Cleveland Clinic

Laboratory Stewardship Committee

2024 Annual Report

Anita J. Reddy, MD, MBA, and Walter H. Henricks, MD
Co-Chairs

Grace Kroner, PhD
Vice-Chair

Karen Smith, MS
Program Coordinator

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Executive Summary

Cleveland Clinic's Laboratory Stewardship Committee (LSC) is a multidisciplinary team established in 2017 comprised of clinicians, pathologists, laboratory scientists, administrators, and other caregivers. LSC focuses on optimizing testing by addressing over and underutilization to provide the best possible patient care while ensuring patient safety and reducing laboratory testing costs.

This past year, LSC collaborated with multiple groups within and outside Cleveland Clinic, including Information Technology Division (ITD), Pathology & Laboratory Medicine Analytics, and Infectious Disease.

Anita J. Reddy, MD, MBA, and Walter Henricks, MD, serve as Co-Chairs of the Committee and guide the team with their complementary skill sets and knowledge gained through years of practice. Karen Smith, MS, is the Program Manager of the Committee. This past year, Grace Kroner, PhD, was named Vice-Chair of the Committee given her tremendous work in establishing sound practices and oversight of send-out testing.

The committee's goals include:

- Decreasing unnecessary phlebotomy to improve patient satisfaction while reducing the likelihood of iatrogenic anemia and unnecessary downstream testing (and the sequelae thereof).
- Optimizing evidence-based use of laboratory resources and standardizing them to the best extent possible throughout Cleveland Clinic.
- Creating evidence-based guidelines and recommending interventions to guide cost-effective and clinically appropriate laboratory testing.
- Ensuring laboratory testing is developed and used to ensure patient safety.
- Determining applicable constraints or limitations to be placed on ordering certain laboratory tests to develop and promote best practices.
- Reducing health care costs through thoughtful and judicious use of resources related to laboratory testing.
- Developing and maintaining an enterprise Laboratory Test Formulary that determines what tests are available for Cleveland Clinic providers to order.

Longitudinal committee work and records are accessible through the LSC SharePoint site.

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Practice Transformation through Laboratory Stewardship

Since 2011, LSC has driven and maintained the integration of laboratory test ordering interventions into the Cleveland Clinic practice model. These interventions, embedded into the decision support of the electronic health record (EHR) system, deter excessive or largely unnecessary tests—such as unneeded or repetitive tests—notify providers of duplicate and expensive tests and guide the use of complex molecular genetic testing.

Laboratory test order interventions include:

– Hard Stops
– Restricted Use
– Laboratory Genetic Counseling
– Regional Smart Alerts
– Expensive Test Notifications
– Extended Hard Stops
– Once-In-A-Lifetime Test Alert
– 3-Day Stool Culture / O&P Alert
– Blood Culture Order Optimization
– Test Eliminations

In 2024, these test order interventions resulted in:

61,120
prevented unnecessary tests

$1,476,432
in cost-savings

Since implementation, these interventions have prevented **539,857 unnecessary tests** and saved Cleveland Clinic **$12,777,747**.

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2024 Completed & Ongoing Projects

Project	Status
1. Miscellaneous Test Review	**Ongoing**
2. Blood Culture Bottle Stewardship	**Complete**
3. CMV Drug Resistance Testing Stewardship	**Complete**
4. New Test Request Reviews	**Ongoing**

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1. Miscellaneous Test Reviews - *Ongoing*

In July 2022, the Pathology & Laboratory Medicine (PLM) Send-Out team initiated a review process that uses the same framework as genetic test reviews (GTRs). The goal was to review miscellaneous requests for chemistry tests, including biochemical genetics, endocrinology, therapeutic drug monitoring, toxicology, and trace metal testing. Miscellaneous tests are tests that are not defined by name in Epic or the Test Directory.

The project was initially selected as a resident quality improvement project in 2022, and five pathology residents were assigned. Eventually, pathology residents rotating through chemistry and the clinical chemistry fellow became responsible for the daily test review. The experience provided the residents and fellows valuable exposure to stewardship concepts and esoteric test requests during their training.

In 2024, 2,049 orders were reviewed. Approximately 31% of orders were from reference laboratory clients through PLM's outreach division, Cleveland Clinic Laboratories (CCL). An additional 7% of orders were from external providers not affiliated with Cleveland Clinic or CCL.

Of all orders, approximately 6.5% were canceled, 11.3% were updated to an equivalent defined order, 1.8% were updated to a different performing laboratory, and 1.3% were updated to a different test order entirely. In general, we have observed an increase in the proportion of reviewed tests that undergo an intervention since the establishment of this review process, suggesting increased familiarity with the process from the review team.

Identifying high-volume miscellaneous test requests or tests with short stability continues to enable a pathway for new test submission to the Laboratory Stewardship Committee (62 requests were submitted for definition in 2024) and highlights the need for educational materials to discourage inappropriate test ordering.

2. Blood Culture Bottle Stewardship – *Complete*

In June 2024, one of the two primary manufacturers of bacterial blood culture bottles announced a worldwide shortage of bottles that was expected to extend for months into the future. This production shortage led to a limited allocation of available supplies and created a significant risk to providing blood culture testing for our patients.

In response to the shortage, Cleveland Clinic rapidly assembled a multidisciplinary team of stakeholders, which included Laboratory Stewardship, Clinical Microbiology Laboratory, Epic/ITD, Laboratory Medicine, Infectious Disease, Nursing Education, and Supply Chain Management.

A series of interventions were implemented to conserve supply, emphasizing best practice guidance for blood culture collection and decreasing overutilization. To the great credit of the teams involved, these interventions maintained both our necessary supply and the accepted standard of care until we could transition to a different manufacturer with an available supply in August of 2024.

Being able to maintain standard of care was a unique success of Cleveland Clinic, which differentiated it from many other hospital systems; this success was only possible because of the strong team of teams at Cleveland Clinic.

Our emphasis on best practices has resulted in lasting change, with decreased blood culture utilization still seen into 2025. In total, 22,195 blood cultures were conserved in 2024, which translates to an enterprise cost avoidance of $194,650.

3. CMV Drug Resistance Testing Stewardship – *Complete*

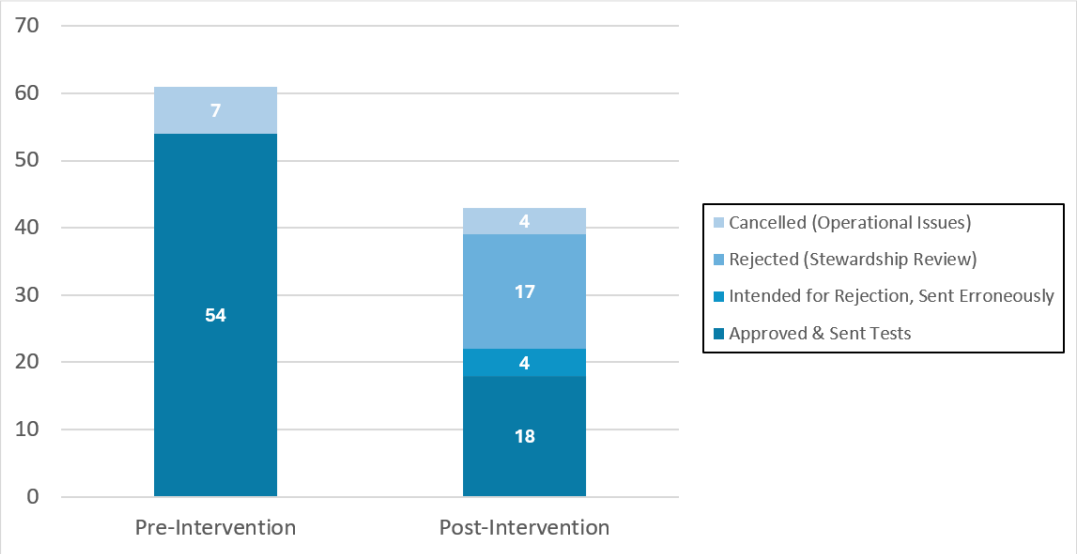
In 2024, a multidisciplinary group from Microbiology and Infectious Disease evaluated the number of cytomegalovirus (CMV) drug resistance tests ordered, costs saved, and rates of drug resistance detected before and after the implementation of a laboratory stewardship initiative.

