



# Updated (2018) ASCO/CAP Guidelines for HER2 Testing in Breast Cancer

HOT TOPIC / 2018

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*Presenters:*

## **Beiyun Chen, M.D., Ph.D.**

Associate Professor of Laboratory Medicine and Pathology  
*Division of Anatomic Pathology*  
*Mayo Clinic, Rochester, Minnesota*



## **Katherine B. Geiersbach, M.D.**

Assistant Professor of Laboratory Genetics and Genomics  
*Division of Laboratory Genetics and Genomics*  
*Mayo Clinic, Rochester, Minnesota*



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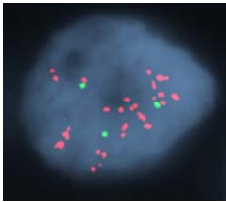
## Disclosures

- None

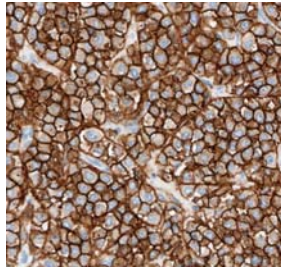
## Learning Objectives

- 5 clinical questions for 2018 Focused Update addressed by ASCO/CAP Expert Panel
- 5 categories of in situ hybridization (ISH) results
- Additional work-up required for 3 less common ISH categories

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**Nuclear DNA:  
HER2 (ERBB2)  
gene  
amplification**



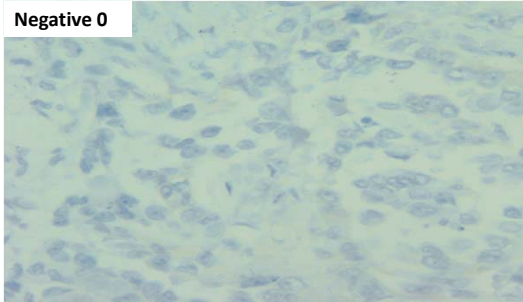
**Cell surface:  
HER2 overexpression**



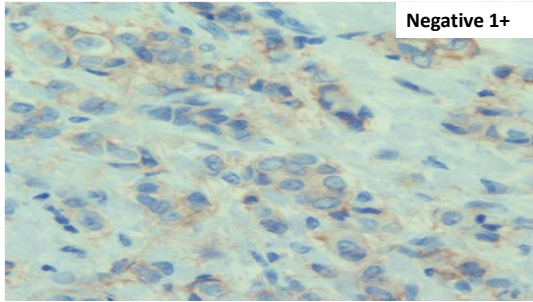
**Monoclonal antibody  
(trastuzumab) binding to  
HER2 protein**

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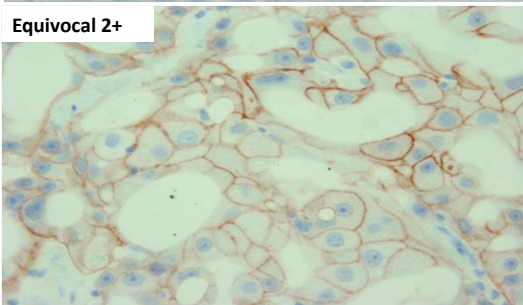
**Negative 0**



