EGFR Mutation Test Options at Disease Progression

Diagnostic EGFR T790M mutation tests at disease progression

There are 2 FDA-approved tests for detecting EGFR T790M mutations at progression.[1]

Company	Test Name	Sample Type	Turnaround Time
Roche[2]	cobas® EGFR Mutation Test v2	Tissue*/blood	7 days
Foundation Medicine[3]	FoundationOne CDx™	Tissue*	<14 days

Reminder: A new sample is required to test for EGFR T790M mutations at the time of progression.

LDTs for detecting EGFR T790M mutations

As you can see in the chart below, there are a number of commercially available laboratory-developed tests (LDTs) to identify the EGFR T790M resistance mutation at progression. While these LDTs are not FDA approved, they are validated and must adhere to specifications established by the Clinical Laboratory Improvement Amendments (CLIA) of 1988.[4]

Companies Offering CLIA-validated LDTs† for Detecting EGFR T790M Mutations

Company	Test Name	Sample Type	Turnaround Time
Guardant Health[5,6]	Guardant360™	Blood	14 days
Biodesix[7,8]	GeneStrat®	Blood	3 days
Sysmex Inostics[9,10]	OncoBEAM™	Tissue/Blood	<10 days
Exosome Diagnostics[11]	ExoDx® *Lung(T790M)*	Blood	5 days
Biocept[12]	Biocept liquid biopsy	Blood	<7 days

10 WORKING DAYS – The recommended turnaround time from the receipt of sample to reporting of EGFR mutation testing results according to guidelines from CAP, IASLC, and AMP.[13]

When ordering an EGFR mutation test, it is important to verify turnaround time when the order is placed. If the test results are taking longer than expected, or exceed the recommended 10 days, it is recommended that you contact the laboratory.

*Formalin-fixed paraffin-embedded (FFPE) tissue samples are approved for testing.[1]

†LDTs were developed and their performance characteristics determined by specific institutions in a manner consistent with CLIA requirements. They have not been cleared or approved by the Food and Drug Administration (FDA).[14]

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References: 1. US Food and Drug Administration. List of cleared or approved companion diagnostic devices (in vitro and imaging tools). http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm. Accessed February 21, 2018. **2.** cobas® EGFR Mutation Test v2 [package insert]. Branchburg, NJ: Roche Molecular Systems, Inc.; 2015. **3.** Foundation Medicine. FoundationOne CDx™ technical specifications. Cambridge, MA: Foundation Medicine; 2017. https://www.foundationmedicine.com/genomic-testing/foundation-one-cdx. Accessed February 21, 2018. **4.** US Food and Drug Administration. Laboratory developed tests. https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/default.htm. Accessed February 21, 2018. **5.** Guardant Health. Guardant360™ 73-gene panel. http://www.guardanthealth.com/medical-professionals/#gene-panel. Accessed February 21, 2018. **6.** Guardant Health. How Guardant360™ works. http://www.guardanthealth.com/guardant360/#how-it-works. Accessed February 21, 2018. **7.** Biodesix. GeneStrat® genomic test. http://www.biodesix.com/genestrat. Accessed February 21, 2018. **8.** Clinical Laboratory Improvement Amendments Certificate of Compliance: Biodesix Inc. Baltimore, MD: Centers for Medicare & Medicaid Services; May 20, 2015. **9.** Sysmex Inostics. Sysmex OncoBEAM™ EGFR. http://www.sysmex-inostics.com/our-services/product-single-view/oncobeamTM-egfr-3805.html. Accessed February 21, 2018. **10.** Sysmex Inostics. Inostics' blood-based mutation testing receives CLIA certification [news release]. Mundelein, IL: Sysmex Inostics Inc; May 30, 2013. http://www.sysmex-inostics.com/news-and-events/press-releases/inostics-blood-based-mutation-testing-receives-clia-certification-83.html. Accessed February 21, 2018. **11.** Exosome Diagnostics. Lung cancer. http://www.exosomedx.com/lung-cancer-0. Accessed February 21, 2018. **12.** Biocept Inc. You need a complete answer to provide the best treatment. http://biocept.com/technology/lung-cancer-offering/. Accessed February 21, 2018. **13.** Lindeman NI, Cagle PT, Aisner DL, et al. Updated molecular testing guideline for the selection of lung cancer patients for treatment with targeted tyrosine kinase inhibitors: guideline from the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. *Arch Pathol Lab Med*. 2018;142(3):321-346. doi:10.5858/arpa.2017-0388-CP. **14.** Centers for Medicare & Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA). https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia. Updated April 5, 2017. Accessed February 26, 2018.

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