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Laboratory Stewardship Committee

2021 Annual Report

Anita J. Reddy, MD, MBA and **Walter H. Henricks, MD**
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.

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 is 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, which are 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

In 2021, these nine test order interventions resulted in:

65,755
prevented unnecessary tests

$850,685
in cost-savings

Since implementation, these interventions have prevented **302,641 unnecessary tests** and saved Cleveland Clinic **$8,567,421**.

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2021 Completed and Ongoing Projects

Project	Status
1. Respiratory Viral Panel Soft Stop	**Complete**
2. Factor V Leiden and APC Resistance Inpatient Algorithm	**Complete**
3. Removal of MTHFR Testing	**Complete**
4. Order Fructosamine if HbA1c Variant Present	**Complete**
5. D-dimer Inpatient 48 hour Hard Stop	**Complete**
6. Standard Procedure for Inpatient Genetic Testing	**Complete**
7. Removal of Outdated Genetic Tests	**Complete**
8. New Test Request Reviews	**Ongoing**
9. Laboratory Test Utilization Dashboard development	**Ongoing**

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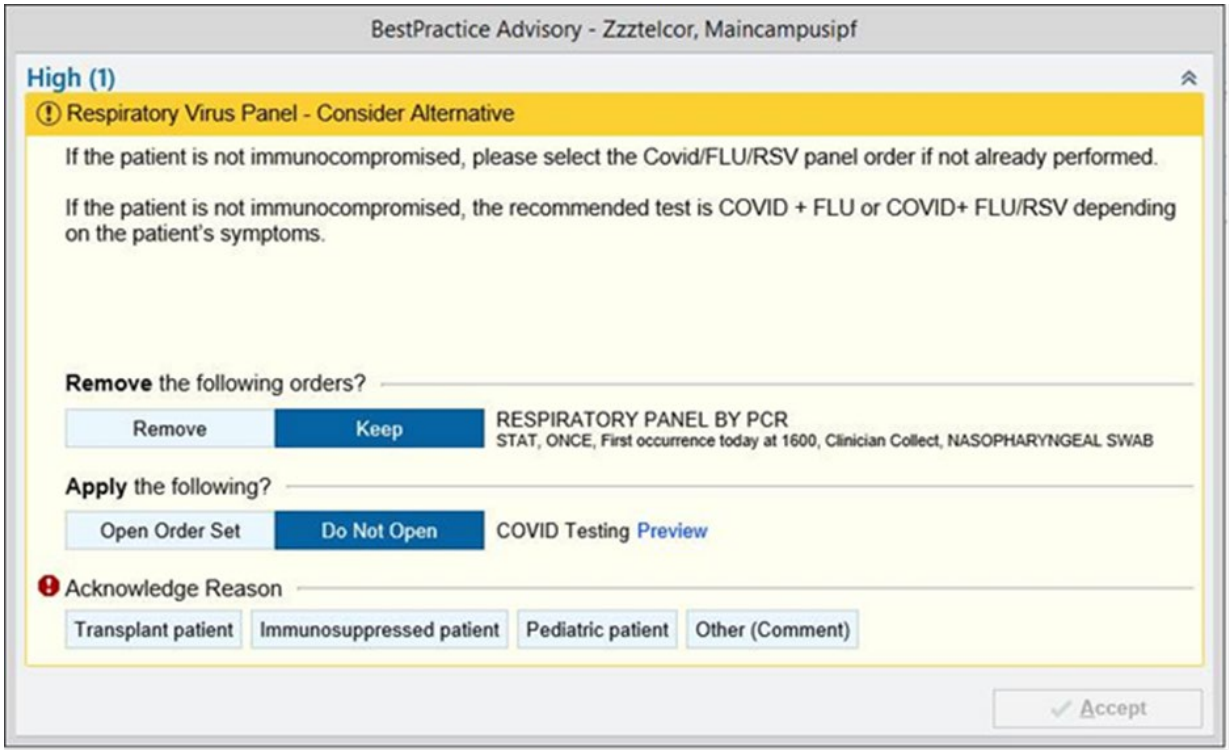
2021 Completed & Ongoing Projects

1. **Respiratory Viral Panel Soft Stop** – *Complete*

   This soft stop alert was created to direct the use of the respiratory viral panel (RVP) in patient populations where clinical care would be altered based on the results.

   This alert was implemented in all outpatient settings and for main campus inpatients in January 2021. In addition, rapid RVP testing was restricted to the inpatient setting only in November 2020.



