Cleveland Clinic

Laboratory Stewardship Committee

2022 Annual Report

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Co-Chairs, Laboratory Stewardship Committee


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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, nurses, and other caregivers. LSC focuses on optimizing testing by addressing over and underutilization to provide the best possible patient care while reducing laboratory testing costs.

This past year, we collaborated with many other groups within and outside Cleveland Clinic, including Functional Medicine, Pharmacy Informatics, Medical Operations, New York Presbyterian Hospital, and Palantir.

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.

The committee's goals include:

- Decreasing unnecessary phlebotomy to improve patient satisfaction while reducing the likelihood of iatrogenic anemia (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.
- 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: http://sp.ccf.org/projects/LSC/SitePages/Home.aspx

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

In 2022, these test order interventions resulted in:

112,612
prevented unnecessary tests

$1,093,543
in cost-savings

Since implementation, these interventions have prevented **415,253 unnecessary tests** and saved Cleveland Clinic **$9,650,405**.

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2022 Completed & Ongoing Projects

Project	Status
1. HIV Phenotyping Tests	**Complete**
2. Daily Inpatient Labs	**Complete**
3. Standard Procedure for Inpatient Genetic Testing	**Complete**
4. Removal of Obsolete Genetic Tests	**Complete**
5. Miscellaneous Test Review	**Ongoing**
6. New Test Request Reviews	**Ongoing**
7. Laboratory Test Utilization Dashboard Development	**Ongoing**

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2022 Completed & Ongoing Projects

1. HIV Phenotyping Tests – *Complete*

Under the leadership of Dr. Grace Kroner and Dr. Daniel Rhoads, HIV Phenotype (SQHIVPHE) and HIV PhenoSense GT (SQHIVPHS) were both converted to lab-only orders.

Genotyping to identify mutations that might confer antiretroviral resistance is preferred to phenotype-based testing. Therefore, to limit confusion and accidental incorrect ordering, the HIV phenotype tests were limited to ordering by the laboratory only.

This change resulted in a savings of **$5,177**.

Reference: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/drug-resistance-testing

2. Daily Inpatient Labs – *Complete*

Daily inpatient lab draws can lead to many unintended consequences, including anemia that requires transfusions, unnecessary downstream testing, and increased length of stay. In addition, current staffing and blood collection tube shortages compound the strain on lab services, which account for up to 25% of hospitalization costs.

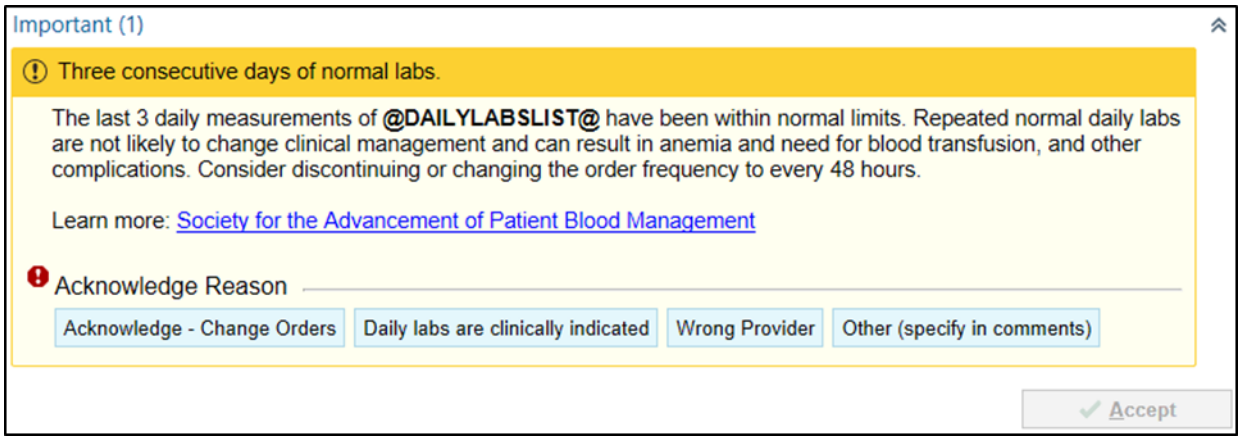
Reducing unnecessary phlebotomy improves patient experience by preventing multiple early awakenings and pain—both of which directly cause patient dissatisfaction—reduces downstream testing and blood transfusions, and prevents harm without impacting care.

These factors led to creating a best practice alert to support lab ordering based on clinical necessity and to notify providers when a specific lab test has been within normal range for the last three days. It encourages them to discontinue that daily lab or decrease the frequency if appropriate.

This BPA went live throughout Cleveland Clinic on March 15, 2022, and affected the following tests:

Complete Blood Count *CBC*	**Phosphorus** *PHOS*	**Activated Partial Thromboplastin Time** *PTT*
Basic Metabolic Panel *BMP*	**Magnesium** *MG1*	**Renal Function Panel** *RFP*
Complete Metabolic Panel *CMP*	**Prothrombin Time** *PT*	**Hepatic Function Panel** *HFP*

The BPA displays once per day in Chart Review, Manage Orders, and at the point of placing orders.



This intervention prevented 60,981 unnecessary tests and associated patient phlebotomy, resulting in a cost savings of $92,474.

3. Inpatient Genetic Testing Standard Operating Procedure - *Complete*

Following extensive multidisciplinary meetings with representation from Cleveland Clinic's LSC, RT-PLMI, Center for Personalized Genetic Healthcare (CPGH), Neonatology, Pediatric Neurology, and Center for Bioethics, new policies and procedures for governing the ordering of germline genetic testing on inpatients—developed by RT-PLMI leadership and CPGH—are now available for Cleveland Clinic.