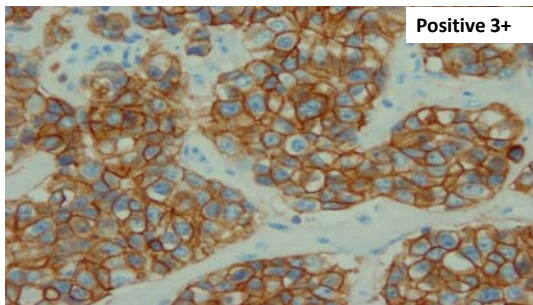
**Negative 1+**



**Equivocal 2+**



**Positive 3+**



**Table 2**

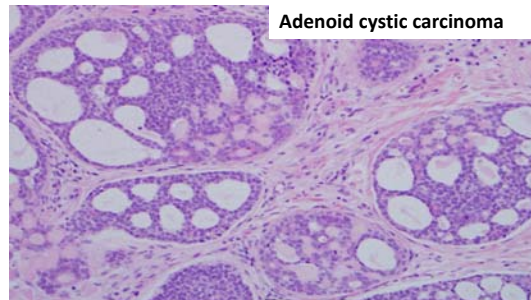
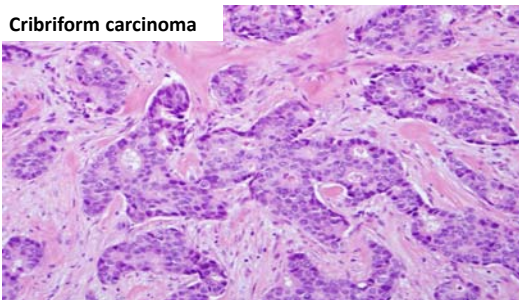
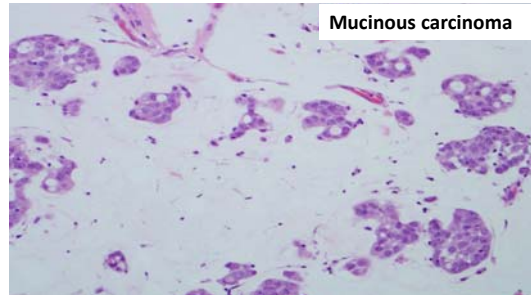
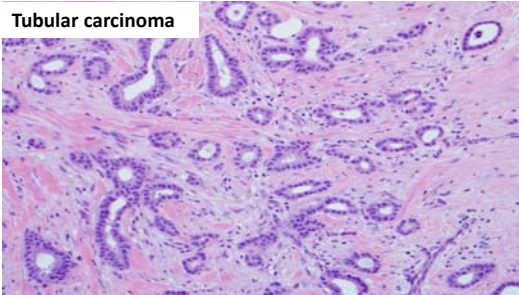
Arch Pathol Lab Med. 2014 Feb; 138(2): 241–256.

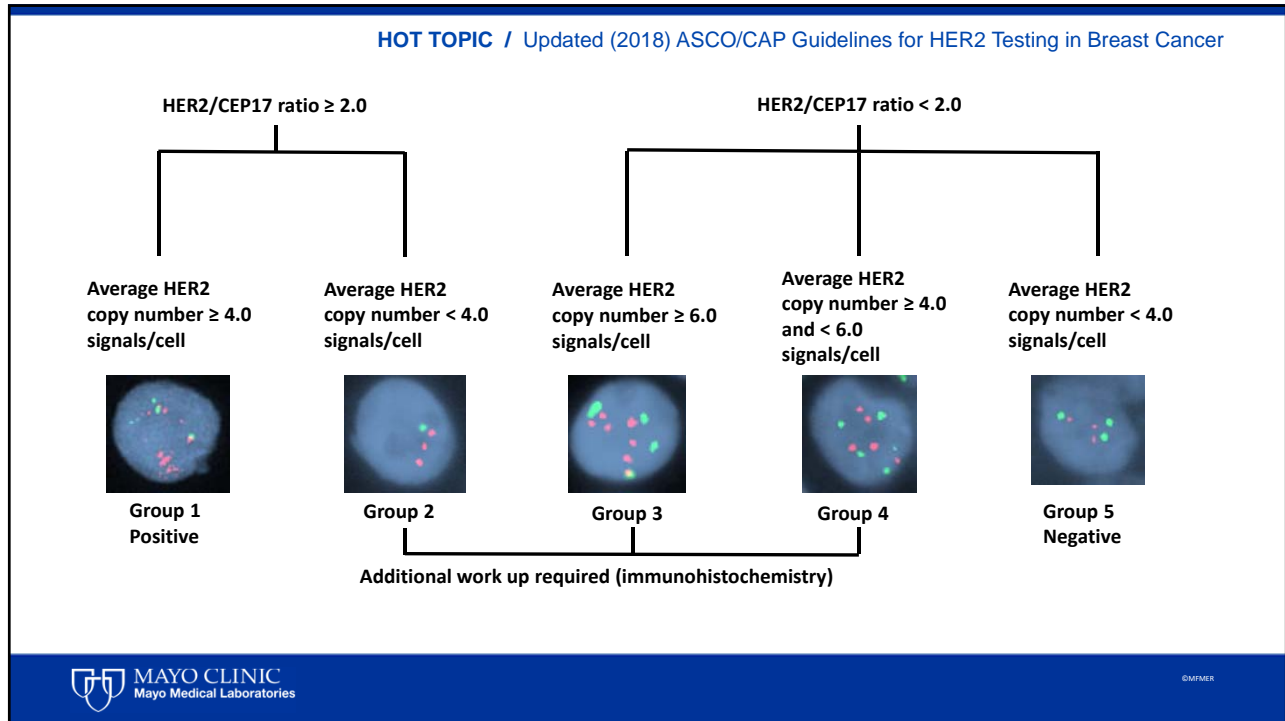
**Histopathologic Features Suggestive of Possible HER2 Test Discordance**