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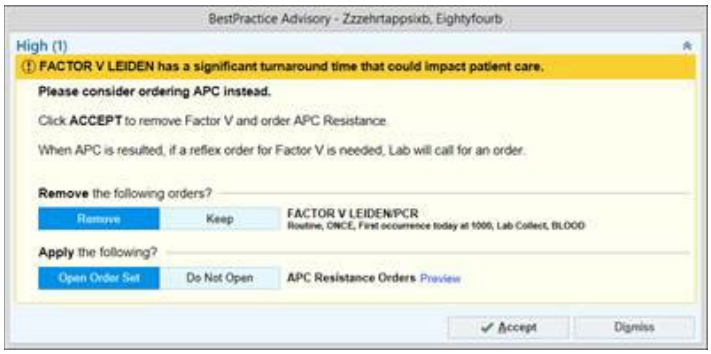
2021 Completed & Ongoing Projects

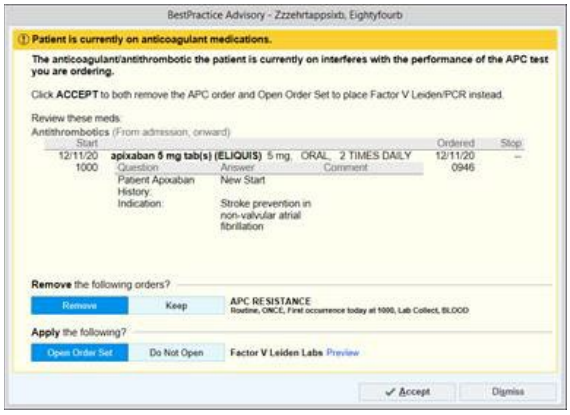
2. Factor V Leiden and APC Resistance Inpatient Algorithm – *Complete*

This soft stop alert was created to provide decision support to providers as to when it is most appropriate to order Factor V Leiden and Activated Protein C (APC) Resistance tests. A duplicate alert will display to prevent providers from ordering both tests at the same time.

If the patient is not receiving anti-thrombotic medication and Factor V Leiden is ordered, a BPA will recommend ordering APC Resistance instead. If a reflex order for Factor V Leiden is necessary based on the APC result, the lab will notify the provider to place an order.



If the patient is on anti-thrombotic medication and APC Resistance is ordered, a BPA will display active medications and recommend ordering Factor V Leiden instead.



Modeled after the outpatient alert launched in early 2020, this inpatient alert went live in December 2020. As a result, appropriate test ordering has led to a savings of $1,027.

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2021 Completed & Ongoing Projects

3. Removal of *MTHFR* Testing – *Complete*

There is no conclusive evidence supporting the clinical value of *MTHFR* (methylenetetrahydrofolate reductase) polymorphism genotyping; therefore, *MTHFR* testing was removed from both the outpatient and inpatient test directories.

If providers have a clinical concern regarding hyperhomocysteinemia, it is recommended to utilize Homocysteine (HOMCYS) testing instead.

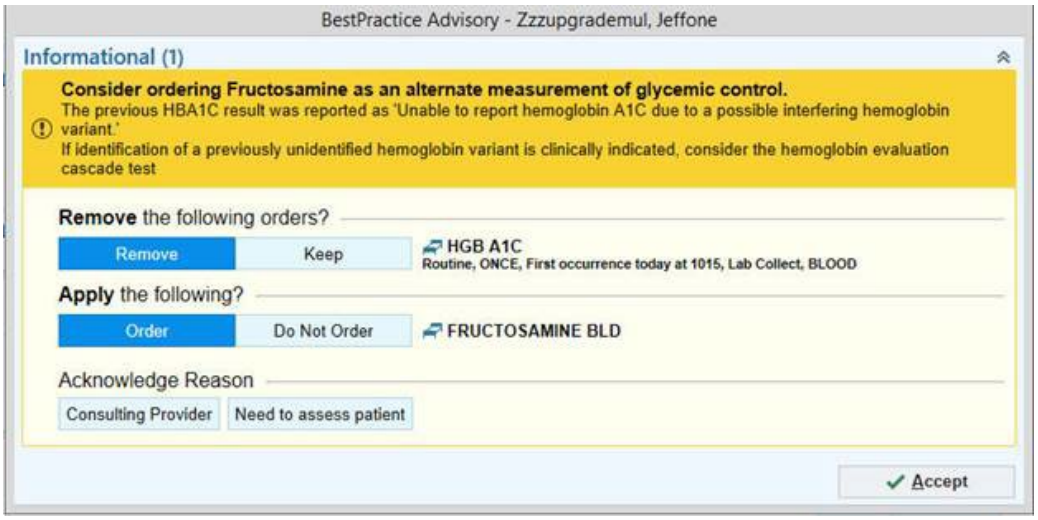
This effort went live in late March 2021 and prevented 144 tests, saving $6,735.

