP-17 Ratio:</b>		<b>1.35</b>
<b>REFERENCE RANGE</b>		
Negative (Unamplified)	Her-2/CEP-17 ratio < 2.0 with <4.0 HER-2/neu signals per cell	
Equivocal	Her-2/CEP-17 ratio <2.0 with ≥ 4.0 and <6.0 HER-2/neu signals per cell	
Positive (Amplified)	Her-2/CEP-17 ratio ≥2.0 or ≥6.0 HER-2/neu signals per cell	

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**Molecular Pathology Report**

**DIAGNOSIS**

**A. "LEFTY BREAST (A1)":**  
**Negative for HER2 gene amplification by FISH. Please see comment and image.**

**Summary Notes / Comments :**  
 HER2 testing algorithms and reporting cutoffs at our institution adhere to the 2013 revised ASCO/CAP HER2 testing algorithm (1). In addition, when the tumor is positive but HER2 copy average is very close to the positive cutoff, we report these results as "Positive for low levels" of gene amplification. These results do not affect the patient's eligibility for anti-HER2 targeted therapy. As part of our HER2 quality assurance program launched in 2000 (2), parallel IHC testing (performed at either the referring institution or at our laboratory) is required and data collected for QA/QC purposes.

References:  
 1. Wolff A, et al. American Society of Clinical Oncology/College of American Pathologists Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Arch Pathol Lab Med 2013;138(2):241-255.  
 2. Yaziji H, et al. HER2 Testing in Breast Cancer Using Parallel IHC and FISH-Based Methods. JAMA 2004;291:1004-1010.

**Table of Fluorescence In Situ Hybridization Results:**

Block	Target DNA	Probe	Av. Copy #	Ratio	Result(s)
M18-00107	HER2	Red	1.80	1.06	Negative
M18-00107	Chromosome 17 Centromere	Green	1.70		

**Images**

Dual Probe

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T x 1} #&4

**FINAL Path Addendum:**

6-22-20 ERA: Positive  
 100%. PRA: Positive 100%. Her-2/Neu: Weakly positive. Her-2/Fish: Negative, **ratio**: 1.2.  
 Number of observers: 1 (single).  
 Her-2 copy number: Less than 4 signals per cell. Ki-67: under 10%.

Field
HER2 Overall Summary
HER2 IHC Summary
HER2 ISH Summary
HER2 ISH DP Ratio
HER2 ISH DP Copy No
HER2 ISH SP Copy No

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## T x 1} #&amp;5

Addendum: 6-7-20 ER pos, <95%, strong intensity. PR neg. HER2 IHC 2+/equivocal. FISH pos, avg HER2 signals/nucleus 5.4, avg CEP 17 signals/nucleus 1.7, HER2/CEP 17 ratio 3.2. Ki-67 not done.

Field
HER2 Overall Summary
HER2 IHC Summary
HER2 ISH Summary
HER2 ISH DP Ratio
HER2 ISH DP Copy No
HER2 ISH SP Copy No

41

41

## T x 1} #&amp;6

Addendum: 1-4-20 ER pos, 95%, 3+/strong intensity. PR pos, 90%, 2+/moderate intensity. HER2 IHC 2+/equivocal. FISH: Avg HER2 signals/nucleus 2.5, Avg CEN17 signals/nucleus 2.0. HER2/CEN17 signal ratio 1.3. Number of observers 1. Results show no evid of HER2 amplification and a HER2/CEN17 ratio of <2.0 /w an avg HER2 copy number of <4.0 signals per cell, this is a neg result.

Field
HER2 Overall Summary
HER2 IHC Summary
HER2 ISH Summary
HER2 ISH DP Ratio
HER2 ISH DP Copy No
HER2 ISH SP Copy No

42

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## T x 1} #&amp; 7

FINAL Path: 4/28/2020 ER pos, 98%, strong. PR pos, 95% strong. HER2 by IHC 2+ equivocal. HER2 by FISH (3.34). CEP-17: 2.72. FISH estimated ratio (1.23), neg for amplification.