The Inpatient Germline Genetic Testing standard operating procedure (SOP) was approved in December 2021 and is available for Cleveland Clinic providers at: https://ccf.policytech.com/dotNet/documents/?docid=70273.

This SOP serves as a guide and resource for circumstances in which germline genetic testing may be appropriate for an inpatient in Ohio, including peri-mortem scenarios. It also ensures that hereditary genetic tests ordered in the inpatient setting directly support improved outcomes and shortened hospital stays for patients, as well as a process for communicating results if the patient is discharged from the hospital before hereditary genetic test results are known.

Bi-annual meetings between stakeholders from RT-PLMI, clinicians, and bioethics occur to evaluate the impact of this procedure, which included reviewing nine patient cases.

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Additional outcomes of these meetings include a new dashboard to track inpatient testing metrics and SOP revisions for indications outside of inpatient management.

4. Removal of Obsolete Genetic Tests - *Complete*

Determining most appropriate hereditary genetic test ordering is challenging. Providers should individualize test ordering based on the patient's personal and family histories, as well as insurance and billing considerations.

RT-PLMI's Laboratory Genetic Counselors (LGCs) worked with the LSC and laboratory send-outs team to identify 58 genetic tests deemed to be obsolete. These obsolete tests were removed from the Test Directory and are not available as order options in Epic. Removal of these tests is aimed at assisting providers in ordering optimal constitutional genetic testing for their patients and reducing the chance of incorrect or unnecessary testing.

As always, ordering providers may always contact the Lab Genetic Counselors for clarification and guidance about test selection and ordering. Reaching out to the LGC team also provides a referral method to the Clinical Genetics team to evaluate and coordinate personal genetic testing if necessary.

5. Miscellaneous Test Reviews - *Ongoing*

Since 2011, the Laboratory Genetic Counselor team has reviewed several types of defined and miscellaneous genetic test orders through Genetic Test Reviews (GTR).

In July 2022, the RT-PLMI Send-Out team initiated a review process that uses the same framework as a GTR. The starting goal was to review miscellaneous requests for chemistry tests, including biochemical genetics, endocrinology, therapeutic drug monitoring, toxicology, and trace metal testing. (Miscellaneous tests refers to tests that are not defined by name in Epic or the Test Directory)

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

Since starting the review process, 671 orders have been reviewed, one-third of which were from reference laboratory clients through RT-PLMI's outreach division, Cleveland Clinic Laboratories. Of these 671 tests, approximately 4% (27) were canceled or changed.

In addition, this new review process triggered IT investigations into at least nine defined tests to identify whether technical problems were causing providers to order genetic tests through the "miscellaneous test" route. Identifying high-volume miscellaneous test requests enables a new pathway for new test submission to the Laboratory Stewardship Committee or highlights the need for educational materials to discourage inappropriate test ordering.

6. New Test and Project Request Reviews - *Ongoing*

LSC received 27 test and ten project requests during 2022, which are outlined in the table on page 11.

LSC leadership, clinical subject matter experts, laboratory section heads, 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 RT-PLMI Send-Out Testing.

Of the 27 test requests:

- Eleven new tests were approved or defined for send-out 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.
    - Of these eleven tests, five underwent expedited approval.
- Twelve tests were removed, nine of which underwent expedited approval.
- One new test request was denied due to a lack of authoritative guidelines or clinical utility supporting the use of the test.

Of the ten project requests, all received approval from the LSC.

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

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Testing Requests	
New Tests:	**Removed Tests:**
Anti-cN-1A (NT5c1A) antibody testing	Epstein-Barr Virus (EBV) EA IgG
Biocept CNSide	*Anaplasma phagocytophilum/E. chaffeensis* microscopic evaluation
CD45 RA/RO	Cytomegalovirus Rapid Culture
Chlamydia serovars by PCR (LGV)	*H. pylori* IgA test
CXC chemokine receptor type 4 (CXCR4)	Giardia Antigen Stool EIA
GVHD Magic Biomarkers	Herpes Simplex Virus 1/2 Antibody (IgM), IFA with Reflex to Titer, Serum
M. hominis PCR on fluid/tissue	HIV-1 Integrase Genotype
Myriad Foresight Carrier Screen, Myriad Fundamental Plus Panel	Specific food allergy panels, FOODS + FOODAD
von Willebrand (VWF) Sequencing	Lipoprotein receptor-related protein-4
VWF GPIbM Activity	Mycoplasma culture/PCR on BAL specimens
	Phospholipase A2 Receptor Ab

Project Requests
Anemia reflex
Hard Stops across CCF
Send-out kit collection
Lab Utilization dashboard development
Non-genetic miscellaneous test view by RT-PLMI residents
Outpatient HgbA1c, Lipid panel, Vitamin D, TSH
Send-out test review by section
Streamlining myeloproliferative neoplasm next-generation sequencing (MPNNGS) orders
TPMT phenotype BPA

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01

Hard Stop Alerts

2022 Updates

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

This clinical decision support tool (CDST) 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 RT-PLMI Laboratory Client Services to receive a code to override the intervention.

In 2022, the alert fired **16,859 times**.