4. Order Fructosamine if HbA1c Variant Present – *Complete*

In patients with a Hemoglobin A1c test that was unable to be reported due to a possible interfering hemoglobin variant, a soft stop alert was created to suggest ordering a fructosamine level as an alternate measurement of glycemic control.

The alert went live in September 2021 in both inpatient and outpatient settings. Ordering providers have the options to: 1.) remove or keep the HbA1c order, 2.) add or skip the fructosamine order, or 3.) dismiss the alert.

Approximately two-thirds of outpatient alerts led to order changes, suggesting that the alert successfully guides providers to optimized monitoring of glycemic control when a patient has a hemoglobin variant that interferes with HbA1c tests.



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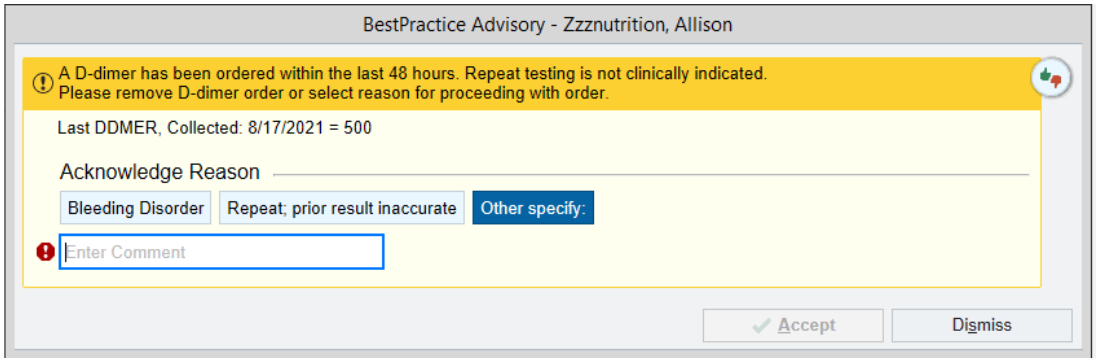
2021 Completed & Ongoing Projects

5. D-dimer Inpatient 48-Hour Hard Stop – *Complete*

D-dimer ordering increased substantially during the COVID-19 pandemic—especially during the early stages—leading to limited quantities of reagents and blood tubes.

To combat this, an alert aimed at preventing D-dimer orders placed more frequently than 48 hours was implemented, as daily measurements of D-dimer do not change clinical care. This alert went live in August 2021.



6. 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, RT-PLMI leadership and CPGH developed new policies and procedures for governing the ordering of germline genetic testing on inpatients.

The Inpatient Germline Genetic Testing standard operating procedure (SOP) is available at: https://ccf.policytech.com/dotNet/documents/?docid=70273

Approved in December 2021, this SOP will serve as a guide and resource for circumstances in which germline genetic testing may be indicated for a patient in the inpatient setting in Ohio, including perimortem scenarios.

RT-PLMI will establish periodic case review meetings to evaluate the impact of this procedure, the first of which will occur by June 2022.

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2021 Completed & Ongoing Projects

7. Removal of Outdated Genetic Tests - *Complete*

RT-PLMI's Laboratory Genetic Counselors worked with the LSC and laboratory send-outs team to identify 58 genetic tests that were deemed to be obsolete and marking them to be removed from the Test Directory. Removing these tests avoids confusion amongst ordering providers regarding the optimal test to order and ensures high-quality patient care.

Nine outdated genetic tests were removed in 2021, and the remaining will be removed in April 2022.

