CASE STUDY

Implementing an in-house CGP solution: An alternative to send-out testing

"My lab uses the FDA-cleared IVD kit to enable verification instead of full validation, reimbursement data and reporting that does not require a third-party vendor."

Director of Clinical Genomics and Cytogenetics
at an integrated Health System with an NCI-designated Cancer Center

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Summary

The PGDx elio™ tissue complete is a solid tumor profiling test that has driven significant improvements for a large health network over their previous 170-gene panel laboratory-developed test (LDT) .

Value Drivers

- A broad panel of >500 genes and complex biomarkers like tumor mutational burden (TMB) and microsatellite instability (MSI)
- A clear and concise in vitro diagnostic (IVD) report delivered through an automated bioinformatics pipeline that enables additional insights across all other targets
- Dedicated product implementation support
- A clear path to reimbursement with the established proprietary laboratory analysis (PLA) code tied to a highly favorable national reimbursement rate

KEY TAKEAWAYS

- Rapid biomarker identification necessitates exploration of comprehensive solutions for biomarker-guided solid tumor testing solutions
- Adopting a U.S. Food and Drug Administration (FDA) cleared solution with a PLA code reduced onboarding and implementation time and effort and facilitates reimbursement
- Professional services with dedicated project management offers a streamlined path to implementation, reducing time to first IVD report by 66%

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Labcorp Oncology offers a comprehensive test menu to assist in the diagnosis and management of patients with breast cancer throughout their continuum of care.

The Laboratory

A large health system with an NCI-designated cancer center

This large health network serves 1.5 million people, providing acute care through community hospitals, a children's hospital, primary and specialty care clinics and more.

Delivering first-tier routine diagnostic work-ups, the laboratory performs ~3,600 tests per year including next-generation sequencing (NGS)-based profiling of solid tumor and hematological malignancies, T-cell receptor/ immunoglobulin receptor (immunoglobulin heavy chain) gene clonality, MSI status and chimerism assays. Other tests—including fragile X testing—are also performed using chromosomal microarrays within the cytogenetics lab.

The challenge

Implementing a more comprehensive solid tumor profiling test while reducing validation time and effort, and enables a faster time to go-live

Initial efforts to enable solid tumor testing leveraged a low input assay that covered 26 genes and enabled straightforward interpretation. Although it addressed needs at the time, the rapid pace at which biomarkers were being identified soon rendered this highly targeted panel outdated. This necessitated exploration of both in-house and send-out testing options for comprehensive genomic profiling.

Exploration of in-house options led to a 170-gene panel. Though this addressed the need for coverage of additional biomarkers, there were several downsides:

- Assay requires increased input, which poses a challenge when tissue is limited
- Libraries generated using this expanded panel assay need to be sequenced using a higher output benchtop sequencer, which required significant capital investment
- The panel, though covering more targets, was still missing key biomarkers and entailed increased interpretation time, requiring significant director time to interpret results

Beyond these concerns, implementing this LDT solution resulted in:

- Increased validation time and cost and a 1.5- to 2 year implementation project
- Difficulty in developing effective bioinformatics pipelines, requiring the use of a third party solution and increasing time, cost and resources needed for validation and implementation
- Poor reimbursement rates

The solution

The FDA-cleared PGDx elio tissue complete assay

Given the challenges, efforts continued towards identifying a future-proof solution that addressed not only the current and near-term needs, but kept up with emerging biomarkers. The health system turned to the PGDx elio tissue complete solid tumor profiling test.

PGDx elio tissue complete is an FDA- cleared assay-to-report IVD solution for solid tumor profiling. It targets >500 genes including important clinically actionable variants[1] targetable by FDA- approved therapies, as well as complex variants like ERBB2 (HER2) amplifications, translocations, TMB and MSI, relevant for any comprehensive genomic assay.

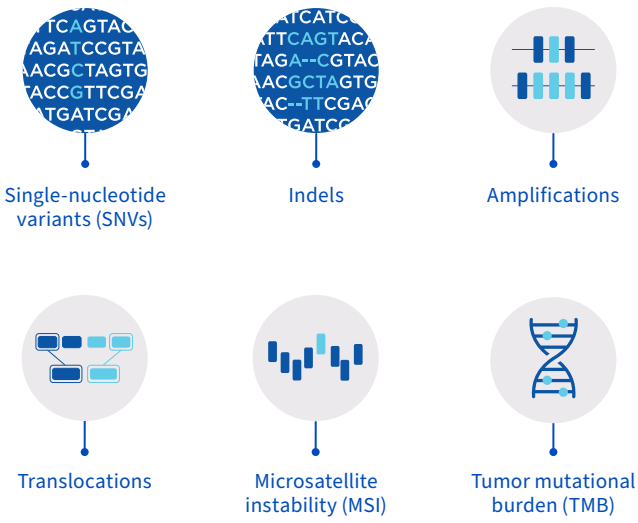
This assay, with its comprehensive set of targets and ability to detect various alterations, opened up the potential to address ongoing needs around expanding biomarkers.

Enabled with an automated bioinformatics pipeline, the elio Platform generates an IVD summary which enables clear and concise reporting integrated readily into a branded template or pulled directly into the health system's electronic medical records (EMR), simplifying the workflow.

