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Backgrounder: Guardant360 TissueNext™ Test

Leading with Guardant360® CDx liquid biopsy followed by new Guardant360 TissueNext™ test introduces an efficient approach to complete genomic testing

After starting with Guardant360 CDx liquid biopsy, oncologists can now run new Guardant360 TissueNext test when needed to help find more patients with actionable biomarkers

- Starting with Guardant360 CDx liquid biopsy to perform complete genomic testing finds 80% of patients with actionable biomarkers in only 7 days[1-3], which is superior to the only 50% of patients found in 2-4 weeks when starting with tissue biopsy[1-3] – the current standard of care
- Liquid biopsy is non-invasive, provides faster results compared to tissue biopsy, and has been shown to have >90% concordance with tissue biopsy[1,2,4]
- Still, no test is perfect and there are instances when liquid biopsy does not identify an actionable biomarker
- In these cases, oncologists can "reflex" to a tissue biopsy to perform additional genomic testing
- The Guardant360 TissueNext tissue test is now available to be ordered alongside the Guardant360 CDx liquid biopsy test and run, if needed, in cases where liquid biopsy does not report actionable biomarkers
- By offering a new tissue test for use after a liquid biopsy, Guardant Health offers an efficient "blood-first, tissue-next" approach to finding more patients with actionable biomarkers in less time

Using the Guardant360 CDx liquid biopsy with Guardant360 TissueNext tissue test offers oncologists the most efficient approach to ensuring no patients are missed for complete genomic testing

- As testing with the Guardant360 CDx liquid biopsy is performed, Guardant Health will procure the tissue sample and run the Guardant360 TissueNext tissue biopsy if needed
    - If an actionable biomarker is reported, the Guardant360 CDx test result is sufficient to start a patient on the appropriate therapy
    - If no actionable biomarker is reported, the Guardant360 TissueNext test is run next as a reflex test
- Tissue specimen requirements for Guardant360 TissueNext are also lower than leading tissue biopsy tests (tumor area >25 mm2, and tumor content >10% tumor nuclei), helping lower failure rates resulting from non-reportable findings
- An integrated approach using liquid biopsy followed by tissue biopsy can lead to improved outcomes, particularly in non-small cell lung cancer (NSCLC) where a growing number of actionable biomarkers exists

The Guardant360 portfolio of tests provides a complete genomic view at every step of the treatment journey

Since 2014, our Guardant360 test has been widely adopted for blood-based genomic testing by more than 9,000 oncologists in over 150,000 tests performed to date. For oncologists treating patients with advanced cancer, the Guardant360 portfolio provides a more complete genomic picture across the treatment journey. The comprehensive set of cancer tests empowers oncologists to optimize treatment and know confidently what to do next. From fast treatment selection with the FDA-approved Guardant360 CDx test, to efficient reflex testing with the Guardant360 TissueNext test, to assessing early treatment response with the Guardant360 Response test, the Guardant360 portfolio helps oncologists unlock the full potential of precision oncology to ensure no patient is left behind.

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