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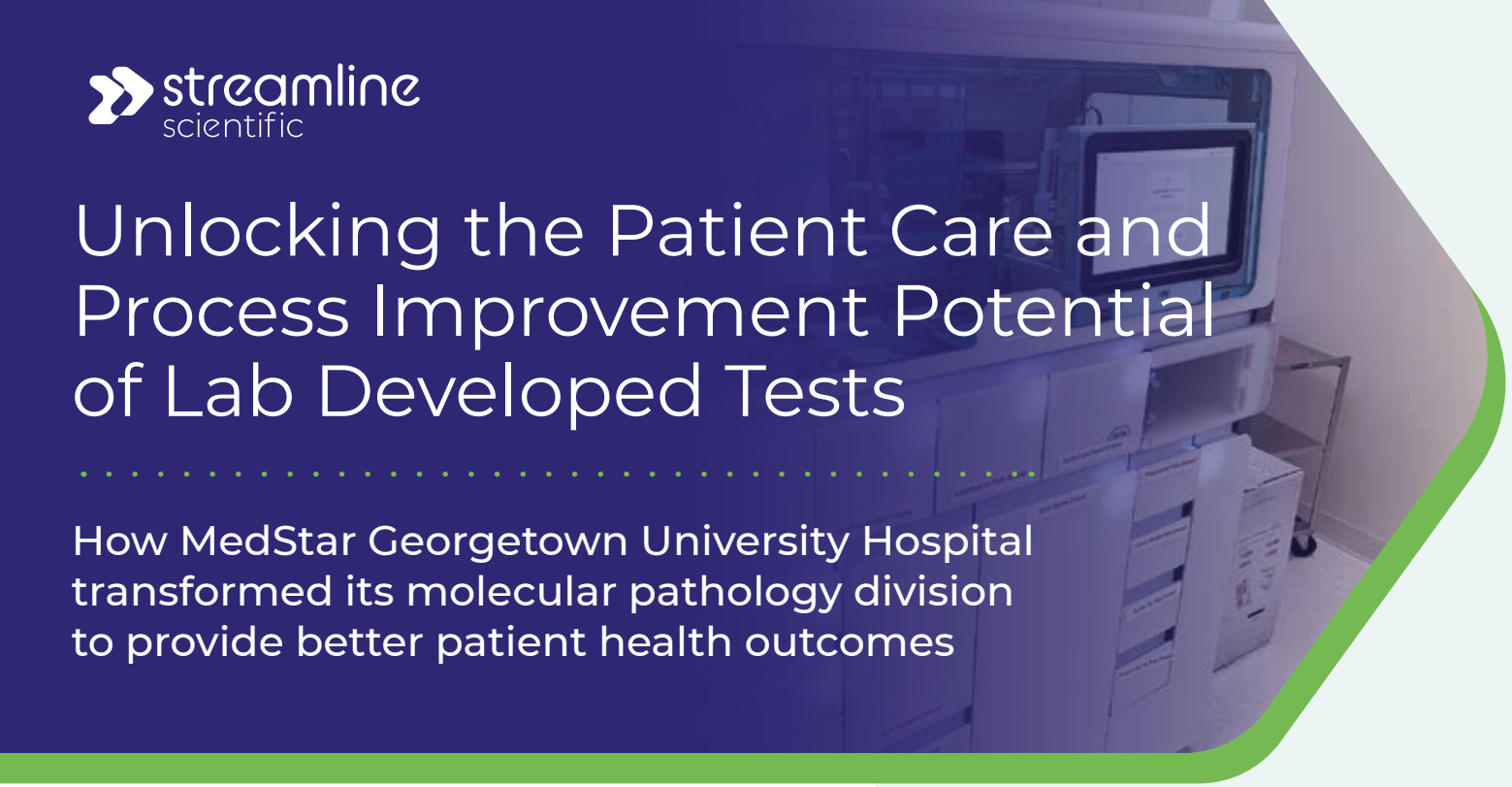
Unlocking the Patient Care and Process Improvement Potential of Lab Developed Tests



How MedStar Georgetown University Hospital transformed its molecular pathology division to provide better patient health outcomes

Operating a hospital in modernity means constantly being subjected to the forces of razor-thin margins. For facilities to thrive, it is incumbent upon each division within it to strive for optimization, both for patient care processes and for return on investment.

This white paper details one such success story, headed by **Joeffrey Chahine, Ph.D., the Technical Director of the Molecular Diagnostics (Pathology) Laboratories at MedStar Georgetown University Hospital (MGUH).**

With limited outsourcing, Dr. Chahine transformed his hospital-based molecular pathology division into a place recognized for its ability to deliver high-volume processing, high-quality results, and accelerated turnaround times, all while minimizing cost, generating profitable revenue, and most importantly improving patient care and management.