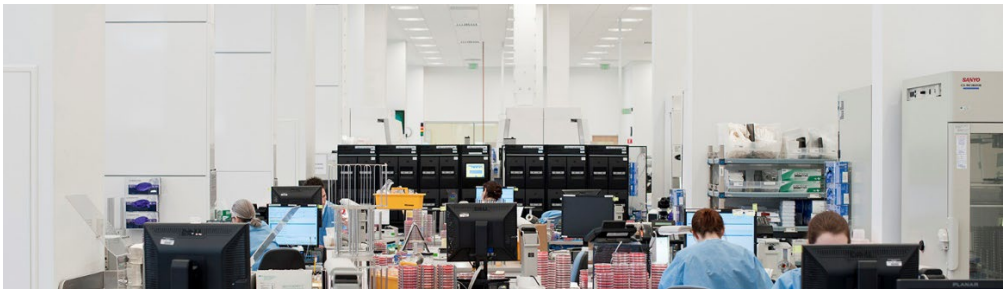
8. New Test and Project Request Reviews - *Ongoing*

LSC received 18 new test and project requests during 2021. These requests were reviewed by LSC leadership, clinical subject matter experts, and laboratory section heads, as well as other subject matter experts depending on the type of request (e.g. send-out test request, genetic test, etc.).

Evaluation of new send-out requests involved close collaboration with Dr. Grace Kroner, Medical Director of Send-Out Testing. Of these requests, six were approved based on the clinical need to provide optimal patient care, adequate literature to support the use of the test, and consideration of the financial impact to the patient and institution.

The following tests/projects were approved:

Test Request	Project Request
Common Hereditary Cancers + RNA Panel	D-Dimer BPA
Eculizumab/sC5b-9 Levels (existing send-out test)	Stool O&P BPA
Genetic Health Screen/Screen + Carrier (Invitae; new send-out)	
HLH Genetic Testing (new send-out; inpatient, peds only)	



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01

Hard Stop Alerts

2021 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 2021, the alert fired **24,533 times**.

- **181 (0.7%) override requests** resulted in a test performed, demonstrating a **99% alert success rate**.
- **24,345 unnecessary duplicate tests** were prevented for a **total savings of $98,928**.
- Related significant benefits include **reduced patient blood draws and savings of phlebotomist time.**

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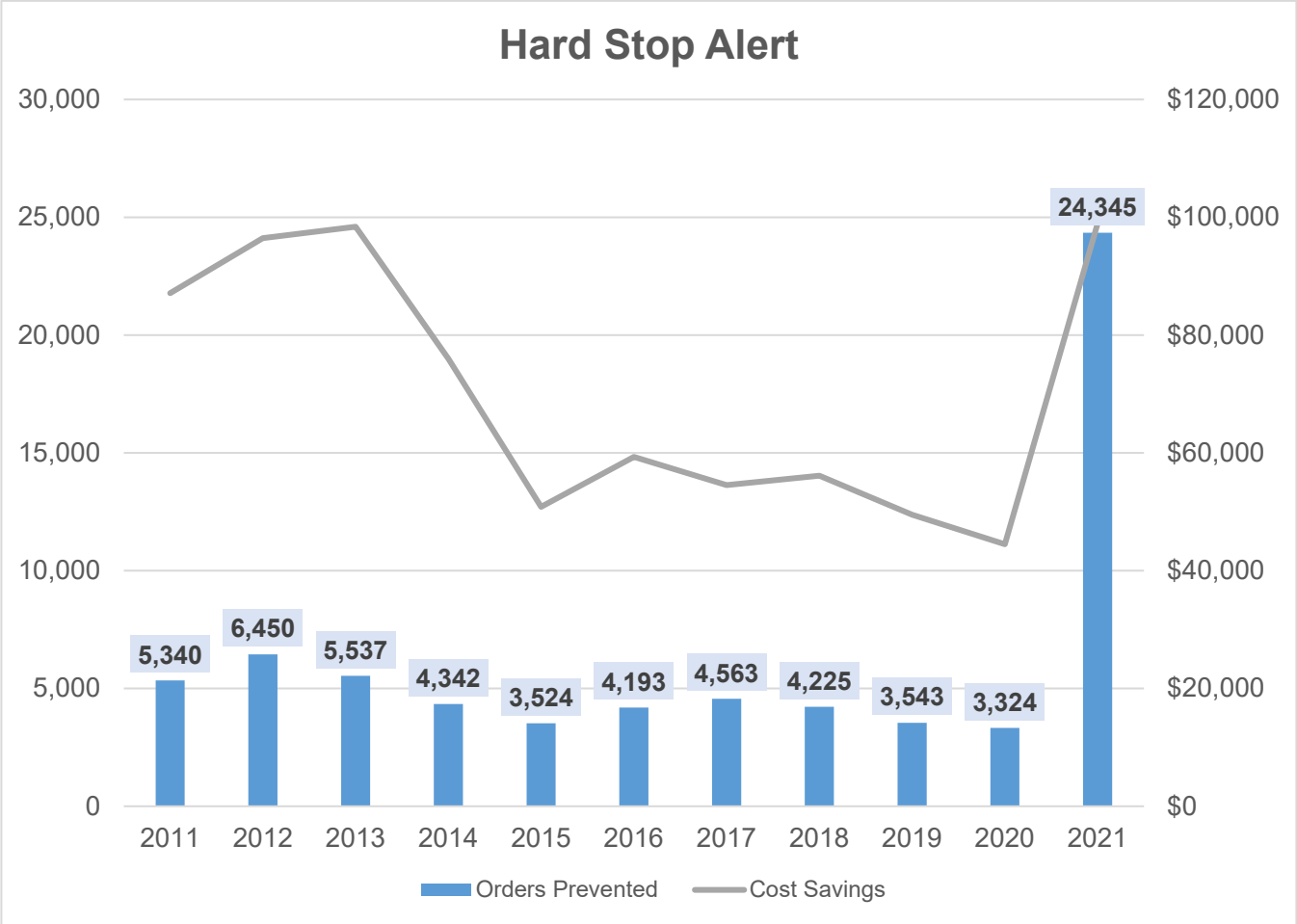