Criteria to Consider*
New HER2 test should not be ordered if the following histopathologic findings occur and the initial HER2 test was negative:  Histologic grade 1 carcinoma of the following types: Infiltrating ductal or lobular carcinoma, ER and PgR positive Tubular (at least 90% pure) Mucinous (at least 90% pure) Cribriform (at least 90% pure) Adenoid cystic carcinoma (90% pure) and often triple negative
Similarly, a new HER2 test should be ordered if the following histopathologic findings occur and the initial HER2 test was positive:  Histologic grade 1 carcinoma of the following types: Infiltrating ductal or lobular carcinoma, ER and PgR positive Tubular (at least 90% pure) Mucinous (at least 90% pure) Cribriform (at least 90% pure) Adenoid cystic carcinoma (90% pure) and often triple negative
If the initial HER2 test result in a core needle biopsy specimen of a primary breast cancer is negative, a new HER2 test must be ordered on the excision specimen if one of the following is observed:  Tumor is grade 3 Amount of invasive tumor in the core biopsy is small Resection specimen contains high-grade carcinoma that is morphologically distinct from that in the core Core biopsy result is equivocal for HER2 after testing by both ISH and IHC There is doubt about the specimen handling of the core biopsy (long ischemic time, short time in fixative, different fixative) or the test is suspected by the pathologist to be negative on the basis of testing error

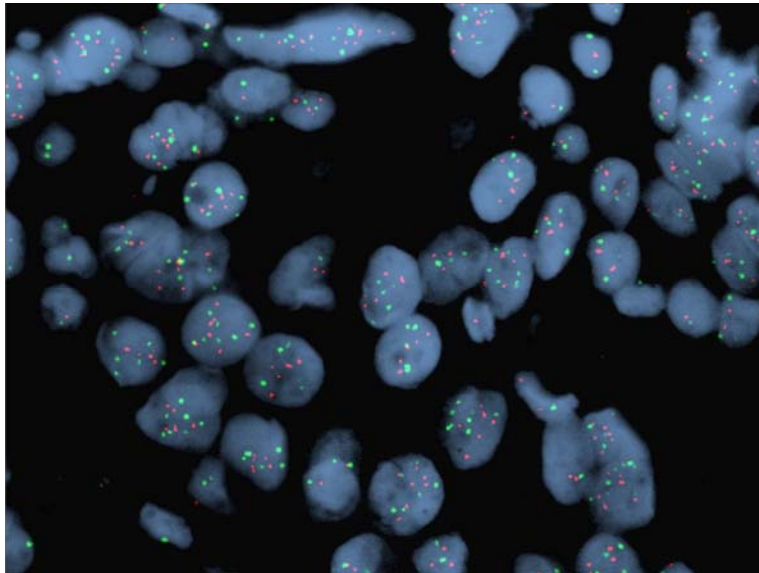
Abbreviations: ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; PgR, progesterone receptor.

\*Criteria to consider if there are concerns regarding discordance with apparent histopathologic findings and possible false-negative or false-positive HER2 test result.





