MOLECULAR DIAGNOSTICS IN **ONCOLOGY**

Knowledge Check 1

1	Fill in the blanks: Biomarker testing in oncology is complex, as of June 2022, there were: FDA-approved biomarker-linked interaction, actionable genomic alterations
	and cancer types:
	a ≥70, 43, and 28
	b ≥75, 47, and 36
	c ≥85, 50, and 40
	d ≥100, 62, and 53
2	How does biopsy choice and site impact testing outcomes? Select all that apply:
	The decalcification process can risk impairing the sample yield and integrity with bone biopsies
	b Receptor status can change over the course of the disease
	c Variability between the primary tumor and metastatic site can occur
	d Rebiopsy after disease progression does not provide clinically meaningful data
3	Which of the following statements is true for liquid biopsy test results?
	Provide a snapshot of the cellular and molecular characteristics of 1 part of a single tumor
	b Can be linked with histology
	c All of the above
	d None of the above
4	Testing for biomarkers generally requires% of tumor nuclei in collected samples to be above the LOD:
	a 10%
	b 15%
	c 18%
	d 20%
5	True or false, ROSE can be performed without a cytopathologist present?
	a True
	b False



ANSWERS



- **A.** As of June 2022, there were more than 70 US Food and Drug Administration (FDA)-approved biomarker-linked indications and 43 actionable genomic alterations.^{1,2}
- A, B, and C.

A: Bone biopsy requires decalcification, which may impair sample yield and integrity, potentially negatively impacting biomarker testing outcomes.³

B: The receptor status may change over the course of the disease in certain cancers. Rebiopsy after disease progression may provide important and/or new information.⁴⁻⁷

C: Biomarker discordance between the primary tumor and a metastatic site may occur. Additional/different drivers/mutations may occur through clonal evolution over the course of the disease.⁸⁻¹²

- C. Liquid biopsy test results may reflect the overall genomic landscape of the tumor and all metastatic sites^{13,14}. It cannot directly correlate ctDNA results with histology or cellular phenotype and it may miss an alteration if ctDNA concentration is below the LOD, leading to a false negative.¹⁴⁻¹⁷
- **D.** Testing for biomarkers generally requires 20% of tumor nuclei in samples.^{18,19} Testing samples with a lower tumor proportion may result in false negatives, depending on the LOD.²⁰⁻²³ Training may help lower discrepancies in estimating tumor content.¹⁸
- TRUE: Telecytology allows ROSE to be done with an off-site cytopathologist; in telecytology-performed ROSE, the cytopathologist reviews images of the slides sent via a secured network.²⁴⁻²⁶





This knowledge check is connected to the chapter "The Growing Role for Molecular Diagnostics in Cancer Care." To get a copy of this and other chapters, please visit: https://www.hcp.novartis.com/precision-medicine



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ctDNA, circulating tumor deoxyribonucleic acid; LOD, limit of detection; ROSE, rapid on-site evaluation.

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