This solution not only enabled a more comprehensive approach to tissue-based tumor profiling, but also addressed the key challenges in implementation and routine operations:

- Required only verification, not full validation, accelerating time to first test
- The included proprietary bioinformatics solution mitigated the need develop new analysis and reporting pipelines using third party solutions
- Offered 60% reduced time per report and only 5 days from extracted nucleic acid to IVD report, meeting standard testing turnaround times and preserving the laboratory's time to sign out despite the nearly threefold increase in panel content.

PGDx elio tissue complete identifies somatic mutations with high accuracy and sensitivity



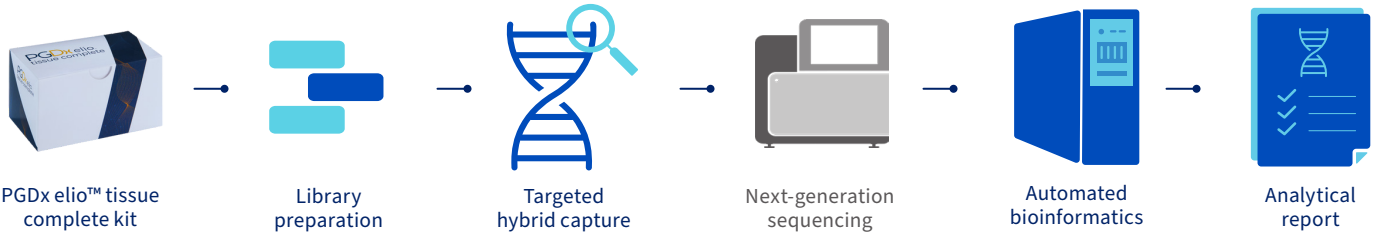


Fig 1. The PGDx elio tissue complete assay-to-report workflow

Going above and beyond

Implementation support

Further, since test verification and implementation requires coordination among various stakeholder teams and entities within the health system, dedicated project implementation and management quickly became an indispensable part of the solution offering, setting realistic benchmarks, tracking project milestones, and facilitating streamlined implementation to meet targets.

Enabling a clear path to reimbursement

In addition to operational benefits, this solution also allows the laboratory to better manage uncertainty around test reimbursement, which is key for any laboratory.

To facilitate reimbursement for a given test, a laboratory, under the MolDx program, has to apply for a DEX™ Z-code, a unique five-character alphanumeric code within Palmetto's Diagnostics Exchange (DEX), to specifically identify their molecular test.[3,4] When included on a claim along with the Current Procedural Terminology or CPT® code, it provides clarity for both payers and providers on the test being ordered, performed and billed[2] , reducing denial rates and enabling a more consistent pricing and revenue model.

Applying for a Z-code involves not only registering the test but also submitting a technical assessment (TA) to determine compliance with a policy. To receive a favorable review, an assay must demonstrate clinical utility, show evidence of medical necessity and meet analytical and clinical validity standards.[5]

To alleviate this burden, PGDx sought a Z code specifically for the FDA-cleared PGDx elio tissue complete assay. By adopting and implementing this test exactly as intended or as described in the product's 510K clearance, the laboratory was obtain use of the same Z code, accelerating the process from the typical 60- to 90- day time frame down to 2 to 3 weeks.[5]

Furthermore, in January 2022, CMS finalized a national reimbursement rate of $2,919.60 for the PGDx elio tissue complete solution under the PLA code 0250U[6], driving further value by facilitating a clear path for reimbursement, reducing denial rates.

By enabling the PGDx elio tissue complete solution with both a Z-code and PLA code tied to favorable reimbursement rates, this solution offers a significant improvement over laboratory developed tests (LDTs). The solution delivers a faster time-to-market for the test while reducing the cost and burden of onboarding and implementation and increasing operational efficiency with more reimbursed claims and lower denial rates, though private insurers still remain a challenge.

Summary

The PGDx elio tissue complete solution has enabled great strides towards making comprehensive genomic profiling solutions accessible. It has several advantages over the health system's previous 170-gene panel LDT. These include 1) a broad panel of >500 genes and complex biomarkers TMB and MSI, 2) an automated bioinformatic pipeline that delivers a clear and concise IVD report, 3) professional services that provide dedicated project management support, and finally 4) a clear path to reimbursement with the established PLA code tied to a favorable national reimbursement rate and an assigned Z-code that can be readily accessed when performing the test on-label.

References

1. Richards S, Aziz N, Bale S, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med. 2015;17(5):405-424.
2. MolDX® Program (administered by Palmetto GBA). Palmetto GBA. https://www.palmettogba.com/palmetto/moldxv2.nsf
3. Welcome to DEX™ Diagnostics Exchange. Palmetto GBA. dexzcodes.com
4. DEX Diagnostics Exchange test registration. Palmetto GBA. https://www.dexzcodes.com/palmetto/dex.nsf/DID/XD94SOIYA6
5. Technical assessment. Palmetto GBA. https://www.dexzcodes.com/palmetto/dex.nsf/DID/ABJFYRZZR8
6. PGDx. PGDx announces an updated Medicare reimbursement rate for the elio™ tissue complete test. January 25, 2022. https://www.personalgenome.com/resources/entries/pgdx-announces-an-updated-medicare-reimbursement-rate-for-the-elio-tissue-complete-test

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