*Since 2011, Hard Stop Alerts have prevented **69,386 unnecessary tests** for a **total savings of $771,670.***

**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

2021 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 2021, **41 unnecessary molecular genetic tests** were avoided for a **total savings of $37,958**.

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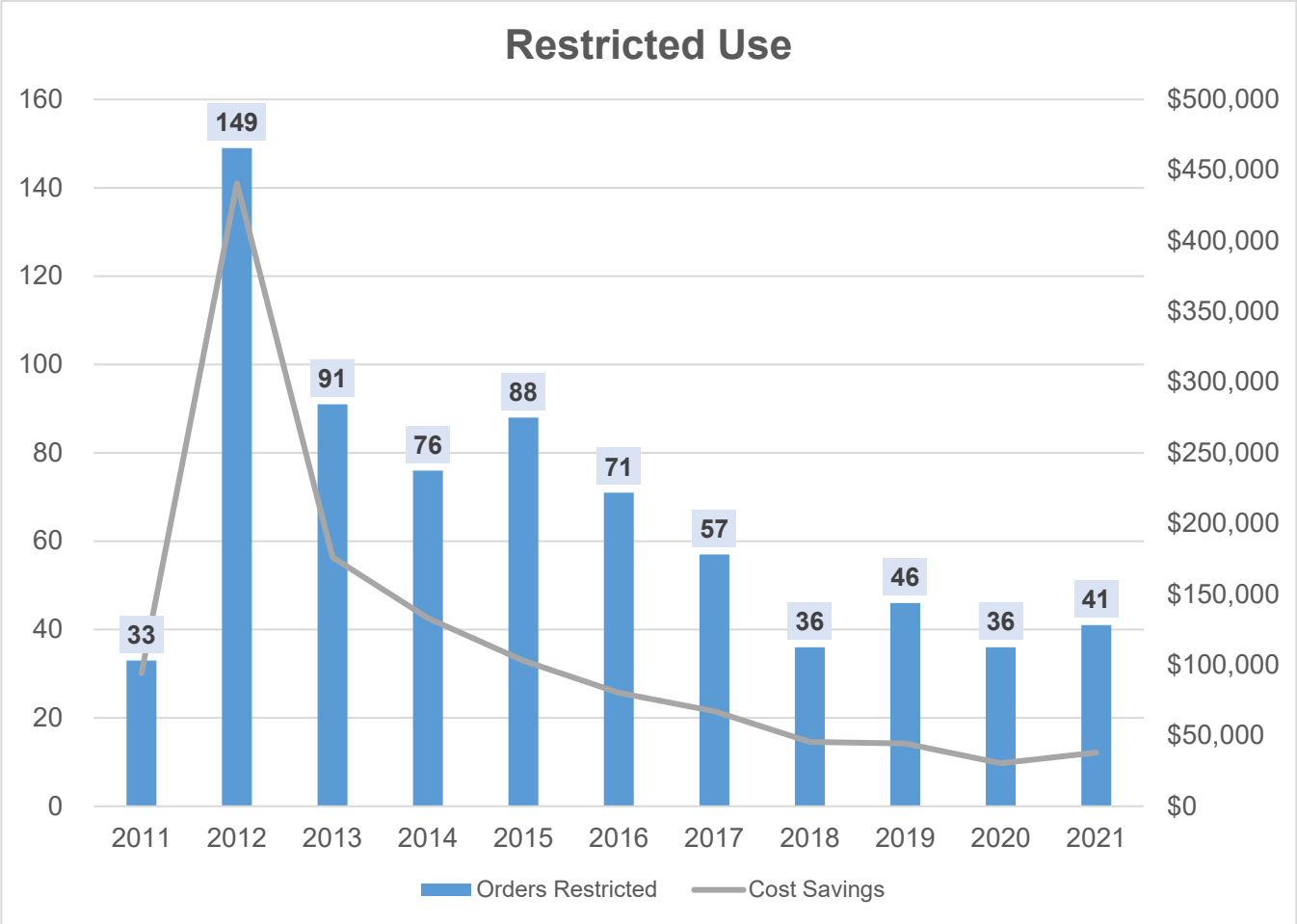