As an expert in molecular hematopathology, molecular oncology, and molecular virology, Joeffrey sits on the advisory boards and discussion panels for numerous pharmaceutical and biotech organizations and has received the M. Joy Drass Cura Personalis Award for exemplary commitment to his hospital's vision, mission, and values.

KEY TAKEAWAYS:

- Before 2010, the molecular pathology division at MGUH supported different oncology departments by offering limited high-complexity and low-volume testing.
- Since 2010, MedStar Health consolidated internal molecular diagnostics, implemented a more efficient use of send-out molecular testing, and optimized the implementation of laboratory-developed tests (LDTs) for high, mid, and low-volume molecular assays.
- Testing selection was based comprehensively on accurate result utility, quick turn-around, improvements in patient care, more efficient result reporting, and a reduced need to depend on reference laboratories in order to cut down testing costs and improve time to result.

Background

Up until 2010, MGUH's molecular diagnostics laboratories offered high complexity/low volume testing supporting a specific niche of clinical disciplines, providing limited productivity.

Up until 2010, MGUH's molecular diagnostics laboratories offered high complexity/low volume testing supporting a specific niche of clinical disciplines, providing limited productivity. This is a very common trend in hospital-based molecular diagnostics laboratories, forcing them to rely heavily on reference laboratories. Up to that point, the molecular pathology division at MGUH operated on a low budget, offering analytically validated home-developed assays notorious for their compliance challenges under College of American Pathologists (CAP) guidelines.

To face these challenges, Dr. Chahine was recruited to manage, develop, and further refine the technical operations and program development of the division's diverse molecular section in collaboration with hospital clinicians and pathology faculty members.

After a close evaluation of the send-out menu, he identified numerous high and low-volume tests that had the potential to be performed in-house. With limited 510(k) tests available on the market, Dr. Chahine analytically validated the laboratory-developed tests (LDTs) needed by the division's clinicians and pathologists.

Analyzing the Test Menu

Dr. Chahine first noticed a high usage of self-developed LDT assays instead of sourcing quality components from outside suppliers.

While the latter may also be considered LDTs, these differed in that they could be used for patient testing after a full-scale CLIA assay performance analytical validation. In contrast, the same could not be said for the LDTs that were currently used.

Consideration was made regarding FDA-cleared 510(k) tests since they are quick to implement, require less training, and are straightforward to apply, but Dr. Chahine still chose to de-prioritize their usage considering several of their inherent challenges. They represent a small bracket of testing needed and offered in the molecular diagnostics world while also being very costly with low profit margins.

Comparatively, LDTs require full-scale validation and are relatively more labor-intensive while requiring close monitoring processes for LDT performance maintenance. This is why LDTs often pose significant concerns and challenges to hospital-based molecular diagnostics laboratories. As a result, these divisions often lean and rely heavily on outsourcing to reference laboratories.

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Reforming the Modern Hospital Laboratory

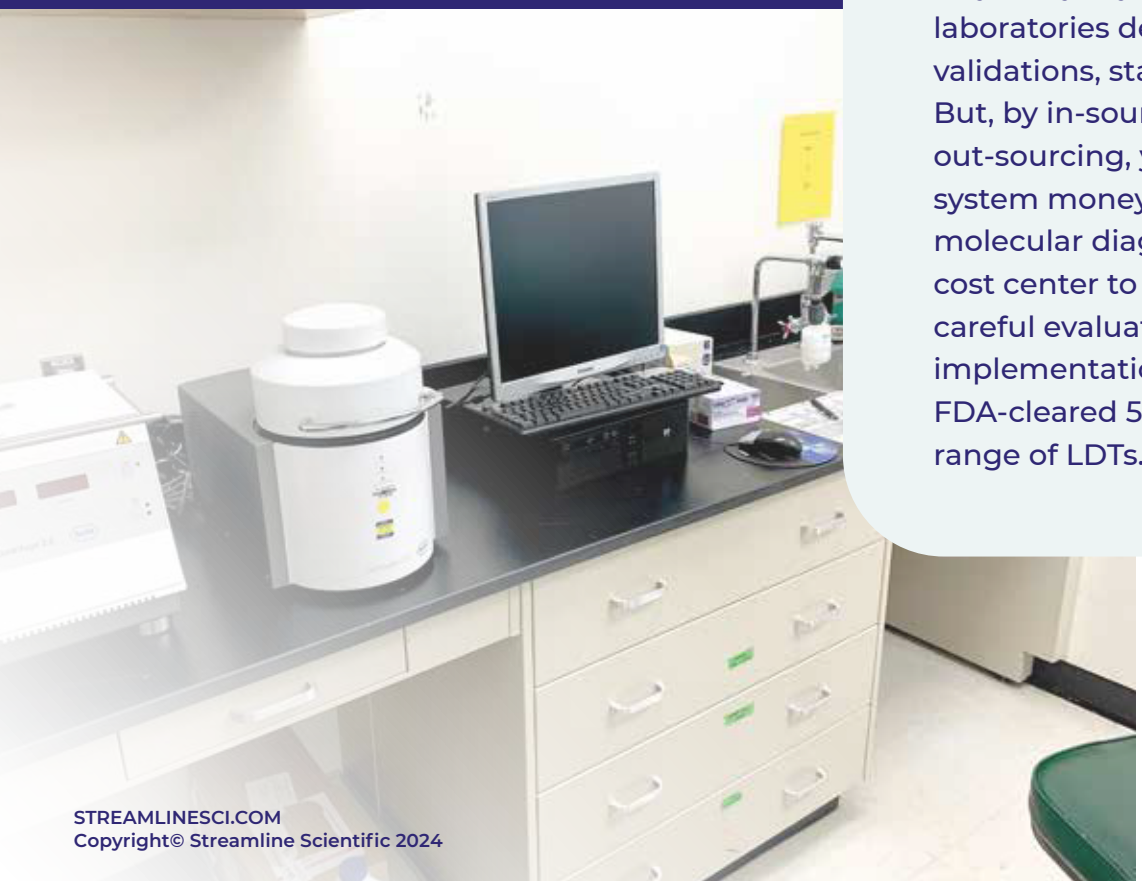
One of Dr. Chahine's first choices was to eschew the few "home-brew", low-volume, and labor-intensive LDTs that were being used, build up in-house molecular testing and reduce the use of outsourced reference laboratories.