- **140 (0.8%) override requests** resulted in a test performed, demonstrating a **99% alert success rate**.
- **16,719 unnecessary duplicate tests** were prevented for a **total savings of $71,192**.
- Related significant benefits include **reduced patient blood draws** and **savings of phlebotomist time.**

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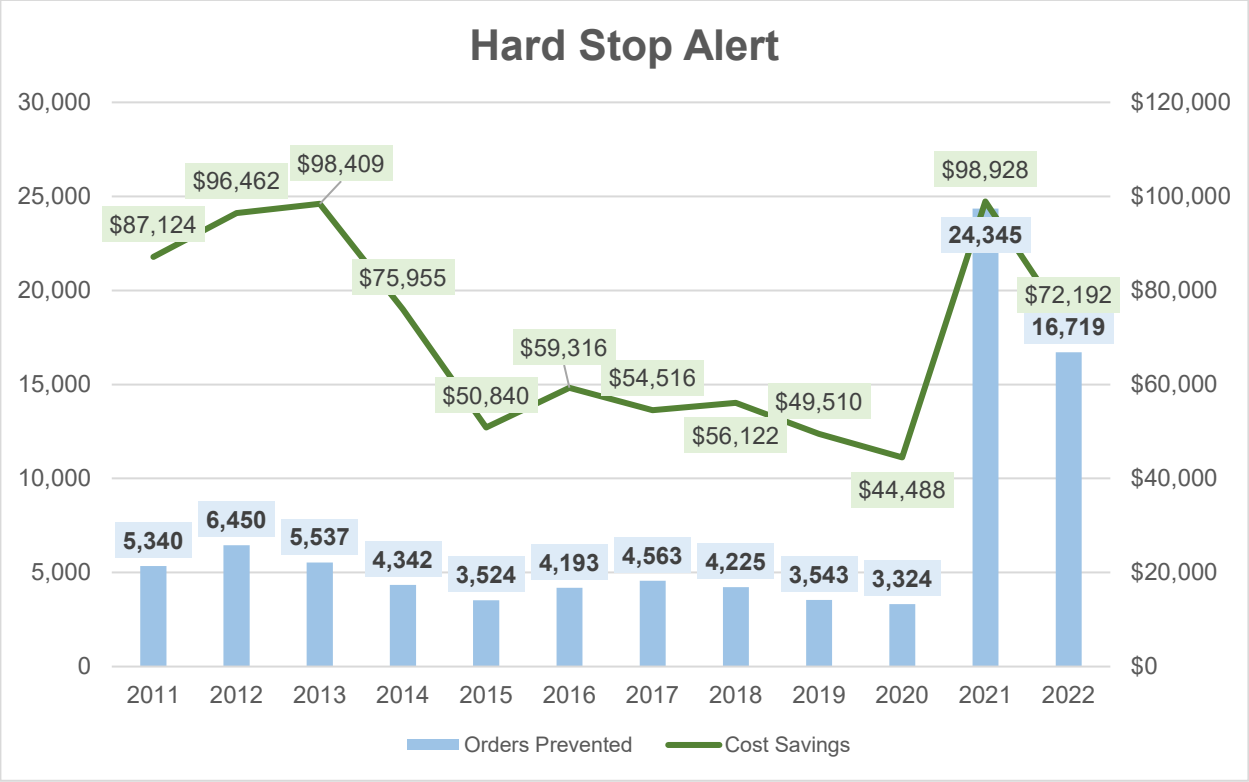

*Since 2011, Hard Stop Alerts have prevented **86,105 unnecessary tests** for a **total savings of $843,862.***

**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

2022 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 2022, **28 unnecessary molecular genetic tests** were avoided for a **total savings of $23,185**.

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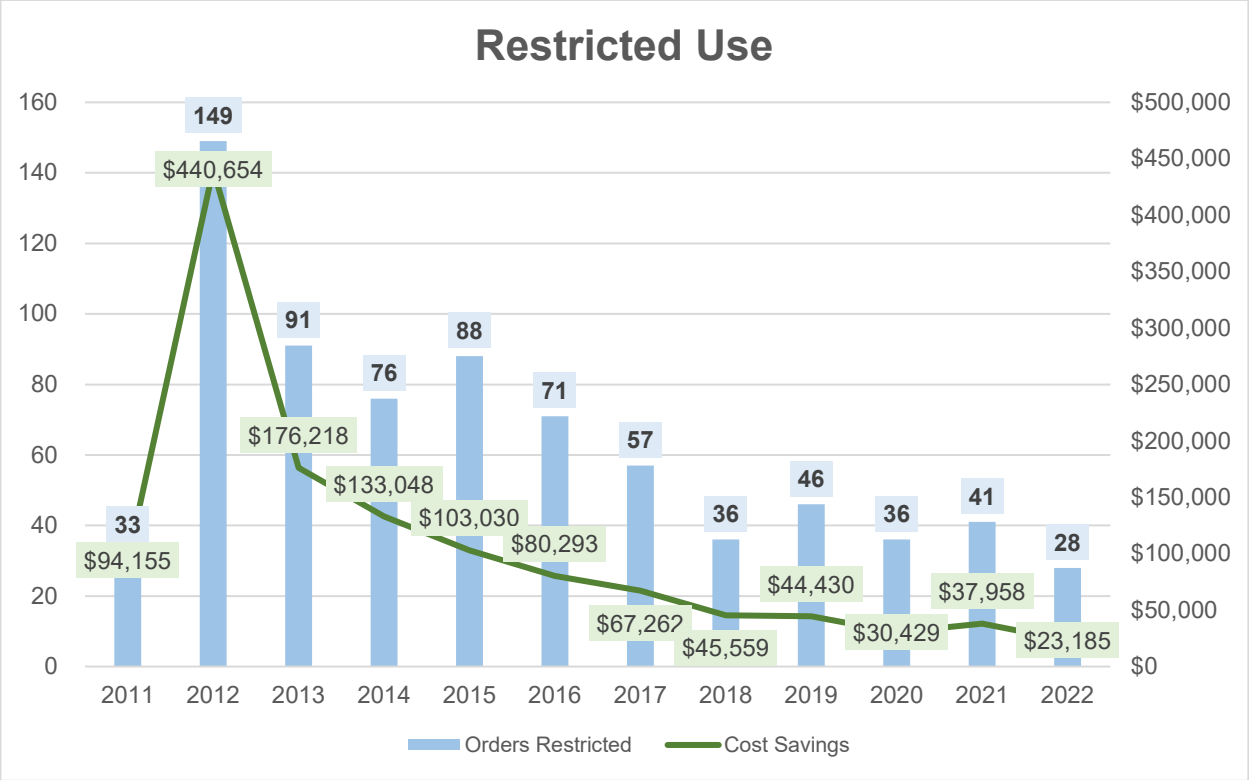