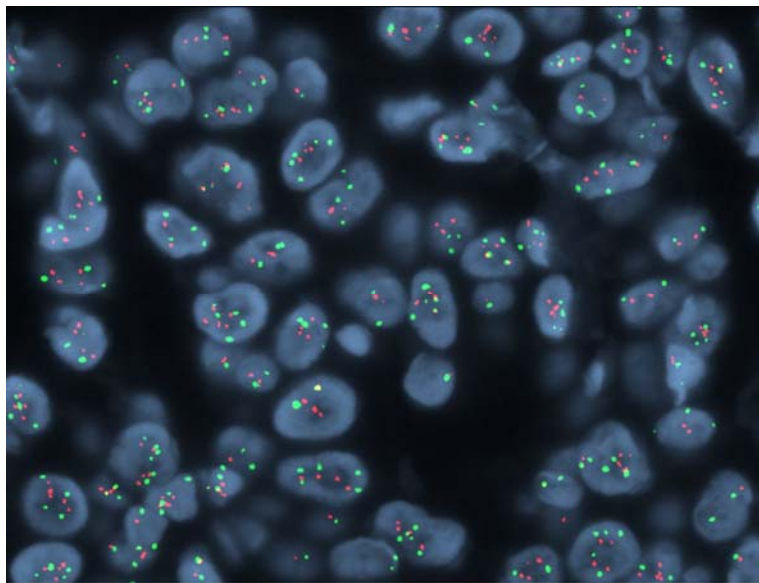
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Average HER2/ cell: 6.5  
Average 17 cen/cell: 5.0  
HER2/cen ratio: 1.3

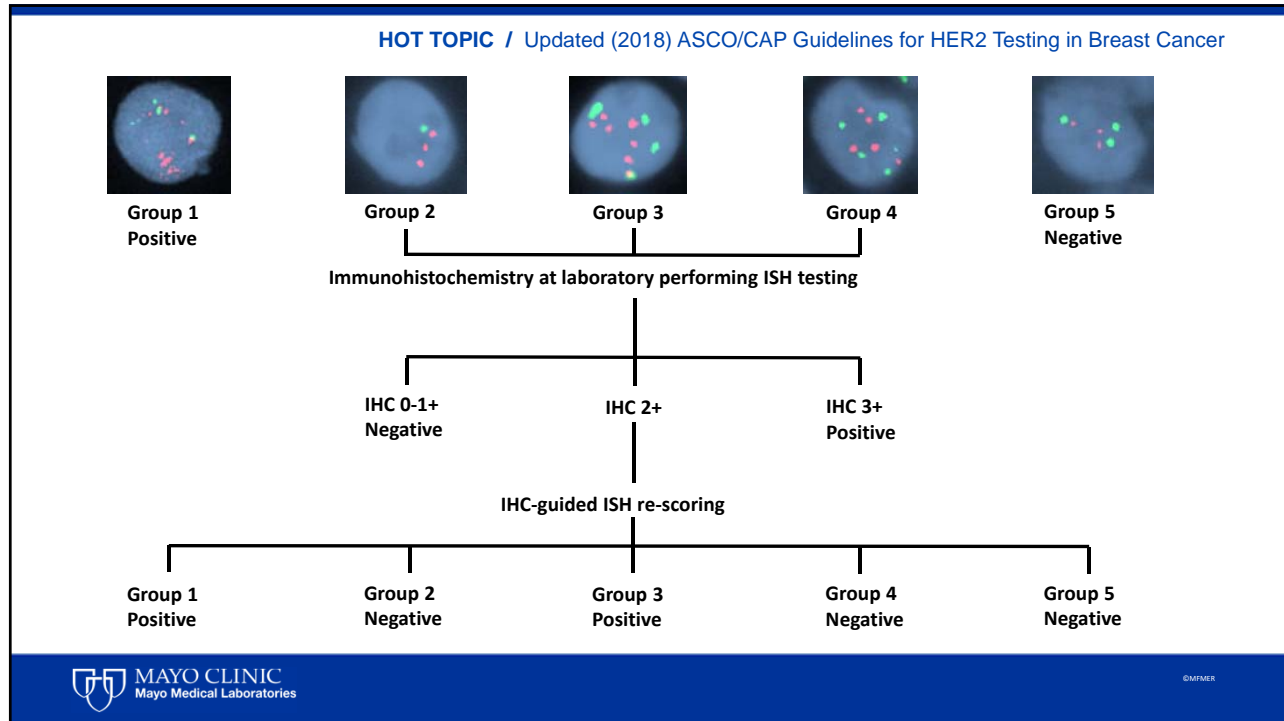
“Group 3”

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Average HER2/ cell: 5.2  
Average 17 cen/cell: 4.3  
HER2/cen ratio: 1.2

“Group 4”



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## Summary

- 5 clinical questions for 2018 Focused Update were addressed by the ASCO/CAP Expert Panel
- 5 categories of in situ hybridization (ISH) results
  - Groups 1, 2, 3, 4, and 5
  - Additional work-up (IHC) required for Groups 2, 3, and 4

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## References

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## Questions or requests...

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