Since late 2011, the Restricted Use initiative has prevented

***724 unnecessary molecular tests** for a **total savings of $1,253,035**.*

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03

Laboratory Genetic Counseling

2021 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 2021, **322 genetic** tests were changed or canceled, resulting in a **cost savings of $211,210**.

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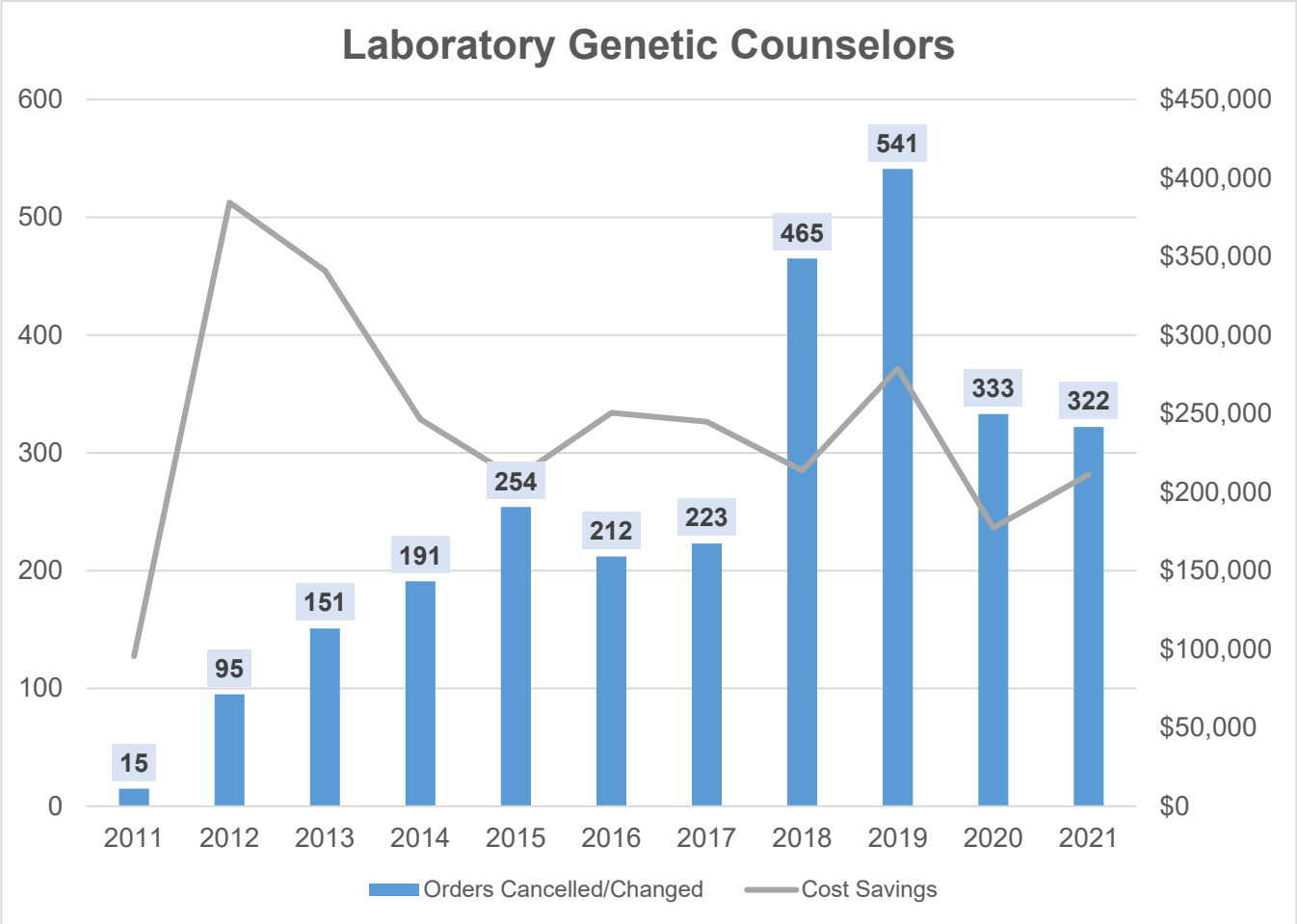