In the post-intervention group, CMV resistance tests were reviewed for appropriateness by a team of transplant, infectious disease, and laboratory specialists before sending and performing the test, including the CMV viral load associated with each test, and the prevalence of resistance genes detected.

54 tests were ordered in the pre-intervention group (6.8 tests/month), and 39 tests were ordered in the post-intervention group (4.9 tests/month). As a result of the stewardship intervention, 17 tests (43.6%) were cancelled in the post-intervention group for reasons including low viral load, duplicate testing, and testing too early into CMV treatment. This led to total cost savings of $14,025.

Prospective audit and stewardship of CMV resistance test orders reduced the overall number of inappropriate tests performed and was associated with health system cost savings.

Breakdown of Cancelled, Rejected, and Approved CMV Antiviral Resistance Tests



4. New Test & Project Request Reviews - *Ongoing*

LSC received **83 test requests** and **12 project requests** during 2024.

LSC leadership, clinical subject matter experts, laboratory medical directors, and other subject matter experts jointly review submissions depending on the type of request (e.g. send-out test request, genetic test, etc.). The evaluation of new send-out test requests involves close collaboration with Dr. Grace Kroner, Medical Director of PLM Send-Out Testing.

Of the 83 test requests:

- 81 tests were approved for definition based on the clinical need to provide optimal patient care, adequate literature to support the test use, and consideration of the financial impact to the patient and institution.
    - Five were submitted by clinical staff.

  - Four were submitted by PLM staff.
  - Ten requests were related to new electronic interfaces with reference laboratories.
  - 62 requests were expedited reviews based on evaluation of historical miscellaneous test orders.
- Two of the new test requests were denied.

All 12 project requests received approval from the LSC:

- Nine requests were to discontinue outdated, inappropriate, or duplicative test options.
- Two requests were for initiation of proactive test review programs, one of which is highlighted above (CMV Drug Resistance Testing Stewardship).
- One request was for clinical decision support for hematologic NGS panel ordering.

Implementation of these projects is at various stages, dependent on current ITD and PLM resources.

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Test Requests
Clinical requests: 7AlphaC4 for Bile Salt Diarrhea Autoimmune Myelopathy Panel Basophil Activation Test PBC Serology (sp100, gp210) Stiff Person Syndrome Panel **PLM requests:** Acute Leukemia Monitoring CD52 Cell Expression Evaluation by Flow Cytometry Killer-Cell Immunoglobulin-like Receptor (KIR) Panel by Flow Cytometry Lyme Antibody Testing in CSF **Interface requests:** Ten test requests for Caris, Invitae, and Tempus electronic interfaces **Requests based on historical MISC orders:** Acanthamoeba PCR Allergen Test Definitions (32 total) ALPS Panel by Flow Cytometry Anti-Drug Antibodies for Fabry and Pompe Disease Aripiprazole Chitotriosidase Assay Disaccharidase in Tissue Fabry and Gaucher Disease Biomarkers FLT3 MRD Assay hATTR Amyloidosis Sponsored Test Hereditary Cancer Genetic Test (Myriad) HEX4, Urine HHV8 - Human Herpes virus 8 (HHV-8) by Quantitative PCR Metagenomic Next-Generation Sequencing (mNGS), Plasma (Karius) Mucorales by PCR NMDAR Antibody [N-methyl-D-Aspartate Receptor] Oxysterols Partial D Pediatric Immunology: CD107a Pediatric Immunology: Lymphocyte Antigen Stimulation Pediatric Immunology: Perforin/Granzyme B Pediatric Immunology: PSTAT5

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Pediatric Immunology: SAP and XIAP
Pediatric Immunology: TH17 Enumeration
Red Cell Genotyping Panel
Telomere Biology Disorders Panel
Telomere Length Measurement
Tubular Reabsorption of Phosphorus
Ustekinumab
Vedolizumab
Weak D

Denied requests:
Galleri
Mycoplasma IgM Antibody

Project Requests

CMV Drug Resistance Testing Stewardship
Advanced Molecular Diagnostics Stewardship
Clinical Decision Support of Hematologic NGS Panel Ordering

Test Discontinuation Requests:
CKMB
Euglobulin Lysis
Farr Assay
HIV-2 PCR
HSV IgM Antibody
Listeria Antibody
Pediatric Allergen Profile & Allergen Food Panel RL1
Serotonin Release Assay- Low Molecular Weight Heparin
Urine Free Light Chain

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01

Hard Stop Alerts

2024 Updates

Launched in 2011, the Hard Stop Alert is now embedded in Cleveland Clinic culture.