Since late 2011, the Restricted Use initiative has prevented

***752 unnecessary molecular tests** for a **total savings of $1,276,220**.*

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03

Laboratory Genetic Counseling

2022 Updates

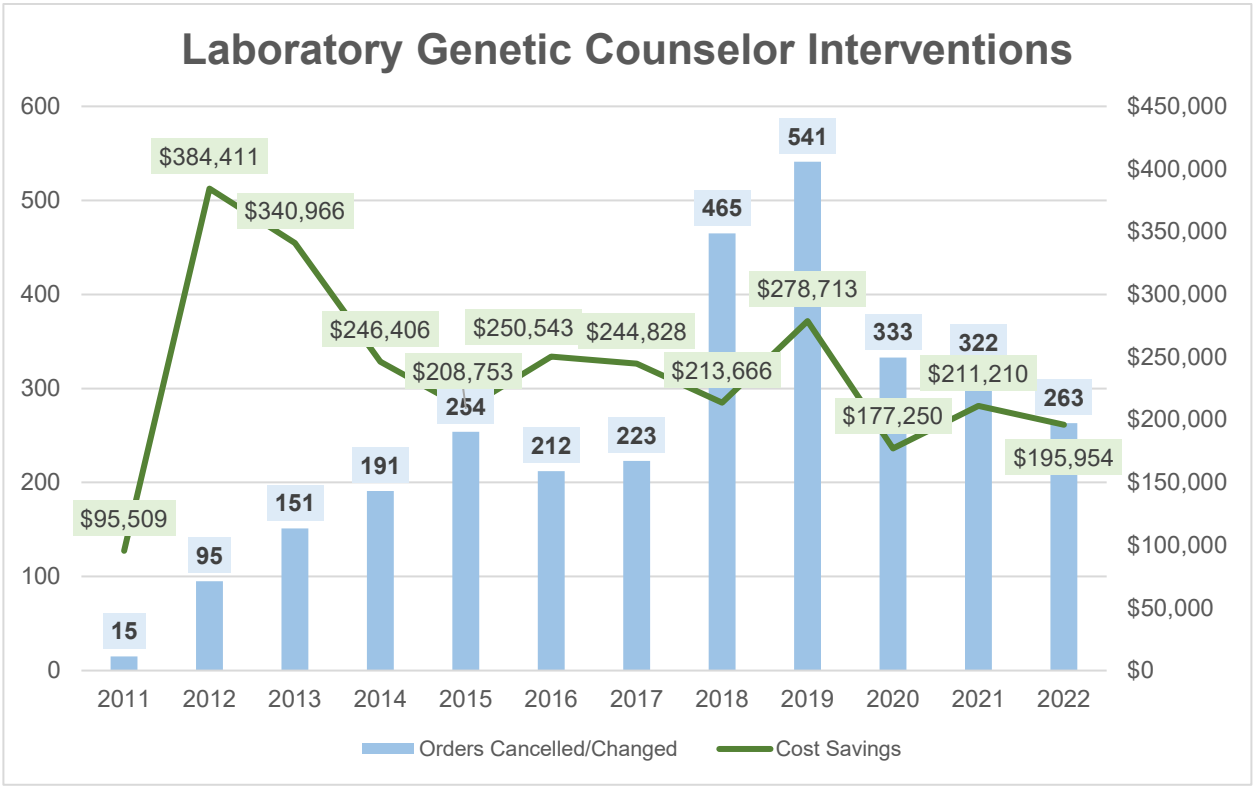
Utilizing genetic counselors within the laboratory is a proven laboratory stewardship strategy.

Cleveland Clinic's Laboratory Genetic Counselors in RT-PLMI 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 2022, **263 genetic** tests were changed or canceled, resulting in a **cost savings of $195,954**.



*Since 2011, Laboratory Genetic Counselors have prevented **3,065 unnecessary tests** for a **total savings of $2,848,209**.*

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04

Regional Soft Stop Alerts

2022 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. Similar to 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 2023 in place of utilizing soft stops.

In 2022, Soft Stop Alerts deterred **16,154 unnecessary duplicate tests**, yielding a **cost savings of $77,660**.

- Because they are bypassable, *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**.

