

BIOMARKER TESTING IN **BREAST CANCER**

Knowledge Check **1**

1 Categorization of Select Biomarkers in Breast Cancer

Biomarker	Prognostic	Predictive	Susceptibility
ER/PR			
HER2			
Ki67			
BRCA1/2			
PD-L1			
PIK3CA			

2 Which of the following statements are true about PD-L1 expression in mBC? (Choose all that apply)

- a Choice of PD-L1 antibody can affect the results
- b PD-L1 can inform treatment decisions for all patients with mBC
- c Results are observer dependent
- d A CPS score of $\geq 15\%$ is considered informative

3 PIK3CA mutation is found in what percentage of patients with breast cancer?

- a 5%
- b 70%
- c 36%
- d 25%

4 True or False: HER2 and PIK3CA mutations are generally stable during the course of the disease.

- a True
- b False

5 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) recommend testing all patients with recurrent/stage IV breast cancer for which of the following biomarkers? (Select all that apply)

- a ER/PR
- b HER2
- c BRCA1/2
- d PD-L1
- e ESR1
- f PIK3CA

1	Biomarker	Prognostic	Predictive	Susceptibility
	ER/PR ¹	---	X	---
	HER2 ²	---	X	---
	Ki67 ^{3,4}	X	---	---
	BRCA1/2 ⁵	---	X	X
	PD-L1 ^{6,7}	X	X	---
	PIK3CA ⁷⁻¹¹	X	X	---

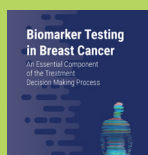
(pages 5, 18)

2 **A and C.** Anti-PD-L1 antibodies are not interchangeable when testing tissue from a patient with breast cancer. PD-L1 expression level may be impacted by interobserver agreement.¹²⁻¹⁴ PD-L1 positivity is associated with eligibility for a treatment with an immunotherapy in patients with TNBC. There are different ways to assess PD-L1 positivity. In TNBC, PD-L1 expression CPS \geq 10 is clinically informative.^{6,14-16} (page 15)

3 **C.** PIK3CA is a common mutation in breast cancer, found in 36% of all patients with breast cancer and 42% of patients HR-positive/HER2-negative disease.¹⁷ (page 17)

4 **False.** PIK3CA mutations are generally stable but may change in some patients.¹⁸ Receptor switching may occur in 2.9%-10.3% of cases for HER2.^{19,20} HER2 mutations may arise during treatment and confer resistance to anti-HER2 therapies.²¹ (page 11)

5 **A, B, C, D, F.** NCCN Guidelines[®] recommend testing all patients with mBC for ER, PR, HER2, BRCA1/2, PIK3CA, and PD-L1.¹⁵ (page 6)



This knowledge check is connected to the chapter “Biomarker Testing in Breast Cancer: An Essential Component of the Treatment Decision Making Process.” To get a copy of this and other chapters, please visit: <https://www.hcp.novartis.com/precision-medicine>



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BRCA1/2, breast cancer gene 1/2; CPS, combined positive score; ER, estrogen receptor; ESR1, estrogen receptor 1; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; mBC, metastatic breast cancer; PD-L1, programmed death-ligand 1; PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; PR, progesterone receptor; TNBC, triple-negative breast cancer.

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References:
 1. Allison KH et al. *J Clin Oncol.* 2020;38(12):1346-1366; 2. Wolff AC et al. *J Clin Oncol.* 2018;36(20):2105-2122; 3. Smith I et al. *Lancet Oncol.* 2020;21(11):1443-1454; 4. Nielsen TO et al. *J Natl Cancer Inst.* 2021;113(7):808-819; 5. Harbeck N et al. *Nat Rev Dis Primers.* 2019;5(1):66; 6. Matikas A et al. *Clin Cancer Res.* 2019;25(18):5717-5726; 7. Schick J et al. *Breast Cancer (Auckl).* 2021;15:1178223421995854; 8. Mosele F et al. *Ann Oncol.* 2020;31(3):377-386; 9. Alvarez-Garcia V et al. *Sci Rep.* 2018;8(1):4290; 10. Keraite I et al. *Sci Rep.* 2020;10(1):17082; 11. Sobhani N et al. *J Cell Biochem.* 2018;119(6):4287-4292; 12. Rugo HS et al. *J Natl Cancer Inst.* 2021;113(12):1733-1743; 13. Van Bockstal MR et al. *Cancers (Basel).* 2021;13(19):4910; 14. Cirqueira MB et al. *Cancers (Basel).* 2021;13(23):6090; 15. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Breast Cancer V.4.2022. ©National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed June 30, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way; 16. Erber R, Hartmann A. *Breast Care (Basel).* 2020;15(5):481-490; 17. Martínez-Sáez O et al. *Breast Cancer Res.* 2020;22(1):45; 18. Arthur LM et al. *Breast Cancer Res and Treat.* 2014;147(1):211-219; 19. Thompson AM et al. *Breast Cancer Res.* 2010;12(6):R92; 20. Schrijver WAME et al. *J Natl Cancer Inst.* 2018;110(6):568-580; 21. Yi Z et al. *NPJ Breast Cancer.* 2020;6:59.