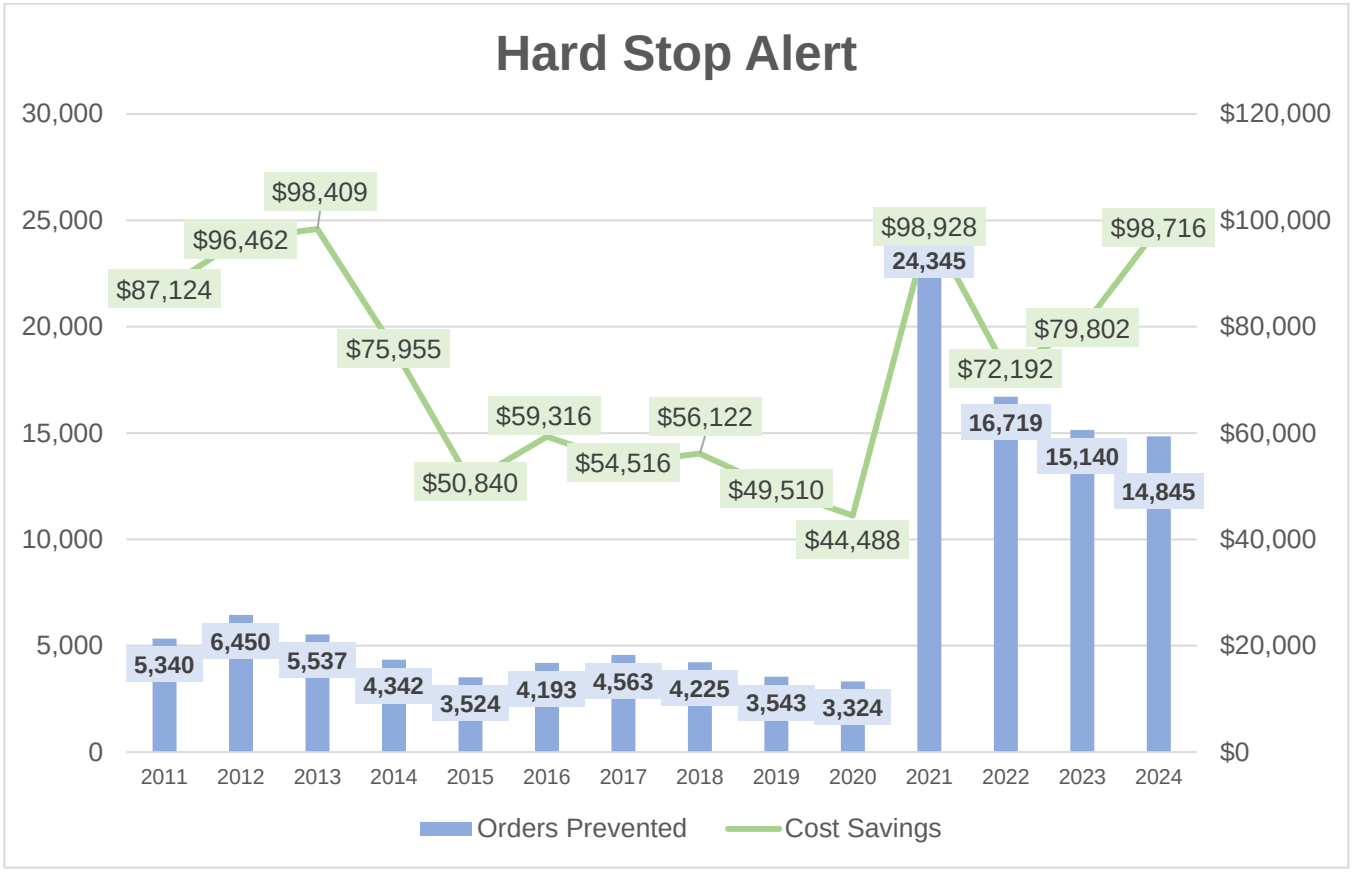
This clinical decision support tool notifies providers who attempt to order a test on the Hard Stop list. Tests that trigger a Hard Stop Alert include those that should not be repeated within 24 hours and constitutional / selected germline genetic tests.

If a provider attempts to order a test on the Hard Stop list, an alert will appear to notify the provider. To prevent duplicate testing, the Hard Stop will display previous test results.

A user cannot electronically bypass a Hard Stop; however, if the duplicate test is necessary for patient care, the ordering provider may contact PLM Laboratory Client Services to receive a code to override the intervention.

In 2024, the alert fired **14,952 times**.

- **107 (0.7%) override requests** resulted in a test performed, demonstrating a **99% alert success rate**.
- **14,845 unnecessary duplicate tests** were prevented for a **total savings of $98,716**.
- Related significant benefits include **reduced patient blood draws** and **savings of phlebotomist time.**



*Since 2011, Hard Stop Alerts have prevented **116,090 unnecessary tests** for a **total savings of $1,022,380.***

**The increase seen in 2021 was related to the addition of CBC w/diff and C-reactive protein (CRP) to the Hard Stop Alert list.*

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02

Restricted Use

2024 Updates

The Restricted Use initiative limits the ordering of molecular genetic tests to providers for whom these tests are a routine part of their practice.

This initiative intends to decrease the use of unnecessary and often costly molecular genetic testing and to improve the care of patients tested. Such tests are restricted to “deemed users” (e.g., Pediatric Neurology).

Inpatient genetic testing is restricted to the Medical Genetics Service. If a provider believes that a Restricted Use molecular genetic test is required for an inpatient, a Medical Genetics consult is required before the test can be ordered.

Although the number of tests prevented is low, the cost per test is high, which has resulted in substantial savings.

In 2024, 282 **unnecessary molecular genetic tests** were avoided for a **total savings of $154,278**.

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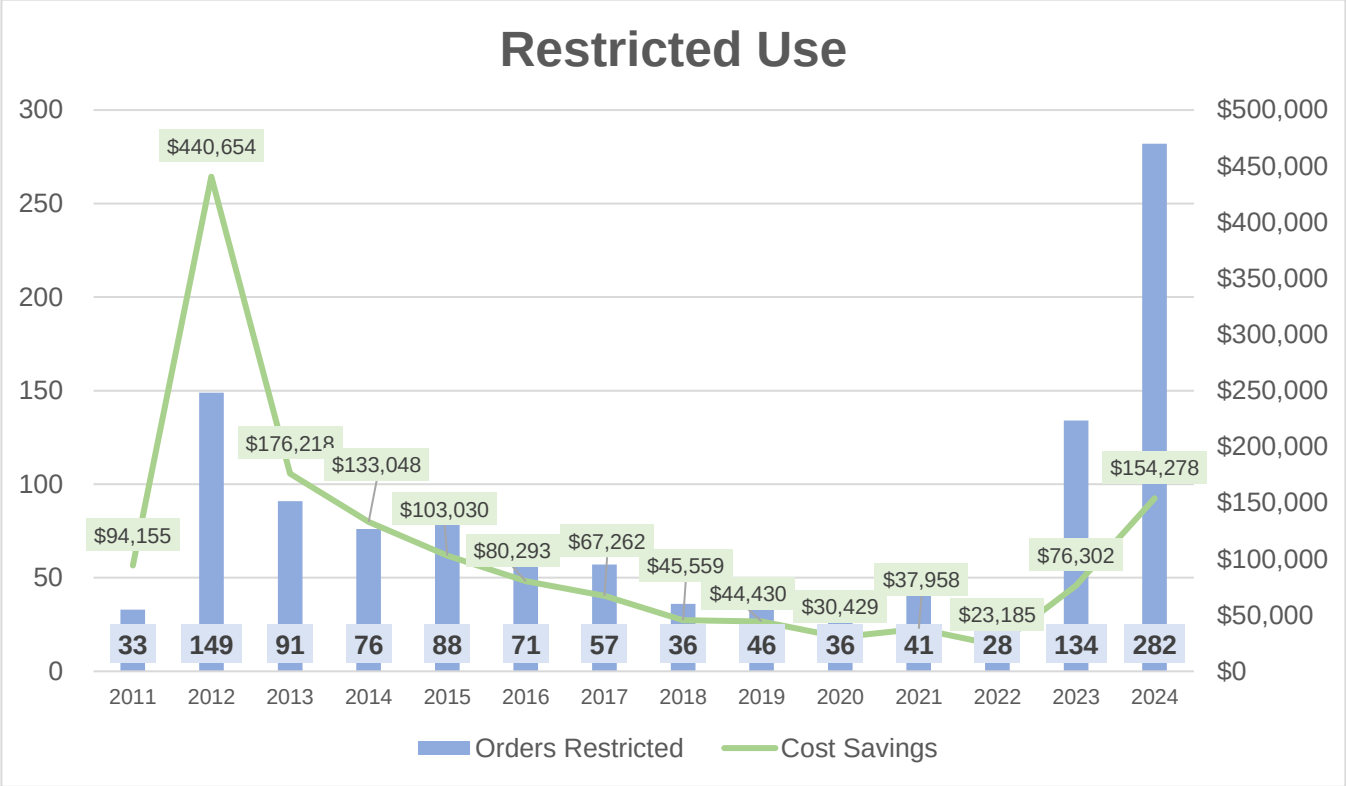

Since late 2011, the Restricted Use initiative has prevented

***1168 unnecessary molecular tests** for a **total savings of $1,506,800**.*

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03

Laboratory Genetic Counseling

2024 Updates

Utilizing genetic counselors within the laboratory is a proven laboratory stewardship strategy.