*Since 2011, Laboratory Genetic Counselors have prevented **2,802 unnecessary tests** for a **total savings of $2,652,255**.*

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04

Regional Soft Stop Alerts

2021 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 time-frame. 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.

In 2021, Soft Stop Alerts deterred **16,625 unnecessary duplicate tests**, yielding a **cost savings of $69,433**.

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

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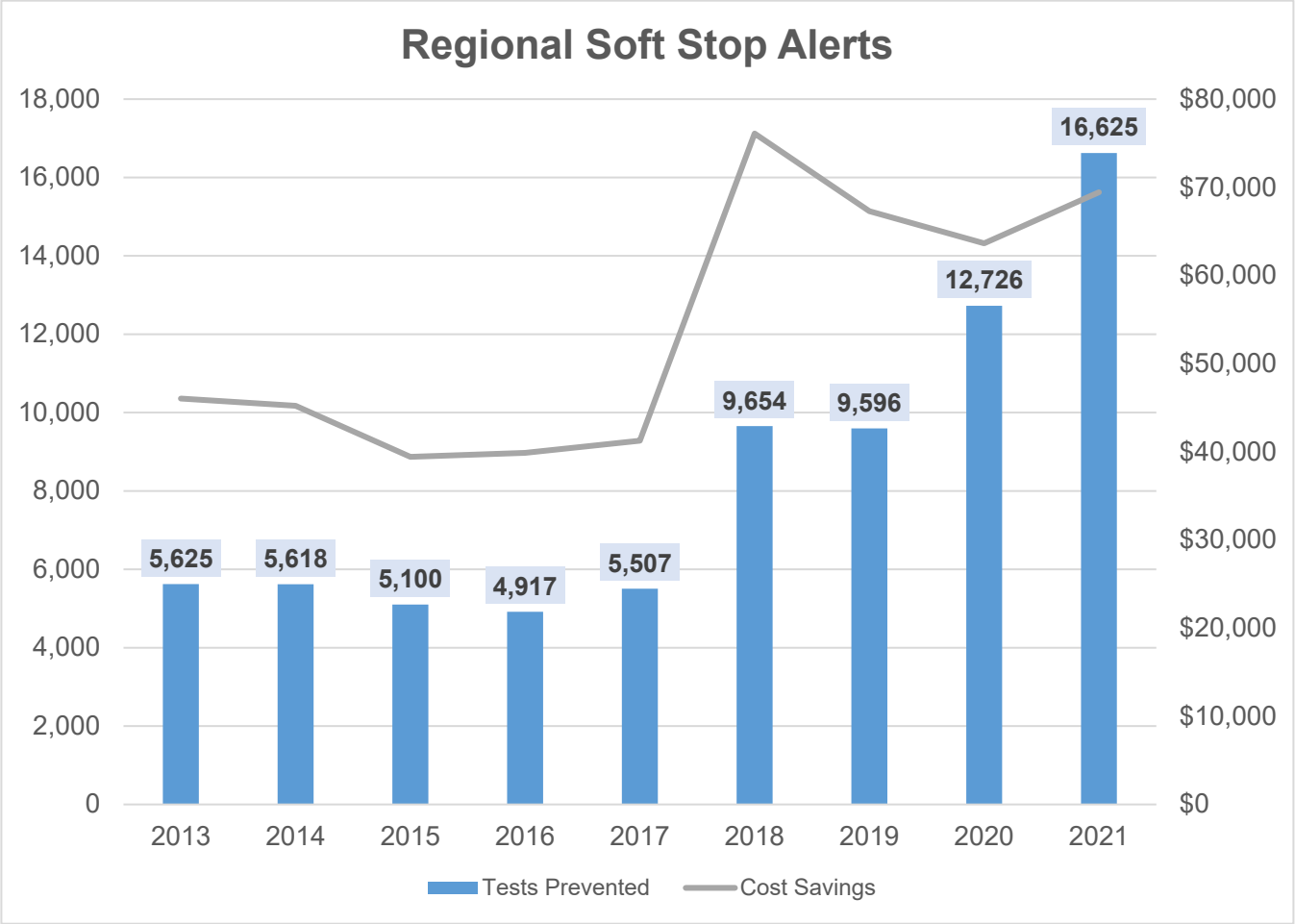

