



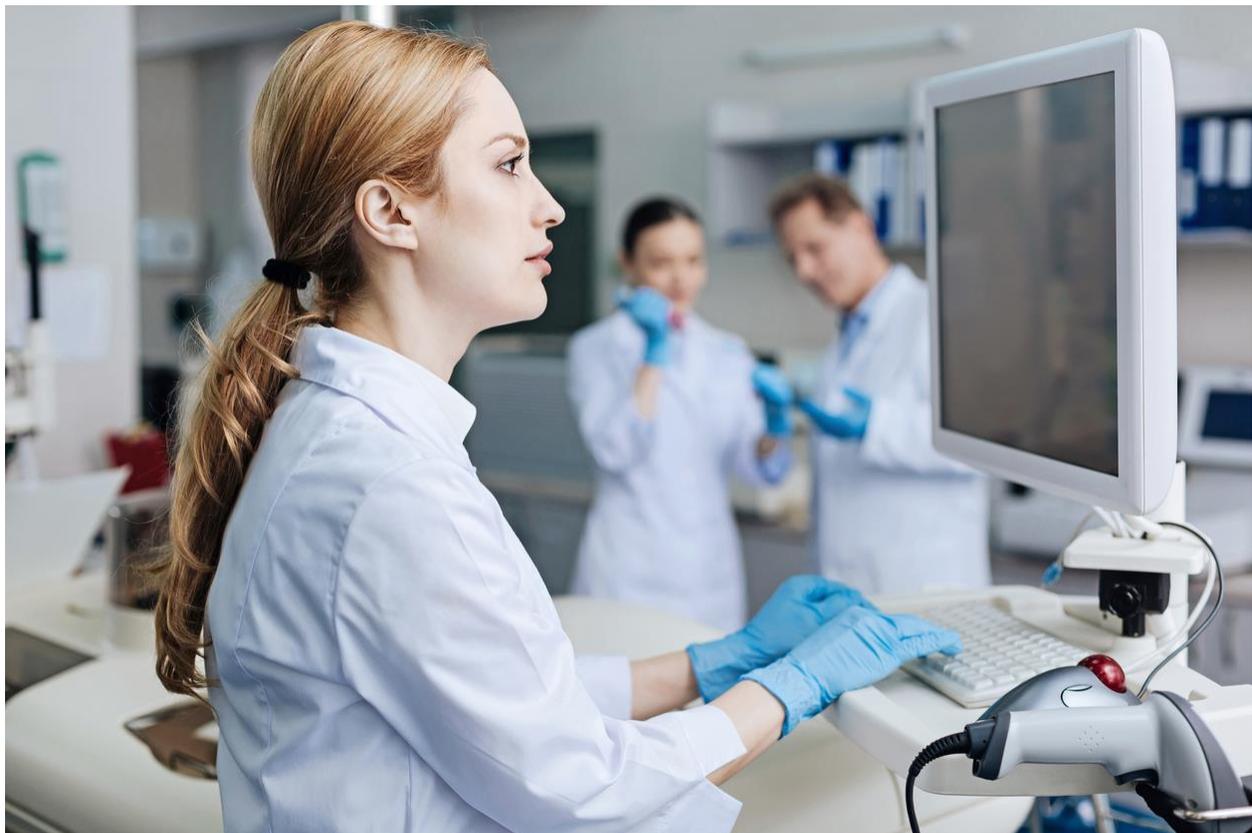
Why Your Lab Should Offer Molecular Oncology Testing

By Maggie Sawyer

According to an [abstract published](#) in the *Journal of Clinical Pathology*,

"Molecular testing is becoming an important part of the diagnosis of any patient with cancer. The challenge to laboratories is to meet this need, using reliable methods and processes to ensure that patients receive a timely and accurate report on which their treatment will be based." (1)

Precision medicine, often referred to as personalized medicine in cancer treatments, is not a new concept. As our knowledge base increases and treatments evolve, Molecular Oncology Testing, especially in patients presenting with hematological tumors, is now considered essential in achieving a more precise diagnosis and treatment plan.