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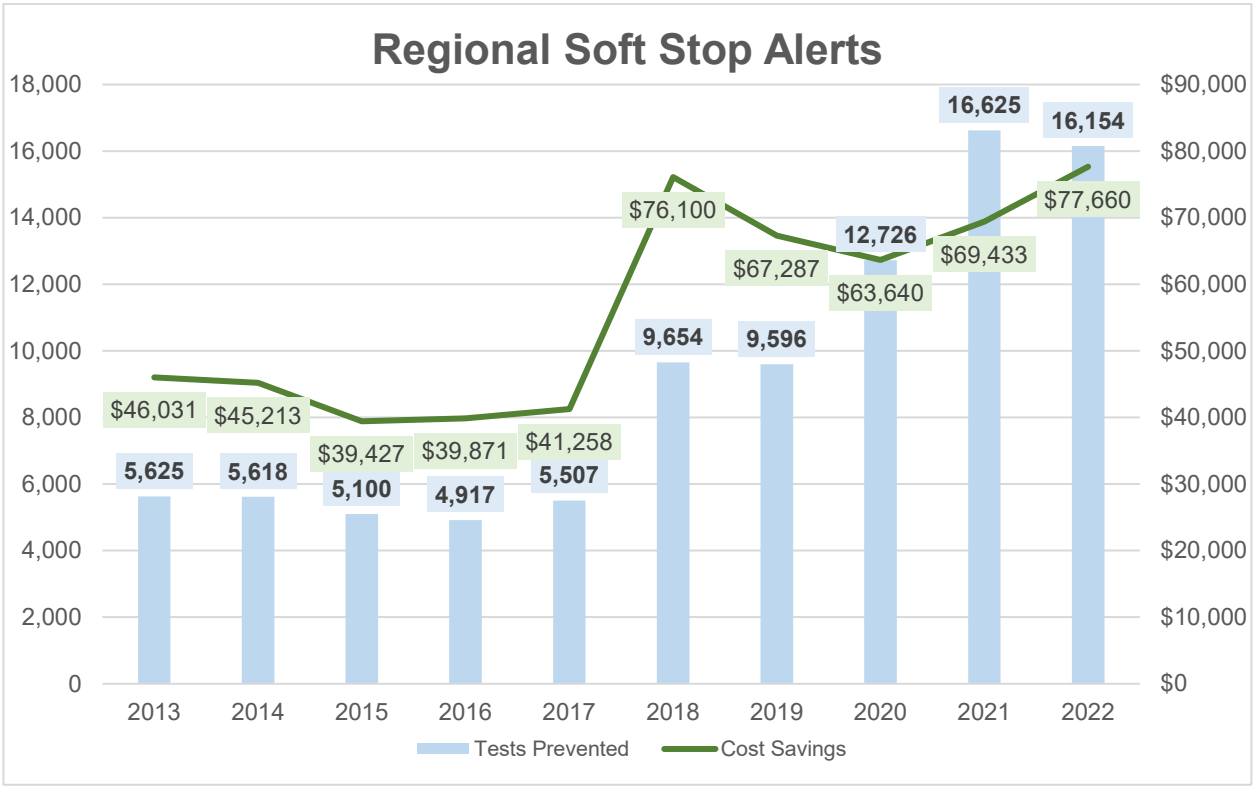

*Since 2013, Regional Soft Stop Alerts have prevented **91,522 unnecessary tests** for a **total savings of $565,919**.*

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05

Expensive Test Notifications

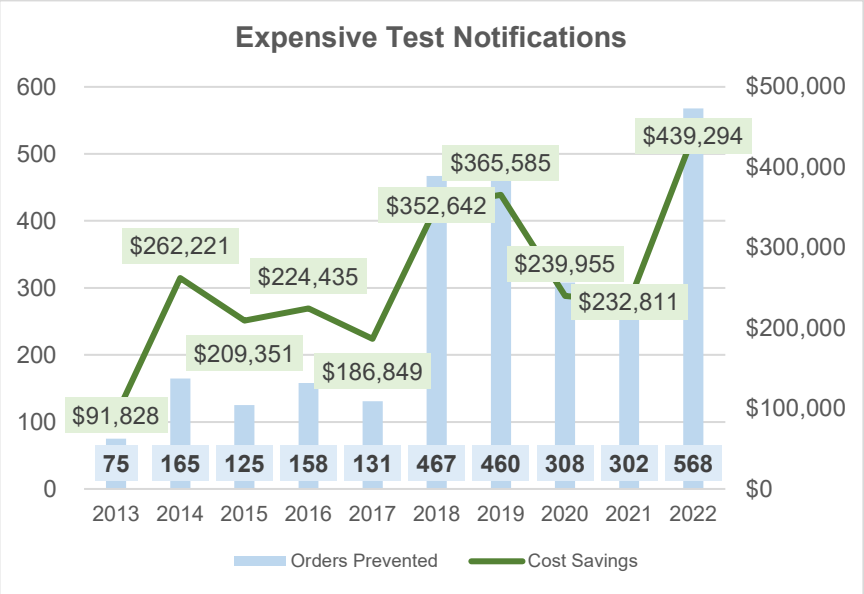
2022 Updates

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 2022, **568 expensive tests** were avoided for a **total savings of $439,294**.



Since August 2013, **2,759 expensive tests** have been avoided and **saved $2,604,970**.

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06 Extended Time Hard Stop

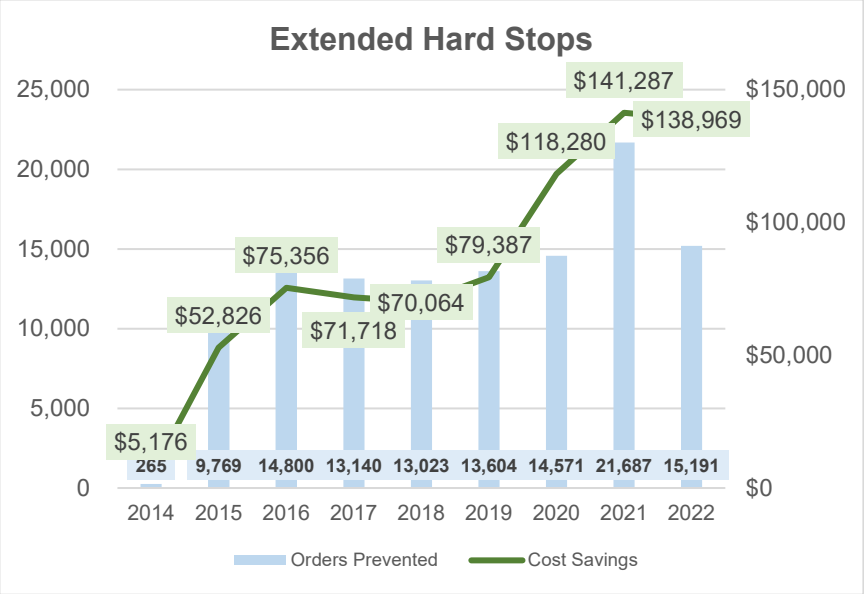
2022 Updates

Extended Time Hard Stops activate if a provider places a duplicate test order within a specified time-frame (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 2022, **15,191 unnecessary duplicate tests** were prevented for a **cost savings of $138,969**.