PLM Laboratory Genetic Counselors review genetic test orders—including clinical indications—before testing occurs. These highly knowledgeable professionals participate in the sign-out of complex genetic test results (e.g. chromosomal microarray analysis and next-generation sequencing) and provide pre-analytic value through test selection guidance and triage.

Working directly with ordering providers, genetic counselors ensure that the provider's ordered test is the optimal choice for the patient and may suggest alternative approaches to consider if necessary.

The laboratory genetic counselors also advise clinicians about the potential patient costs and insurance authorization requirements associated with genetic testing. They were involved in developing the new order entry programming to alert Revenue Cycle Management to submit insurance preauthorization requests. Although a notable achievement, there is still much work to do in the area of preauthorization.

In 2024, the laboratory genetic counselors began tracking the cytogenetic tests that were changed or cancelled because of sample triage. 118 cytogenetic test requests were changed or canceled, resulting in an estimated cost savings of $38,294. Review of genetic test send out requests resulted in 252 tests being changed or canceled, with a cost savings of $163,006. Combined, the intervention and guidance from the laboratory genetic counselor team resulted in 370 genetic tests being changed or canceled with an estimated cost savings of $201,300 for 2024.

In 2024, **370 genetic** test requests were changed or canceled, resulting in a **cost savings of $201,300.**

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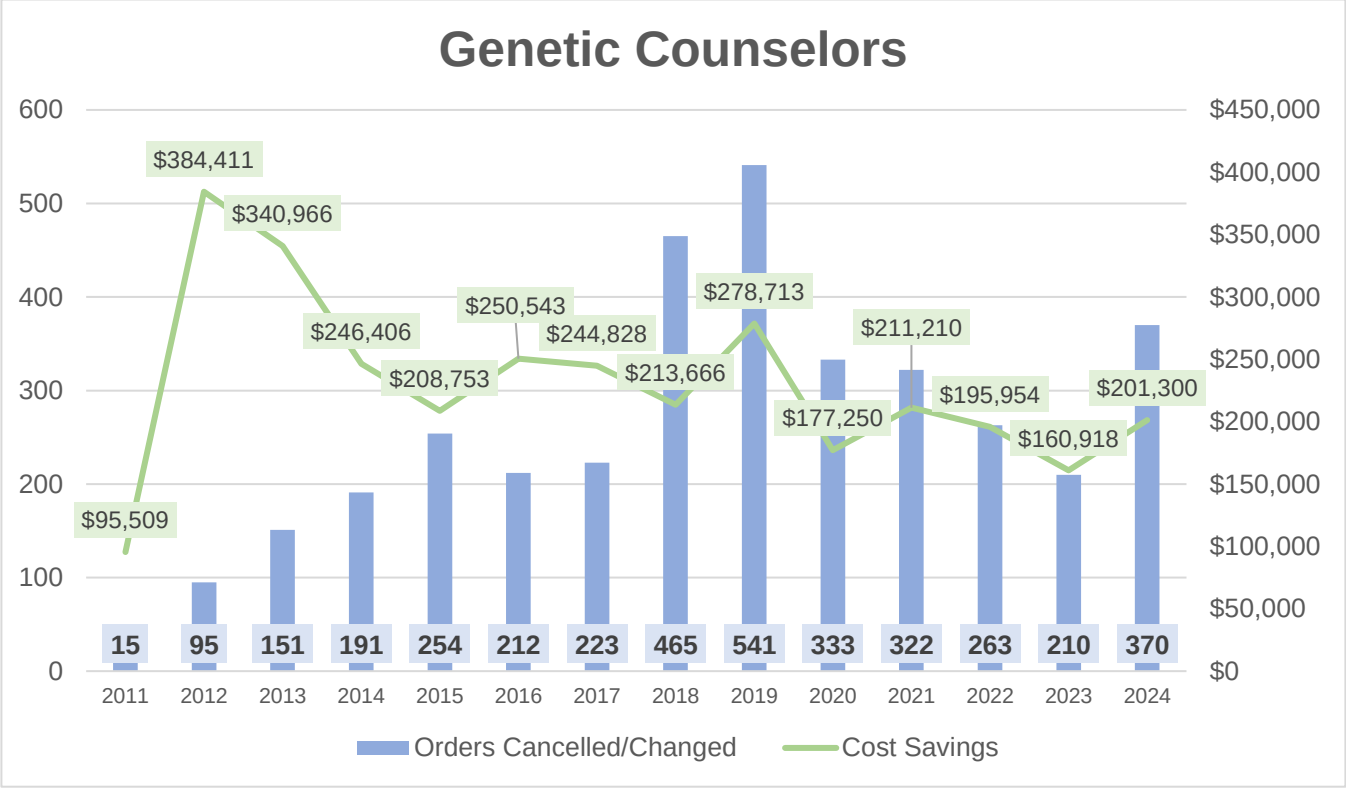

*Since 2011, Laboratory Genetic Counselors have prevented **3,645 unnecessary tests** for a **total savings of $3,210,427**.*

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04

Regional Soft Stop Alerts

2024 Updates

Soft Stop Alerts allow for the flexibility necessary in certain practice settings.