## Field

HER2 Overall Summary
HER2 IHC Summary
HER2 ISH Summary
HER2 ISH DP Ratio
HER2 ISH DP Copy No
HER2 ISH SP Copy No

43

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## T x 1} #&amp; 8

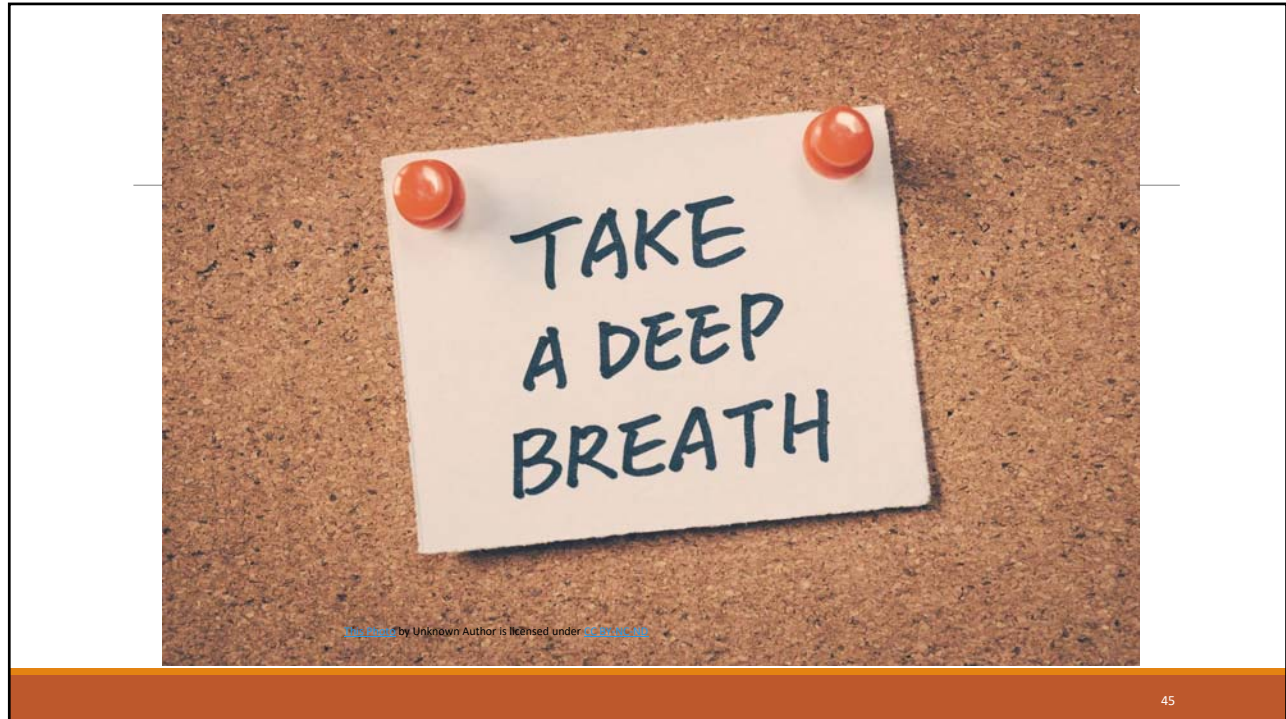
FINAL Path: 7/23/2020 Positive for ER and PR expression (58% and 46% respectively, mod intensity). HER2 by IHC score 2+ equivocal. HER2 by FISH neg. HER2 FISH estimated ratio (1.25). (HER2 FISH: (2.67), CEP-17: 2.14)

## Field

HER2 Overall Summary
HER2 IHC Summary
HER2 ISH Summary
HER2 ISH DP Ratio
HER2 ISH DP Copy No
HER2 ISH SP Copy No

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## 3863 Ki-67

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Note 1: Physician statement of Ki-67 (MIB-1) can be used.

Note 2: Ki-67 is a marker of cell proliferation. High value indicates tumor proliferating more rapidly.

Note 3: Results from nodal or metastatic tissue may be used, ONLY when there is no evidence of primary tumor.

Note 4: Ki-67 results are reported as % of cells stain positive. As of 2017, no established standards for interpretation results or cutoffs for pos/neg

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## 3863: Ki-67

Code	Description
0.0-100.0	0.0 to 100.0 percent positive: enter percent positive
XXX.7	Test done, actual percentage not stated
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in patient record Ki-67 (MIB-1) not assessed or unknown if assessed

Examples: Ki-67 reported as 14%; code as 14.0

Ki-67 reported as 8%; code as 8.0

**From Forum:** Ki-67 reported as range, 5-10%. Since Ki-67 does not have a range, code one number above the lowest number, Code to 6% or 6.0.