Dr.Chahine began reforms with the validation and implementation of the highest volume molecular virology test ordered at MedStar Health - the cytomegalovirus (CMV) DNA PCR quantitative assay, which accounted for approximately 12,000 tests per year. Part of the plan needed to include the acquiring of relevant equipment and sourcing of reagents to support the implementation of the molecular division's first high-volume LDT. Dr. Chahine evaluated available LDT assays in the marketplace based on quality, costs, clinical utility, and speed to results. By starting with CMV DNA PCR quantitative assay, in addition to the re-validated low-volume molecular pathology tests, staff and equipment utilization were maximized. This also enabled leverage for negotiating favorable prices with reagent and disposables vendors.

The performance of high-complexity assays (especially LDTs) requires skilled technicians. Dr. Chahine hired individuals who were motivated to perform benchwork and had a desire to positively impact patient care. A greater hands-on role has attracted and retained talented staff that continues to support the expanding needs of the molecular pathology division at MGUH.

The efforts involved in this reform required a broader initiative from Dr. Chahine than is traditionally expected of a laboratory director, but as he says:

> "The majority but not all laboratory directors adopt the smooth conventional way. They say, 'Let the reference laboratories deal with LDTs' extensive validations, staffing, and communication.' But, by in-sourcing instead of out-sourcing, you can not only save the system money, but you transform a molecular diagnostics laboratory from a cost center to a profitable practice, by careful evaluation, adoption, and implementation of a mixture of FDA-cleared 510(k) supported by a wide range of LDTs."



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Convincing Stakeholders of the Need for Reform

Dr. Chahine found that clinicians had no preference for results obtained from FDA-cleared 510(k) tests over full-scale analytically validated in-house LDTs if the results were consistent and trustworthy.

A critical factor in pivoting to the use of LDTs was establishing a strong relationship between the testing team and the ordering physicians, creating an easy rapport to answer questions related to testing and critical result reporting, and becoming recognized for high accountability. Dr. Chahine worked tirelessly and quickly to implement these processes and establish a point of contact, which only proved to be very beneficial.

The primary impediment to LDT adoption, therefore, was overcoming a status quo of historical patterns. Clinicians were accustomed to ordering tests from the reference laboratories, and they tended to continue that practice. This dynamic changed, however, when providers began to receive faster test results from in-house LDTs.

Whereas the regional reference lab took over 48 hours to return results, **in-house LDT results were returned in 16 hours or less.**

Because the molecular diagnostics laboratory at MGUH now had control over the entire process, EMR notifications for critical results were sent immediately, enabling quick clinical action on the part of the providers.

In addition, the laboratory could prioritize critical samples as they were no longer subject to the reference lab's first-in, first-out testing model. Sample transit times that added hours to reference laboratories' result turnaround were no longer a factor for in-house assays. Rapid, actionable results from in-house LDTs not only convinced clinicians at MedStar Health to adopt LDT testing, but they became active advocates for it, requesting that additional tests be brought in-house.

Convincing the hospital administration encountered greater challenges due to the up-front investments for instrumentation and the ongoing budgetary costs of staffing, reagents, and related ancillaries. However, by bringing the highest volume test in-house first, Dr. Chahine ensured that the financial benefit was realized early on in the process.