Since November 2014, **116,050 duplicate tests** have been avoided and **saved $753,062**.

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07

Once-in-a-Lifetime Test Alert

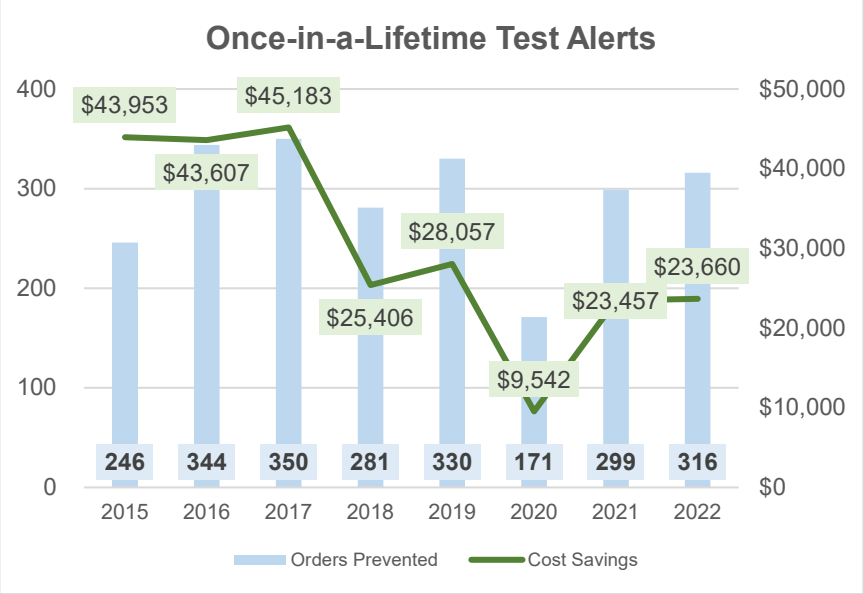
2022 Updates

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 RT-PLMI Client Services for an override code.

In 2022, **316 repeat OIAL tests** were prevented for a **total cost savings of $23,660**.



Since August 2013, **2,337 OIAL tests** were prevented and **saved $242,865**.

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08

Inpatient Stool Culture / O&P Alert

2022 Updates

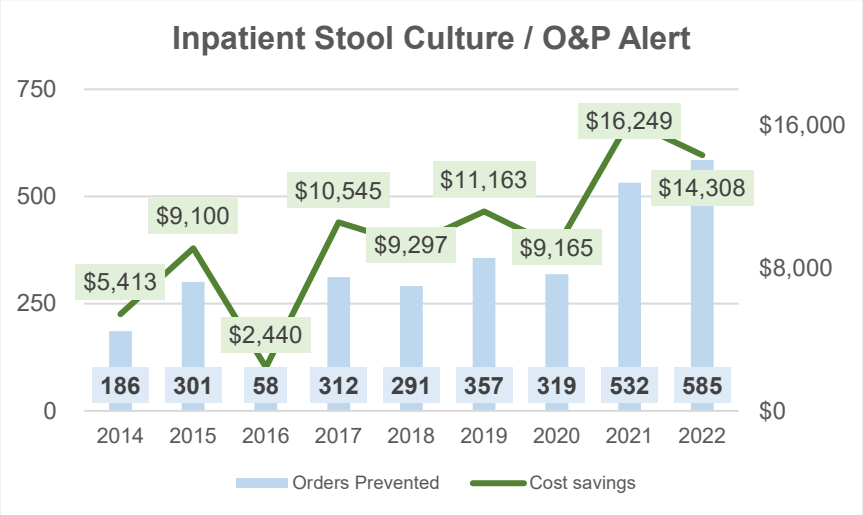
There is substantial evidence regarding the lack of utility of routine stool cultures and ova & parasite (O&P) exams for patients that develop diarrhea after three days of hospitalization.

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 versus O&P exam versus an O&P screen based on this information.

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

In 2022, **585 unnecessary stool cultures / O&P exams** were prevented for a **total cost savings of $14,308**.



Since 2014, **2,941 unnecessary tests** were prevented and **saved $87,680**.

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09

Optimizing Blood Culture Ordering

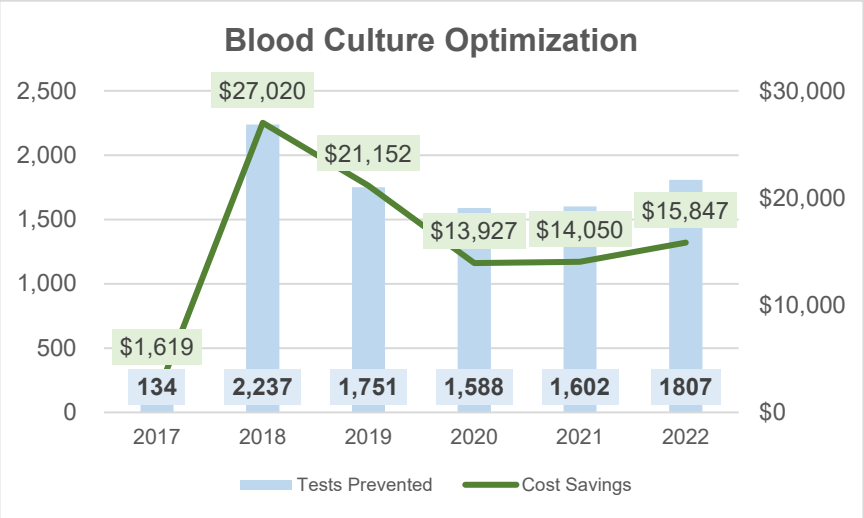
2022 Updates

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 2022, **1,807 unnecessary blood cultures** were avoided for a **cost savings of $15,847**.