Here we examine five reasons why your lab should offer molecular oncology testing:

1. Increased demand

- **As more hospitals incorporate Oncology treatment centers**, the demand for **molecular oncology testing** will increase exponentially, requiring accessibility to labs that can deliver more accurate genetic information in their **molecular pathology reports** on tumors, providing clinicians vital information that would otherwise not be available.
- **As new cancer treatment drugs are introduced**, overcoming resistance to current treatments becomes more essential.
- **These specialized lab reports provide insights and information** to oncologists, creating opportunities for more comprehensive personalized treatments.
- **Molecular pathology** is advancing rapidly, and competition is fierce. Pathologists are now being challenged to provide as much information as possible, especially on the molecular level, to be used as guidance in the treatment of cancer patients within the most condensed timeframe possible.

2. Provide the best service to patients

- Hospitals and clinicians take pride in the level of service provided to their patients, especially since their reputations and procedures are under constant scrutiny. Differences in services offered between labs and healthcare systems will always exist. By providing these types of advanced testing services, you will establish your lab as **one of the most progressive and state-of-the-art molecular pathological labs in the medical community**, one that acknowledges the importance of best service to patients and their providers.
- In addition to providing the most accurate test results, establishing clear chain-of-command for requesting preanalytical sample handling, molecular analysis, nucleic acid extraction, and analysis, are all prerequisites for the operation of a safe and efficient **molecular pathological lab**.

3. Continued Medical Support

- **Molecular testing** is ongoing. Oftentimes, these tests are performed with other procedures such as biopsies and repeated over time; they are not only used to establish a baseline for cancer treatments but also to monitor the effectiveness of the treatment plan, and to monitor progress (or deterioration) of the patient.
- In addition to testing for certain proteins, genes, or other molecules in sample materials, **molecular oncology tests** look for *changes in a chromosome or gene* that may impact the chances of developing certain disorders, such as cancer. These tests can be used to determine more accurate prognoses.



4. Molecular Pathology - An emerging discipline

- ***This is one of the most difficult aspects of operating a molecular pathology laboratory:*** Molecular testing is expensive. Multi-disciplinary teams typically make the decision to request these tests; this requesting process ensures not only that the request is made appropriately, but also that **every patient in need of such a test is offered one** in a timely manner. It is equally important to **ensure that unnecessary tests are not performed.**
- **Molecular pathology** is cutting-edge science focused on the study and diagnosis of cancer and infectious diseases through the examination of tissue, organs, etc. on the molecular level. As an emerging discipline, requests for molecular analysis is vital in defining a treatment strategy for patients.
- **Genomic Testing in the Molecular Testing Process** - As part of precision cancer treatment, **Genomic tumor assessments** can help identify any DNA alterations driving the growth of specific tumors. (3)

5. FDA Approval

*On November 2017, the [FDA approved](#) the FoundationOne CDx (F1CDx)... [the]next generation sequencing (NGS)... test[ing] that **can detect genetic mutations in 324 genes and two genomic signatures** in any solid tumor type. The Centers for Medicare & Medicaid Services (CMS) at the same time proposed coverage of the F1CDx...facilitat[ing] earlier access to innovative medical technologies for Medicare beneficiaries.*

FDA Commissioner Scott Gottlieb, M.D. said, *"By leveraging two policy efforts aimed at expediting access to promising new technologies, we've been able to bring patients faster access to a breakthrough diagnostic that can help doctors tailor cancer treatments to improve medical outcomes and potentially reduce health care costs..."* (2)

This translates into your lab delivering timely information to clinicians treating Medicare/Medicaid patients while providing you opportunities to grow the Molecular Oncology testing area. Developing your LIS (laboratory information system) vital and will allow you to operate more efficiently and more effectively, staying two steps ahead of the competition when it comes to delivering results in the most expeditious manner.

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- (1) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4215286/>
 - (2) <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587273.htm>
 - (3) <https://www.forbes.com/sites/elaineschattner/2018/03/06/all-cancer-patients-should-have-access-to-molecular-and-genomic-testing/#3c3d5bbd43d4>
<https://www.nature.com/subjects/next-generation-sequencing>