Knowledge Check ❷

1

How is biomarker testing utilized in precision oncology?

a   Diagnosis purposes
b   Treating cancers
c   Aiding prognosis
d   All of the above

2

A good biomarker test should have which of the following characteristics? Select all that apply:

a   Actionable, prognostic and/or predictive
b   Sufficient sensitivity, specificity, accuracy, and precision to detect actionable biomarkers
c   Tightly controlled specimen collection, handling, and processing
d   Highly regulated process to returning results to inform clinical decisions

3

Which statement(s) best describes clinical utility?

a   Accurately and reliably measures the presence or absence of a biomarker
b   Accurately and reliably identifies a biologically defined disorder
c   Evidence to support the use of a biomarker that can guide clinical decisions
d   B & C
e   All of the above

4

Which testing method(s) can reliably detect fusions? Select all that apply:

a   IHC
b   FISH
c   RT-PCR
d   RNA-based NGS
e   DNA-based NGS

5

Which of these statements are true about reflex testing?

a   Can reduce turnaround time
b   Can be integrated into patients EHR
c   Tests are automatically added in specific situations
d   All of the above

Precision
Medicine

ANSWERS

ANSWERS

1

D. Precision oncology uses molecular biomarkers to aid in the diagnosis, prognosis, or treatment of cancer.[1]

2

A, B, and C. According to clinical guidelines and expert opinions, the 7 characteristics of a good biomarker test are as follows:

- It is actionable, prognostic, and/or predictive[2,3]
- It is supported by the highest level of evidence[2]
- It provides reproducible results (>95%)[4,5]
- It possesses sufficient sensitivity, specificity, accuracy, and precision (<1% to 5% LOD) to detect actionable biomarkers[2-5]
- It has tightly controlled specimen collection, handling, and processing[2]
- It delivers timely results which impact treatment decisions[6-8]
- It has predetermined cutoff points/categories[2]

3

C. Clinical utility is when a biomarker test has high levels of evidence that use of the biomarker can result in guiding clinical decisions that result in improved clinical outcomes compared with those if the biomarker test results were not applied.[9]

4

B, C, & D. Gene rearrangements can be reliably detected by FISH, RT-PCR (known rearrangements) and RNA-based NGS. Some, but not all, DNA-based NGS assays can detect fusions, as the enrichment strategy will impact the ability to detect fusions in these assays. IHC assesses protein expression; therefore, it cannot differentiate between protein overexpression and a bona fide fusion event.[1]

5

D. Reflex testing is the automatic addition of tests in the SOPs by pathologists, and it may be integrated into the electronic health record. Studies suggest reflex testing may reduce the turnaround times for molecular testing results.[10-13]
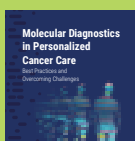
This knowledge check is connected to the chapter
"The Growing Role for Molecular Diagnostics in Cancer Care."
To get a copy of this and other chapters, please visit:
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