This reform not only improved patient care while paying for itself, but it also generated funds used to improve the molecular pathology division and support the purchasing of additional platforms, the further introduction of in-house assays, and the expansion of testing personnel.

Overall cost savings were realized for bringing testing in-house despite a greater initial cost. As a result, the administration joined clinicians in becoming advocates for expanded in-house testing, relying heavily on LDT assays.

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Convincing Stakeholders of the Need for Reform

The molecular diagnostics laboratory at MGUH serves as the centralized molecular diagnostics operation for MedStar Health, which means that testing offered at MGUH is offered for all MedStar Health hospitals. Because of the increased capacity for in-house testing, the volume of tests ordered climbed, leading to a practice with higher productivity and efficiency.

The LDTs offered in-house were analytically validated for sensitivity, specificity, and other reportable values. Despite all the implementation efforts and processes, a small percentage of specimens for which testing was offered within MGUH were still being sent to reference laboratories. To minimize this trend, Dr. Chahine and administrative leaders invested heavily in generating orderables, providing a blueprint matching that of the reference laboratories. More importantly, reporting templates were generated in a familiar layout, easing the interpretation of results for clinicians accustomed to the reference laboratories' testing.

The selection of testing offered at the molecular pathology division was evaluated very carefully. Low-volume assays with extensive hands-on protocols were also offered in the molecular laboratory when deemed essential for quick and accurate diagnosis. However, the in-sourced high-volume testing represented the backbone of the operation. Due to the sharing of universal testing platforms, highly trained personnel were available to perform all types of testing very efficiently.

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Enabling a Scalable Solution to Pandemic Testing

The capability to run LDTs was most impactful during the COVID pandemic.

By using pre-existing infrastructure and equipment, and by leveraging the experience of their staff, **the molecular pathology division at MGUH became the first provider in the region to perform COVID testing in March of 2020** – just weeks after the first sequence for SARS-CoV-2 was available. At this early stage of the pandemic, most hospital systems were unable to offer any tests, as they were waiting on assays to gain Emergency Use Authorization (EUA) and be manufactured.

By using LDT assays, MedStar was able to begin testing earlier and increase the volume of testing faster for improved patient care. Scaling up was only dependent on purchasing reagents in bulk. Outsourced test manufacturers could not scale up so easily, so LDTs were required to meet the growing need for COVID testing.

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The Benefits of LDT Testing are Seen Throughout the MedStar Health System

Today, the molecular diagnostics laboratory performs:

36
tests

7
of which are FDA-cleared (510k) assays

+50,000
samples processed per year by its technicians

Having developed a strong molecular testing capability, the laboratory continues to attract talented technicians who desire to grow their careers and develop their expertise. Staff retention rates exceed industry standards, and technical staff are viewed as leaders in molecular diagnostics.

The clinical insights and financial support provided by the laboratory reform have changed the operation's perception across the MedStar system. No longer viewed as a supporting department, the molecular diagnostics laboratory is now seen as a critical aspect of MedStar's growth strategy. This consolidated practice and operation has improved and expanded patient care throughout the system.

Because the division has been able to develop effective patient care while continuously growing revenues, the division has gained and maintained the trust of hospital administration executives and now garners the respect needed to request funds for expansion and necessary resources, whether in terms of personnel, equipment, or budget expansion.

> "By being good stewards of the consolidated molecular diagnostics laboratory, we improve clinical care and provide financial stability for the division specifically which is equally contributory to the entire system in general."
>
> — Dr. Joeffrey Chahine, Ph.D.

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Dr. Chahine's Message to Health Systems:

At a time when hospital systems are struggling to care for patients while lowering costs effectively, **administrators must reform their revenue-neutral and revenue-losing departments**. In many systems, the best candidate for reform is the diagnostic laboratory, which has historically been seen as a costly service. If implemented effectively, in-house testing relying on LDTs in the diagnostic laboratory can improve patient care since the in-house lab can quickly adapt to changing clinical testing needs and provide faster results to providers and patients than outsourcing - with the added benefit of becoming revenue-positive.

By improving efficiency and in-sourcing, health systems can provide additional value to their patients while also improving their financial health.

About Streamline Scientific

Streamline Scientific is proud to partner with Dr. Chahine to help enable his vision to patient care.

Streamline Scientific is a team of medical doctors and scientists working to simplify the delivery of molecular technologies. In addition to helping set up over 200 labs in 43 states, Streamline Scientific maintains its own CLIA-certified reference labs in Alabama and Texas. As experts in PCR in-house lab setup and operation, their consulting services provide an end-to-end implementation solution for physician practices, hospitals, and reference labs nationwide.

For more information, visit:

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