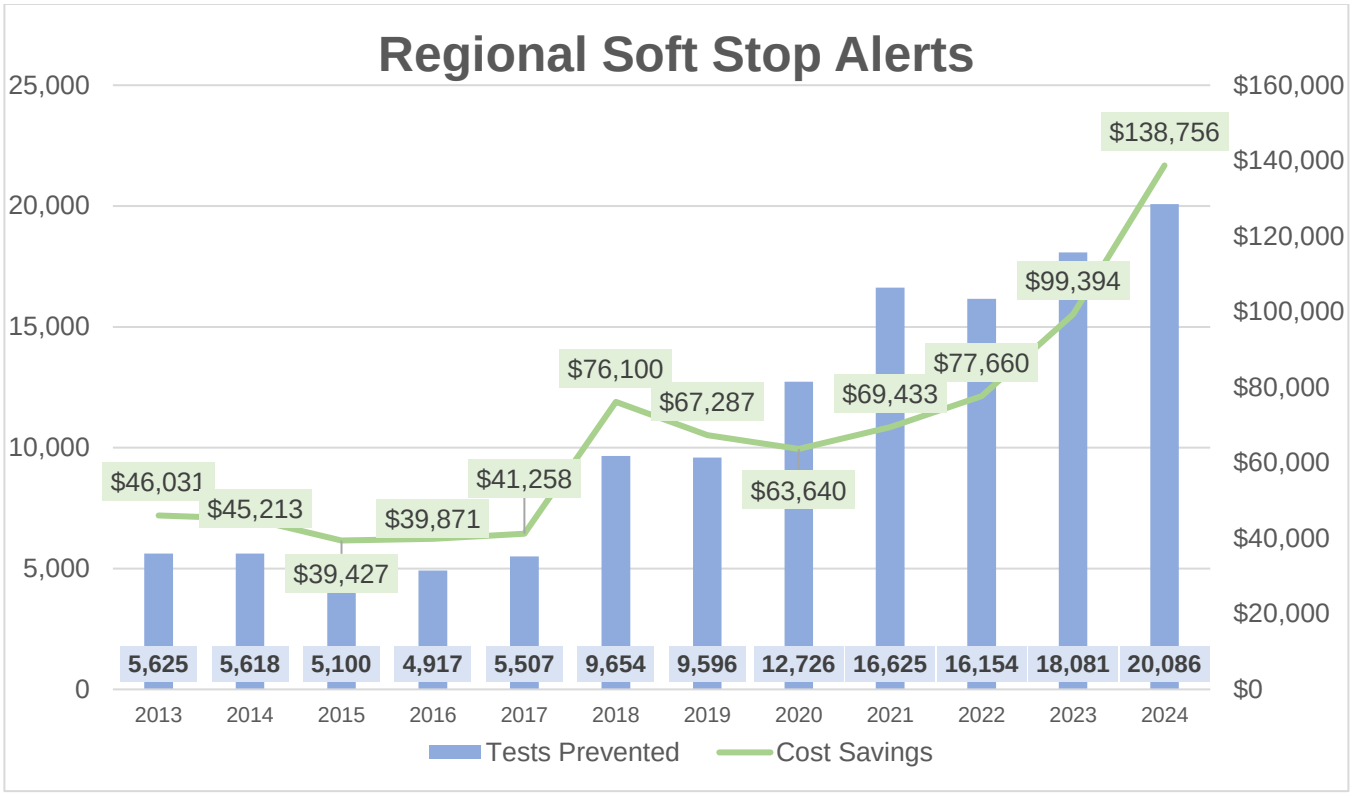
Hard Stops are not always optimal for Cleveland Clinic's Regional Hospitals for several reasons, such as provider mix and incomplete provider use of electronic order entry. A thorough investigation determined that a bypassable duplicate order notification is often the most effective solution in these settings.

A Soft Stop Alert appears when a provider attempts to order a duplicate test within a specified timeframe. Like a Hard Stop, this alert displays previous test information if available. Although they are discouraged from proceeding with a duplicate test, in contrast to a Hard Stop, providers can independently override the Soft Stop Alert from their workstation without assistance.

The development of Soft Stop Alerts expands the best practices and cost-savings achieved through Hard Stop Alerts implemented at Main Campus to regional locations. We plan to extend hard stops across the regional locations in 2024 in place of utilizing soft stops.

In 2024, Soft Stop Alerts deterred **20,086 unnecessary duplicate tests**, yielding a **cost savings of $138,756**.

- Because they can be bypassed, *Soft Stop Alerts* are only ~**15% effective** in stopping duplicate orders.
    - There is a trend towards a higher percentage of dismissed Soft Stop Alerts over time.
- In comparison, *Hard Stop Alerts* are **99% effective**.



*Since 2013, Regional Soft Stop Alerts have prevented **129,689 unnecessary tests** for a **total savings of $804,069**.*

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05

Expensive Test Notifications

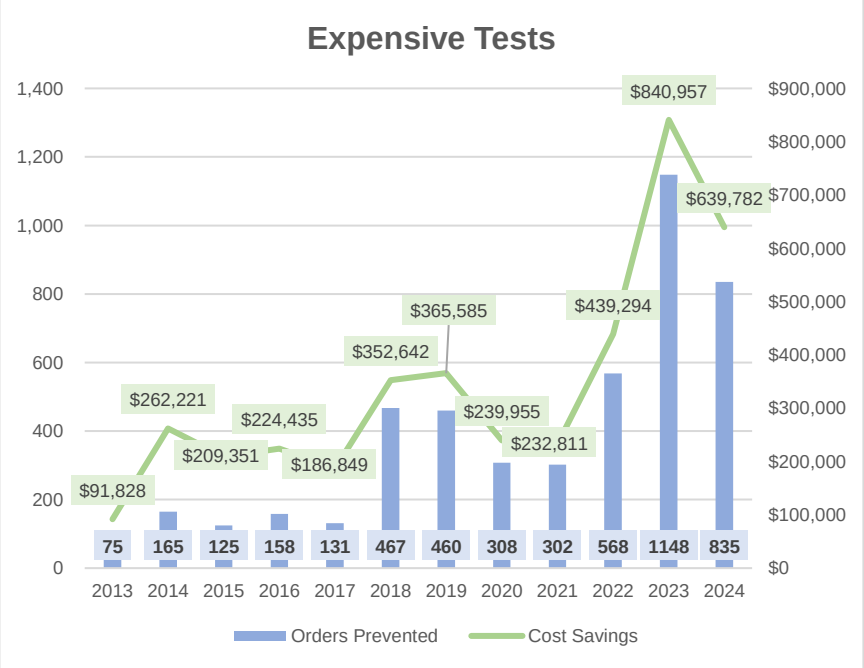
2024 Updates

Expensive Test Notifications alert providers when a test costs $500 or more.

With the ever-growing list of activities involved in patient care, providers may be unaware of costs associated with the services that they recommend.

By informing them of the price at the time of ordering, providers can evaluate other diagnostic approaches and engage the patient in discussions about their options, since insurance may not fully cover these costs. Following tests that exceed $500, notifications are categorized in $1,000 increments (>$1,000, >$2,000, etc.).

In 2024, 835 **expensive tests** were avoided for a **total savings of $639,782**.



Since August 2013, **4,742 expensive tests** have been avoided and **saved $4,085,708**.

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06

Extended Time Hard Stop

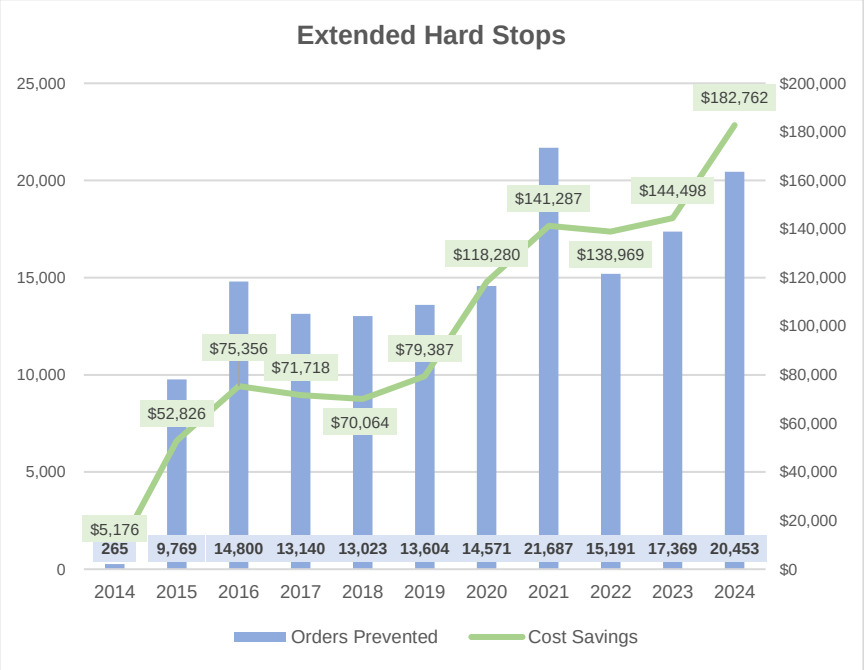
2024 Updates

Extended Time Hard Stops activate if a provider places a duplicate test order within a specified timeframe (e.g. >24 hours).