Since late 2017, **9,119 unnecessary blood cultures** were prevented and **saved $93,615.**

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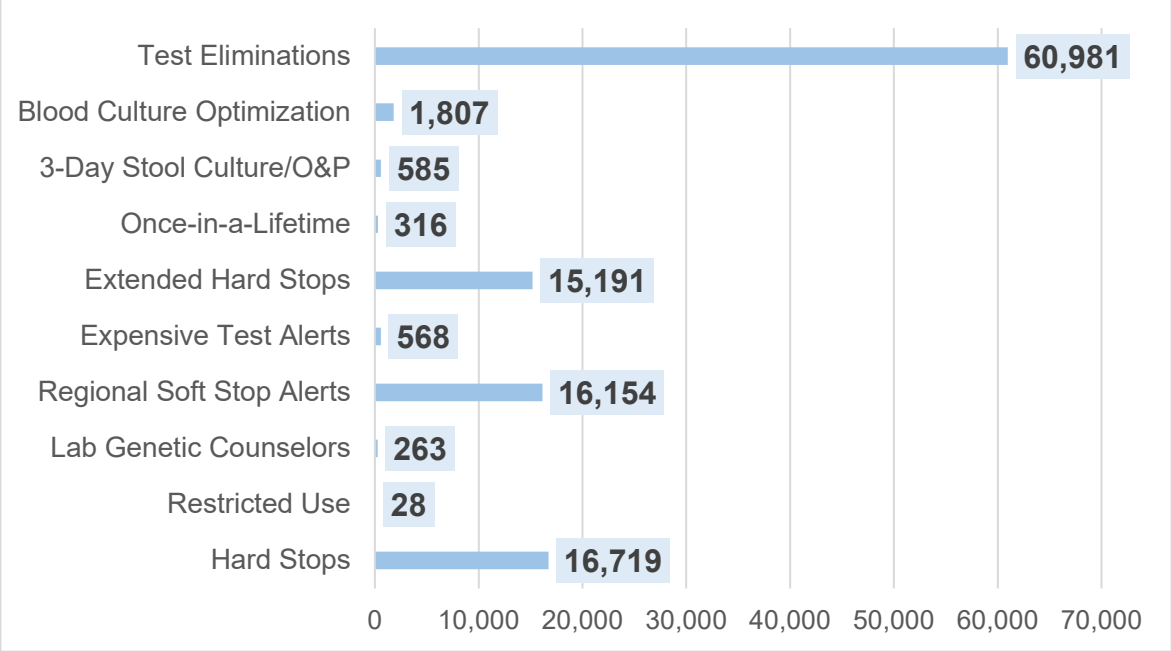
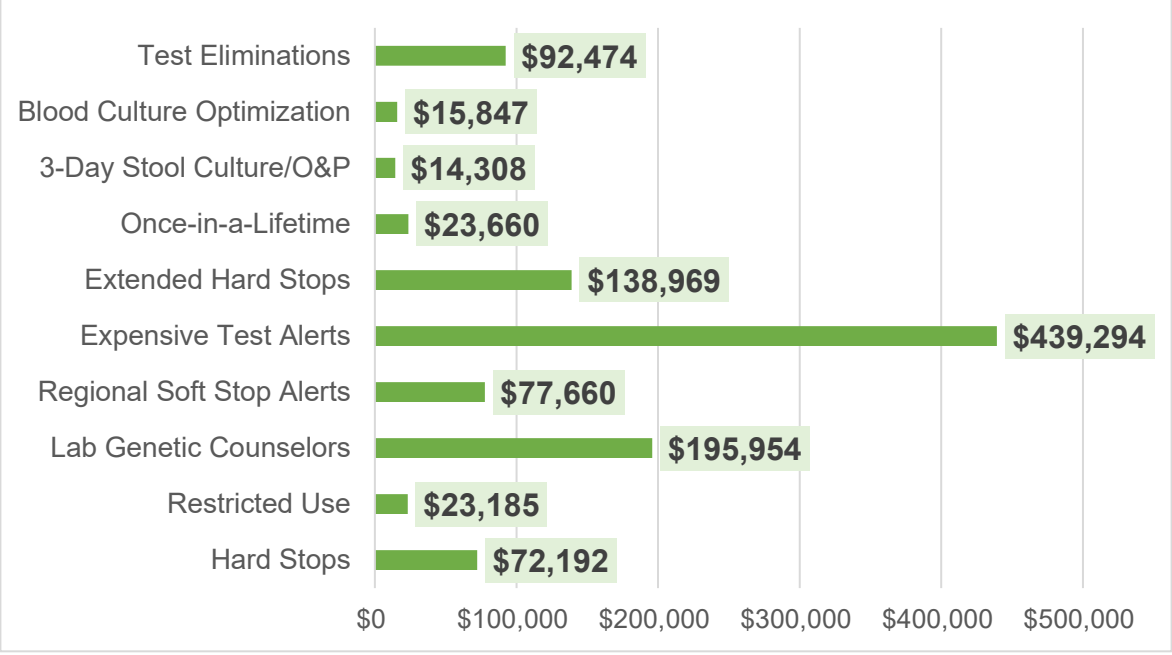
2022 Financial Summary