**From Forum:** Ki-67 stated as <16%. Code as 15.9% or 15.9.

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## Oncotype Dx Tests

- Oncotype Dx Recurrence Score-**Invasive** [NAACCR Data Item # 3904]
- Oncotype Dx Risk Level-**Invasive** [NAACCR Data Item # 3906]
- Oncotype Dx Recurrence Score-**DCIS** [NAACCR Data Item # 3903]
- Oncotype Dx Risk Level-**DCIS** [NAACCR Data Item # 3905]

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## 3904 Oncotype Dx Recurrence Score- Invasive

Note 1: Physician statement of Score can be used

Note 2: Score is reported as whole number 0-100. Actual recurrence score takes preference over codes XX4 and XX5

Note 3: Record only Oncotype Dx invasive recurrence score in this field. If other test used for scoring, code XX9.

Note 4: Linear regression models and Magee equations are not reported in this field.

- Code this info in field 3894/3895 Multigene Signature Method

Note 5: Oncotype Dx reported on more than one breast tumor specimen, record highest value.

Note 6: Only use Nodal or Metastatic tissue results when no evidence primary tumor.

Note 7: Staging for Breast cancer now depends on Oncotype Dx recurrence score. Score <11 cut off value for staging purposes.

Note 8: Only have Oncotype Dx – Invasive Risk level, assign XX7

Note 9: Code using same report sued to record 3906, Risk level-Invasive.

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## 3904 Oncotype Dx Recurrence Score- Invasive

Code	Description
000-100	Enter actual recurrence score between 0 and 100
XX4	Stated as less than 11
XX5	Stated as equal to or greater than 11
XX6	Not applicable: in situ case ←
XX7	Test ordered, results not in chart
XX9	Not documented in medical record Oncotype Dx Recurrence Score-Invasive not assessed or unknown if assessed

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## 3906: Oncotype Dx Risk Level - Invasive

Code	Description
0	Low risk (recurrence score 0-17)
1	Intermediate risk (recurrence score 18-30)
2	High risk (recurrence score greater than or equal to 31)
6	Not applicable: DCIS case
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Oncotype Dx Risk Level-Invasive not assessed or unknown if assessed

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## 3903: Oncotype Dx Recurrence Score-DCIS

Code	Description
000-100	Enter actual recurrence score between 0 and 100
XX6	Not applicable: invasive case
XX7	Test ordered, results not in chart
XX8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX8 will result in an edit error.)
XX9	Not documented in medical record Oncotype Dx Recurrence Score-DCIS not assessed or unknown if assessed

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## 3905: Oncotype Dx Risk Level - DCIS

Code	Description
0	Low risk (recurrence score 0-38)
1	Intermediate risk (recurrence score 39-54)
2	High risk (recurrence score greater than or equal to 55)
6	Not applicable: invasive case
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Oncotype Dx Risk Level-DCIS not assessed or unknown if assessed

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## 3894 Multigene Signature Method 3895 Multigene Signature Result

- Normally done on **Node-Negative** cases to predict **risk of recurrence or response to chemo**
- May help **Node-Positive w/ small tumors** plan treatment and predict recurrence
- For tests other than Oncotype Dx

Note 2: Only record tests done on tumor tissue that help determine if the cancer is likely to recur. Don't include other tests, such as those that evaluate hereditary mutations that influence a patient's risk of developing cancer (e.g. myRisk, BRCA)

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## 3922 Response to Neoadjuvant Therapy

Record physician statement of response to neoadjuvant therapy.

- Includes systemic or radiation admin prior to surgery

Do not interpret or infer response based on record

Code	Description
0	Neoadjuvant therapy not given <b>For in situ tumors /2, code 0.</b>
1	Stated as complete response (CR) <b>Only if stated total or complete by MD.</b>
2	Stated as partial response (PR)
3	Stated as response to treatment, but not noted if complete or partial
4	Stated as no response (NR)
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Response to neoadjuvant therapy not assessed or unknown if assessed

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## 3882 LN Pos Axillary Level I-II

Note 1: Physician Statement can be used

Note 2: Include only # of pos ipsilateral level I-II axillary LNs.

Includes intramammary. Excludes Internal Mammary.