Multiple areas and Institutes—including Quality, Infectious Diseases, Infection Prevention, Internal Medicine, and Endocrinology—assisted in creating extended hard stops for *C. difficile* PCR (7 days) and hemoglobin A1c (30 days).

Several additions have been made to the Extended Hard Stop list, including molecular hematopathology tests, serum and urine protein electrophoresis (21 days), and the respiratory pathogen panel (14 days).

In 2024, **20,452 unnecessary duplicate tests** were prevented for a **cost savings of $182,762**.



Since November 2014, **153,871 duplicate tests** have been avoided and **saved $1,080,381**.

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07

Once-in-a-Lifetime Test Alert

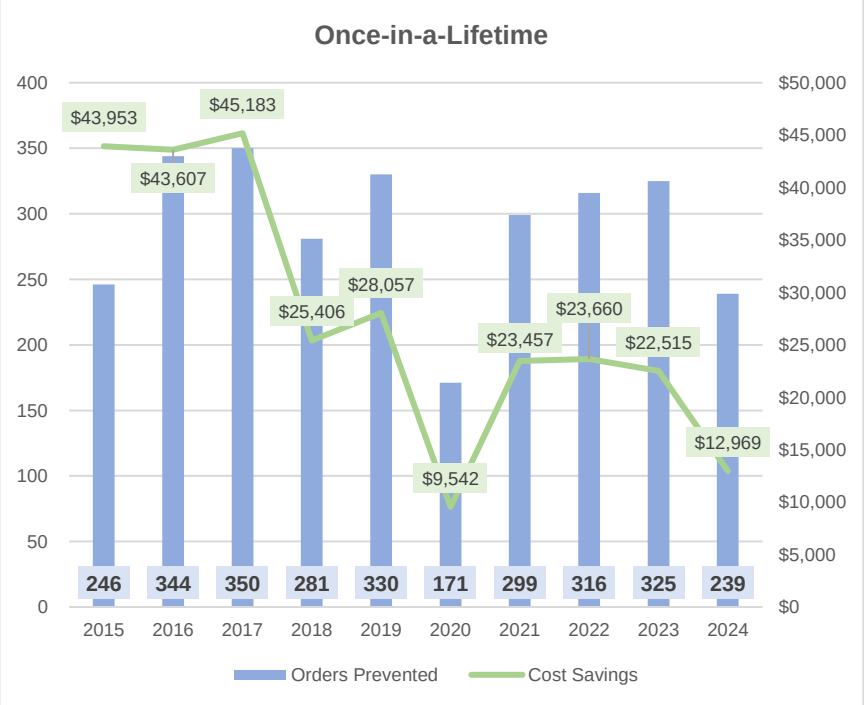
2024 Updates

The results of constitutional genetic tests do not change, meaning that these types of tests need to be performed only once in a patient's life.

Since its implementation in 2015, the Once-in-a-Lifetime (OIAL) intervention stops constitutional genetic tests that are unnecessarily re-ordered and informs the provider that the test has already been performed.

If necessary for patient care, the provider can circumvent this intervention by calling PLM Client Services for an override code.

In 2024, **239 repeat OIAL tests** were prevented for a **total cost savings of $12,969**.



Since August 2013, **2,901 OIAL tests** were prevented and **saved $278,349**.

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2024 Updates

08

Inpatient Stool Culture / O&P Alert

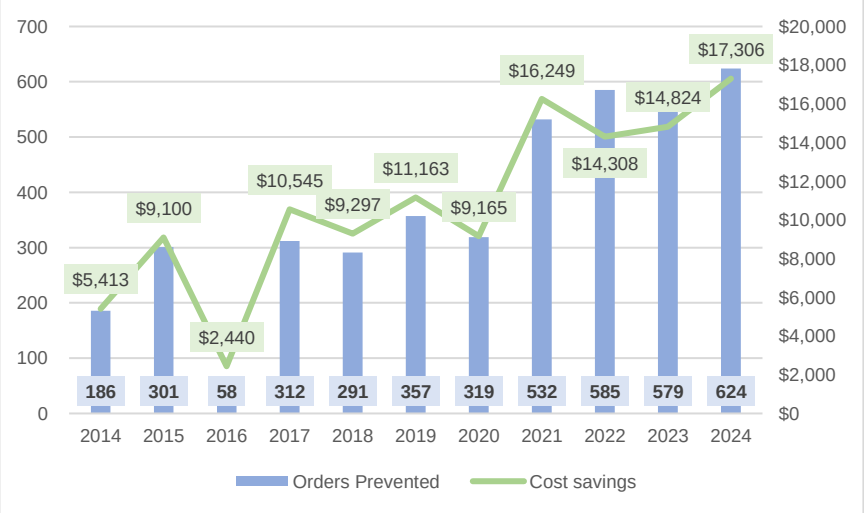
There is substantial evidence regarding the lack of utility of routine stool cultures and ova & parasite (O&P) exams for patients that develop diarrhea after three days of hospitalization.

Implemented in 2014, this initiative prevents the ordering of stool cultures and/or O&P exams placed after three days of a patient's hospitalization.

In July 2021, an additional alert was implemented screening patients for travel and/or exposure to contaminated food products, and guiding providers to select either a comprehensive O&P exam or an O&P screen based on this information.

If necessary for patient care, providers can circumvent this alert by calling PLM Client Services for an override code.

In 2024, **624 unnecessary stool cultures / O&P exams** were prevented for a **total cost savings of $17,306**.



Since 2014, **4,144 unnecessary tests** were prevented and **saved $119,810**.

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09

Optimizing Blood Culture Ordering

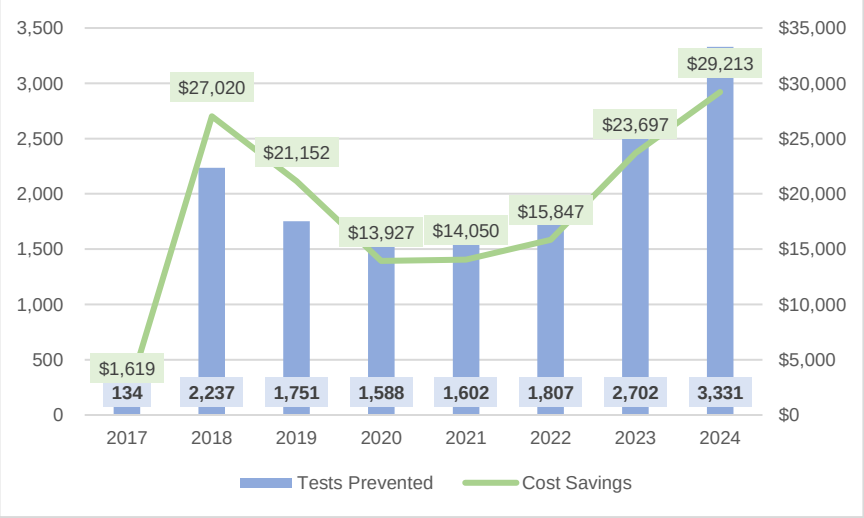
2024 Updates

Collaboration across Cleveland Clinic has resulted in noteworthy cost-savings and quality improvement for blood cultures.