2022 | **Prevented Tests: 112,612**



2022 | **Cost Savings: $1,093,543**



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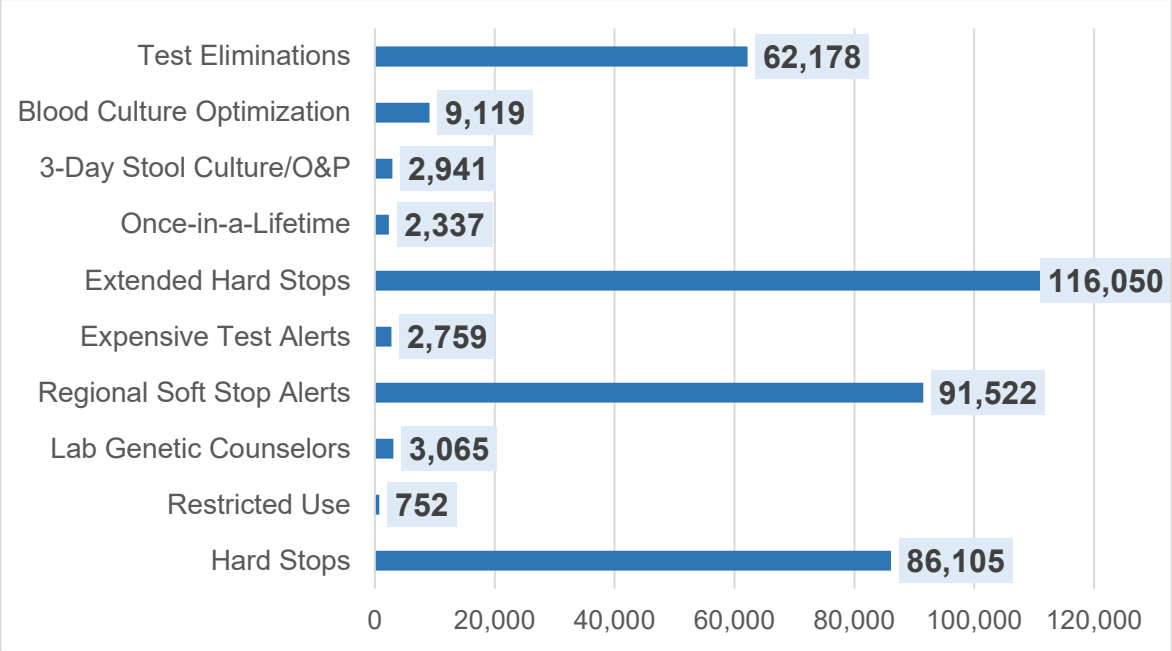
2011 – 2022 Accumulated Totals

LSC Total Prevented Tests: 415,253



LSC Total Cost Savings: $9,650,405

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2023 LSC Goals

1.	Work with RT-PLMI Analytics to create dashboards to track laboratory test utilization across Cleveland Clinic.
2.	Extend existing Hard Stop Alerts across all Cleveland Clinic hospitals in partnership with clinical leaders.
3.	Enhance efforts surrounding ordering inpatient daily labs that do not change clinical management.
4.	Engage with clinical stakeholders to review send-out testing menu and retire outdated testing.
5.	Engage with Cleveland Clinic locations outside of Ohio to implement testing best practices throughout our health system.
6.	Review Hard Stop programming with Epic to ensure optimal performance across ordering locations.
7.	Continue participation with the Patient-centered Laboratory Utilization Guidance Services (PLUGS) network.
8.	Quantify cost savings and other impact associated with each intervention.
9.	Optimize efforts surrounding automated prior authorization of lab tests.

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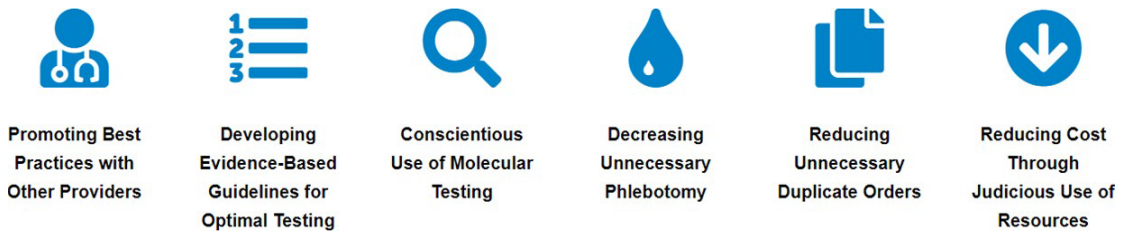
Acknowledgements

These accomplishments result from the tireless efforts, collegial meetings, and great ideas of the Laboratory Stewardship Committee members. This work would not be possible without the assistance of Kim Estremera, who has kept our committee organized and on task—we are grateful that she is part of our team.

We would also like to thank Dr. Brian Rubin and RT-PLMI leadership for their assistance and counsel. We are especially appreciative of the indispensable collaborations and efforts of Dr. Grace Kroner, Director of the Send-Out lab. Special thanks to Mr. Rob Tuttle for performing the financial analyses featured in this report.

Additionally, LSC appreciates the teamwork and collaborative energy from the ITD team – 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.

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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 more than 76,000 caregivers worldwide, including more than 5,600 physicians and scientists. The health system consists of 22 hospitals and 275 outpatient locations, including a main campus in Cleveland; 14 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 in Toronto, Canada; a hospital and outpatient center in London, United Kingdom; and a hospital and cancer center in Abu Dhabi, United Arab Emirates. Cleveland Clinic is currently ranked as one of the nation's top hospitals by *U.S. News & World Report*.
clevelandclinic.org