Note 3: Micro info only. If no axillary nodes eval, code X9

Note 4: Neoadjuvant therapy given code clinical nodal involvement if more extensive, include only nodes removed during clinical workup. If post-neoadjuvant nodal involvement more extensive, include only nodes removed during surgery.

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## 3882 LN Pos Axillary Level I-II

Note 5: ITCs not counted as pos LNs. Only LNs with mets >0.2 mm (micromets or lareger) should be counted as pos. If size of met not stated, assume >0.2 mm.

Note 6: When pos ipsilateral axillary LNs coded, number pos must be less than or equal to Reg Nodes Pos field.

- ✓ The number of pos ipsilateral axillary nodes will always be a subset of the number of pos reg nodes.

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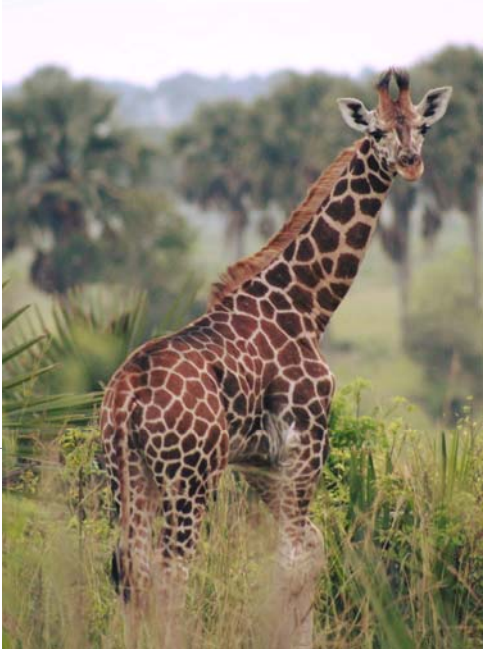
## 3882 LN Pos Axillary Level I-II

Code	Description
00	All ipsilateral axillary nodes examined negative
01-99	1 - 99 nodes positive (Exact number of nodes positive)
X1	100 or more nodes positive
X5	Positive nodes, number unspecified
X6	Positive aspiration or needle core biopsy of lymph node(s)
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Level I-II axillary nodes not assessed or unknown if assessed

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<h1>Srs#T x 1}</h1> <hr/> <p>TEXT from LAB Section:</p> <p>10-31-19 (L Br Stereo Needle biopsy) ER NEG; PR NEG HER2neu/BY IHC 1+ (NEG).</p> <p>1-8-20 (Total L mastectomy) ER POS 16%,ALLRED 4,PR NEG &lt;1%,ALLRED 0; HER-2/NEU BY FISH POS; HER2/CEP RATIO 2.2, HER2 copy 6.4. Ki-67 - 44%(HIGH)</p>	Field
	ER Summary
	ER % Pos
	ER Allred
	PR Summary
	PR % Pos
	PR Allred
	HER2 Overall Summary
	HER2 IHC Summary
	HER2 ISH Summary
	HER2 ISH DP Ratio
	HER2 ISH DP Copy No
	HER2 ISH SP Copy No
	Ki-67

<h1>Grade</h1> <hr/> <p>CLINICAL PATHOLOGICAL POST THERAPY</p>	
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## Grade Clinical

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Grade of solid primary tumor before any treatment

Cannot be blank

Assign highest grade from primary tumor during clinical time frame

Includes FNA, biopsy, needle core biopsy etc.

If only one grade available and cannot determine clin/path; assume it is clinical grade.

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## Grade Pathological

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Grade of a solid primary tumor that has been surgically resected; must meet surgical resection requirements in AJCC.

No neoadjuvant therapy has been given

All info from diagnosis (clinical staging) through surgical resection

Record highest grade from any microscopic specimen of pri site whether from clinical workup or surgical resection. "grade for patient – not the specimen"

Surgical resection has to be done in order to carry higher clinical grade forward.

- If a resection is done of a primary tumor and there is no grade documented from the surgical resection, use the grade from the clinical workup
- If a resection is done of a primary tumor and there is no residual cancer, use the grade from the clinical workup

Cannot be blank

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## Grade Post Therapy

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Grade of solid primary tumor that has been resected following neoadjuvant therapy.