The intensive care units have noted excessive blood culture utilization, where multiple sets of blood cultures are ordered within a 24-hour period. An investigation disclosed that the test naming convention was likely contributing to inappropriate overutilization.

Consensus between ICU Operations, Infectious Diseases, and Clinical Microbiology laboratory led to changes to ensure optimal blood sampling for culture. Additionally, overutilization was addressed with a best practice alert that fires when a blood culture has already been performed in the prior 24 hours. Providers can override this soft stop at the point of order entry.

In 2024, 3,331 **unnecessary blood cultures** were avoided for a **cost savings of $29,213**.



Since late 2017, **15,152 unnecessary blood cultures** were prevented and **saved $146,524.**

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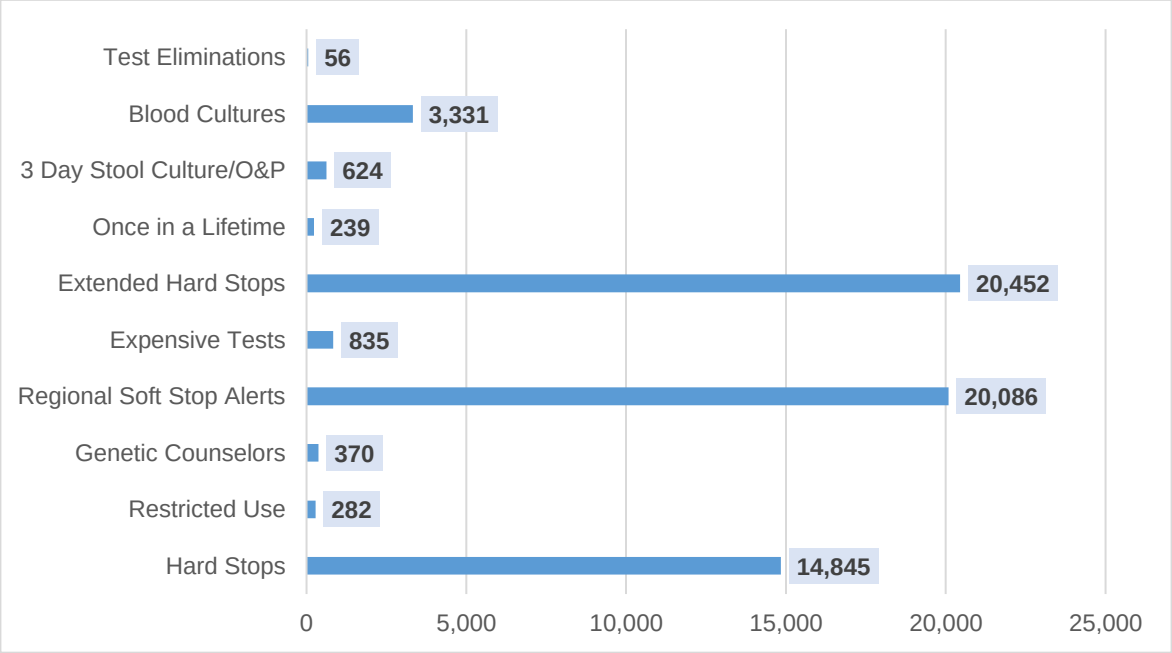
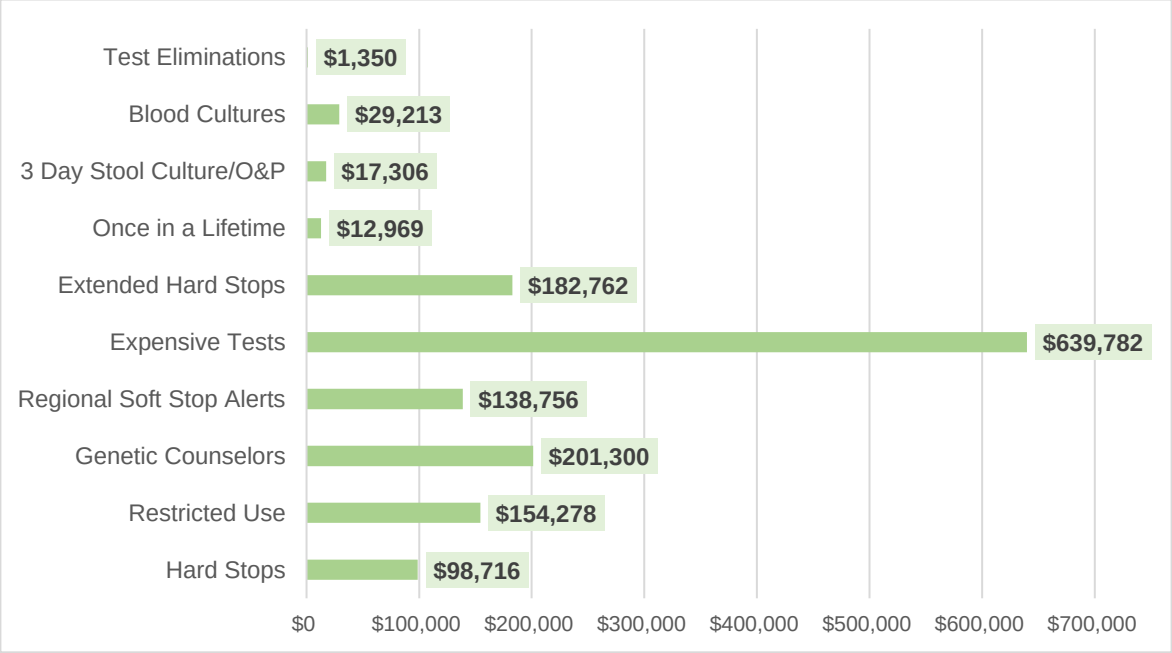
2024 Financial Summary