Corresponds to yp staging period only; must meet surgical resection requirements in AJCC manual

Leave Blank if:

- No neoadjuvant therapy
- Clinical or path case only
- Only one grade avail and cannot determine if clin/path/or post therapy

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## Grade Table 12

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Breast Schema 00480 (includes invasive and DCIS, Paget)

Note 3: Priority order for Codes

- Invasive cancers: codes 1-3 take priority over A-D
- In situ cancers: Codes L, M, H take priority over A-D

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Code	Description
1	G1: Low combined histologic grade (favorable), SBR score of 3-5 points
2	G2: Intermediate combined histologic grade (moderately favorable); SBR score of 6-7 points
3	G3: High combined histologic grade (unfavorable); SBR score of 8-9 points
L	Nuclear Grade I (Low) (in situ only)
M	Nuclear Grade II (interMediate) (in situ only)
H	Nuclear Grade III (High) (in situ only)
A	Well differentiated
B	Moderately differentiated
C	Poorly differentiated
D	Undifferentiated, anaplastic
9	Grade cannot be assessed (GX); Unknown

Invasive cancers  
1, 2, 3 priority

In situ cancers  
L, M, H priority

Invasive cancers: use if no  
1, 2, 3 or Nottingham

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## Generic Grade for Breast

Grade Manual, pg 32

<https://www.naaccr.org/SSDI/Grade-Manual.pdf?v=1603289191>

Note 1: Only use the generic grade table when the appropriate grade table for a cancer uses the generic categories with alphabetic codes A-D, OR for a cancer site which includes codes A-D for when the priority grade system was not used/documented.

Example: Mod well diff ductal carcinoma of the breast.  
Mod well diff is grade II and assign grade code of B.

Description	Grade	Assigned Grade Code
Differentiated, NOS	I	A
Well differentiated	I	A
Only stated as 'Grade I'	I	A
Fairly well differentiated	II	B
Intermediate differentiation	II	B
Low grade	I-II	B
Mid differentiated	II	B
Moderately differentiated	II	B
Moderately well differentiated	II	B
Partially differentiated	II	B
Partially well differentiated	I-II	B
Relatively or generally well differentiated	II	B
Only stated as 'Grade II'	II	B

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Grade Coding Instructions and Tables

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## Grade Exercise #1

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2/1/2020 R breast cancer, bx proven, here for mastectomy.  
No bx report.

2/1/2020 Path: R breast mastectomy, invasive ductal carcinoma, G3 with extensive DCIS, high nuclear grade.  
Score 8.

Grade Clinical

Grade Pathological

Grade Post Therapy

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## Grade Exercise #2

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2/22/2020 Core biopsy L breast Path: invasive mammary carcinoma, Nottingham grade 1. Focal DCIS Elston Ellis grade 2.

3/28/2020 L Lumpectomy Path: Invasive lobular carcinoma, EE grade 2 (score 6). LCIS present

Grade Clinical

Grade Pathological

Grade Post Therapy

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## Grade Exercise #3

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4/10/2020 R breast core needle biopsy Path: Mucinous adenoca, grade 2.

4/26/2020 R breast lumpectomy Path: No evid residual neoplasm.

Grade Clinical

Grade Pathological

Grade Post Therapy

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## Grade Exercise #4

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1/15/2020 L core needle biopsy Path: Inv ductal ca grade 1 with DCIS low nuclear grade.

2/22/2020 L breast mastectomy Path: Inv ductal ca grade 1, score 5.

Grade Clinical

Grade Pathological

Grade Post Therapy

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## Grade Exercise #5

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2/22/2020 US guided core biopsy L breast Path: Infil  
mammary carcinoma, Nottingham grade 1.

3/21-7/5/2020 Chemo x6 cycles

8/22/2020 R simple mastectomy, L MRM Path: Invasive  
carcinoma NST, Nott gr 1 of 3.

Grade Clinical

Grade Pathological

Grade Post Therapy

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## Grade Exercise #6

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6/1/2020 Core biopsy R breast Path: DCIS , solid, low grade.

7/18/2020 R breast lumpectomy Path: Invasive ductal  
carcinoma, Nottingham intermediate grade, score 7 of 9.

Grade Clinical

Grade Pathological

Grade Post Therapy

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## Exercises for SSDI

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### SEER\*Edu Homework:

- DX 2018 SSDI Breast 1-10
- DX 2018 Grade Breast 1-10

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## Questions

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