2024 | **Prevented Tests: 61,120**



2024 | **Cost Savings: $1,476,432**



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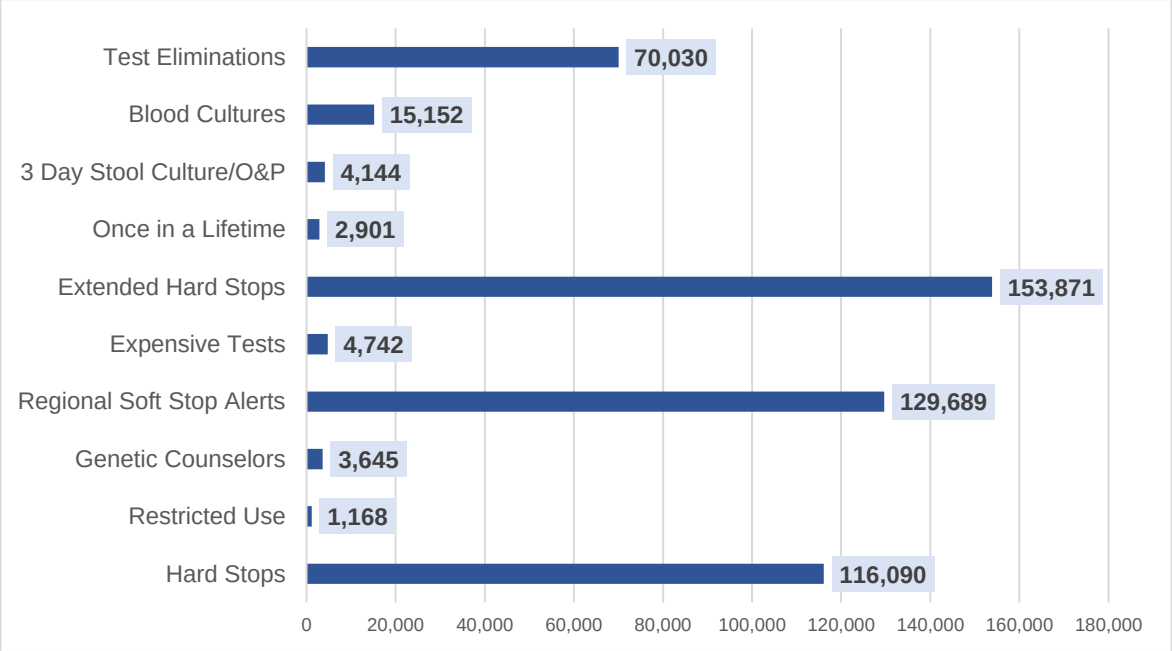
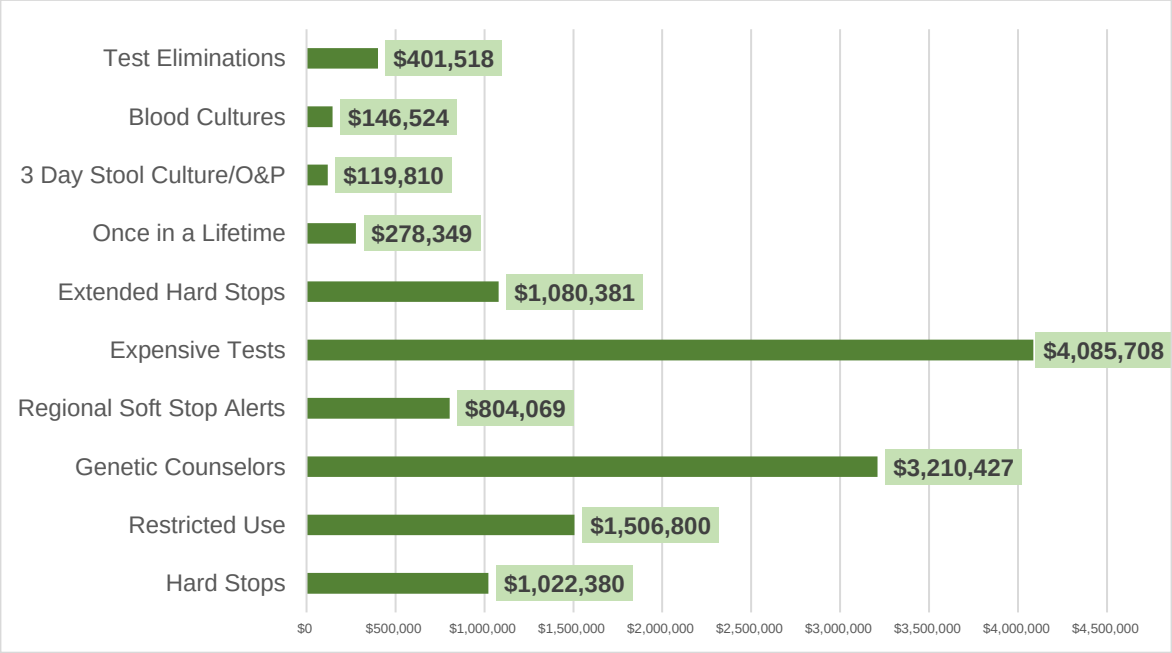
2011 – 2024 Accumulated Totals

LSC Total Prevented Tests: 539,857



LSC Total Cost Savings: $12,777,737



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2025 LSC Goals

1.	Work with PLM Analytics to create dashboards to track laboratory test utilization and cost savings across Cleveland Clinic.
2.	Extend existing Hard Stop Alerts across all Cleveland Clinic Hospitals in partnership with clinical leaders and ITD.
3	Engage with clinical stakeholders to review send-out testing menu, define highly utilized tests and retire outdated testing.
4.	Engage with Cleveland Clinic locations outside of Ohio to implement testing best practices throughout our health system.
5.	Review Hard Stop programming with ITD to ensure optimal performance across ordering locations.
6.	Continue participation with the Patient-centered Laboratory Utilization Guidance Services (PLUGS) network.
7.	Quantify cost savings and other impact associated with each intervention.
8.	Optimize efforts surrounding automated prior authorization of lab tests.

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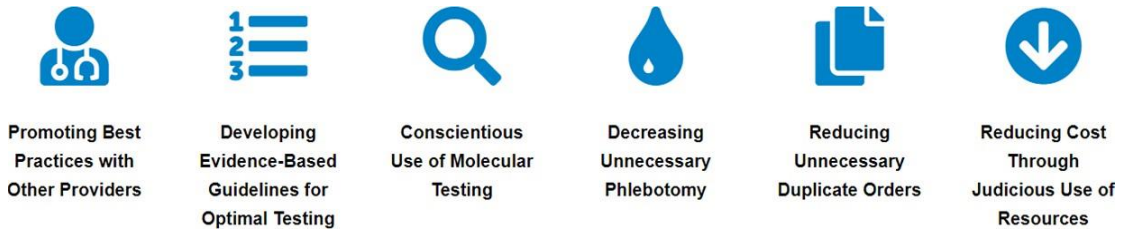
Acknowledgements

These accomplishments result from the tireless efforts, collegial meetings, and great ideas of the Laboratory Stewardship Committee members.

We would also like to thank Dr. Brian Rubin and PLM leadership for their assistance and counsel. Additionally, LSC appreciates the teamwork and collaborative energy from the ITD team, specifically Lauren Fromwiller – they have proven to be great supporters and collaborators, and their insights and assistance are invaluable.



The Right Test for the Right Patient at the Right Time.

Cleveland Clinic

Every life deserves world class care.

9500 Euclid Ave., Cleveland, OH 44195

Cleveland Clinic is a globally integrated multispecialty healthcare system combining hospital and outpatient care with research and education for better patient outcomes and experience. Cleveland Clinic has 80,000 caregivers worldwide, including 5,700 physicians and scientists. The health system consist of 23 hospitals and 256 outpatient locations, including a main campus in Cleveland; 15 regional hospitals in Northeast Ohio; five hospitals in Southeast Florida; a center for brain health in Las Vegas, Nevada; executive health and sports health services at two locations on Toronto, Canada; a hospital and outpatient center in London, United Kingdom; and a hospital and cancer center in Abu Dhabi, United Arab Emirates.
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