*Since 2013, Regional Soft Stop Alerts have prevented **75,368 unnecessary tests** for a **total savings of $488,259**.*

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05

Expensive Test Notifications

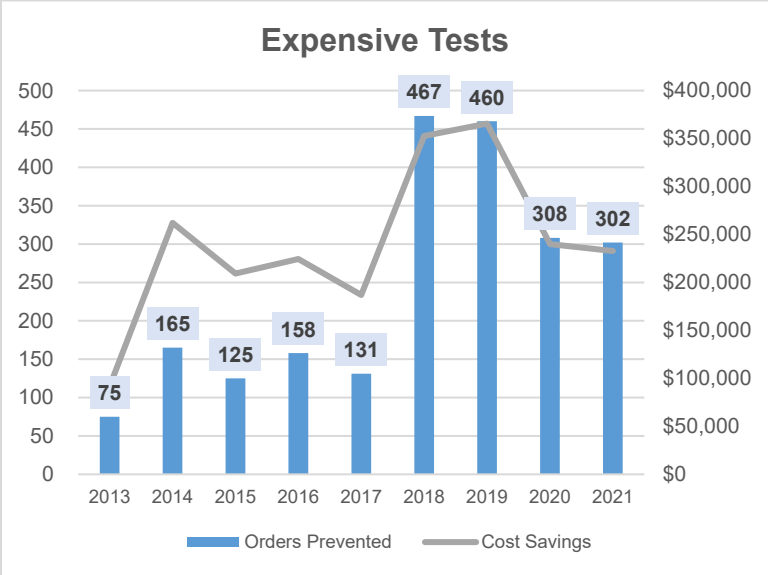
2021 Updates

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 2021, **302 expensive tests** were avoided for a **total savings of $232,811**.



Since August 2013, **2,191 expensive tests** have been avoided and **saved $2,165,676**.

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06

Extended Time Hard Stop

2021 Updates

Extended Time Hard Stops activate if a provider places a duplicate test order within a specified time-frame (>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 2021, **21,687 unnecessary duplicate tests** were prevented for a **cost savings of $141,287**.

Since November 2014, **100,859 duplicate tests** have been avoided and **saved $614,093**.

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07

Once-In-A-Lifetime Test Alert

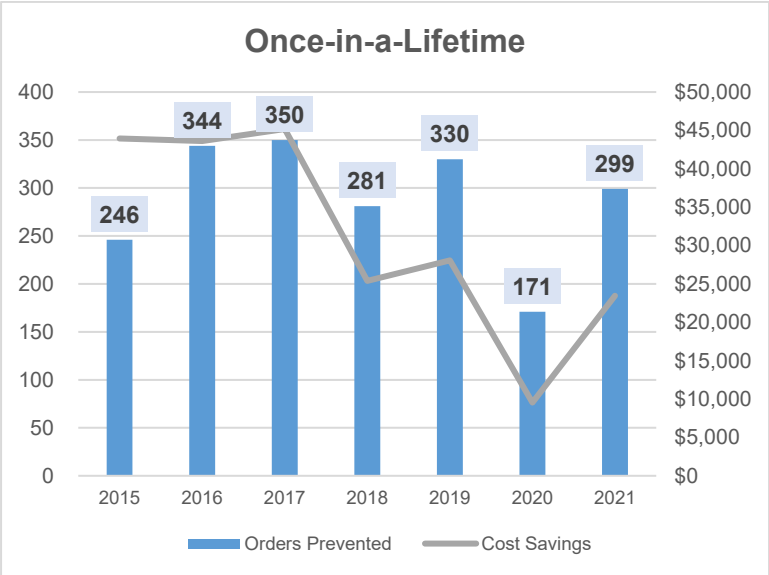
2021 Updates

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 2021, **299 repeat OIAL tests** were prevented for a **total cost savings of $23,457**.



Since August 2013, **2,021 OIAL tests** were prevented and **saved $219,205**.

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08

Inpatient Stool Culture / O&P Alert

2021 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.

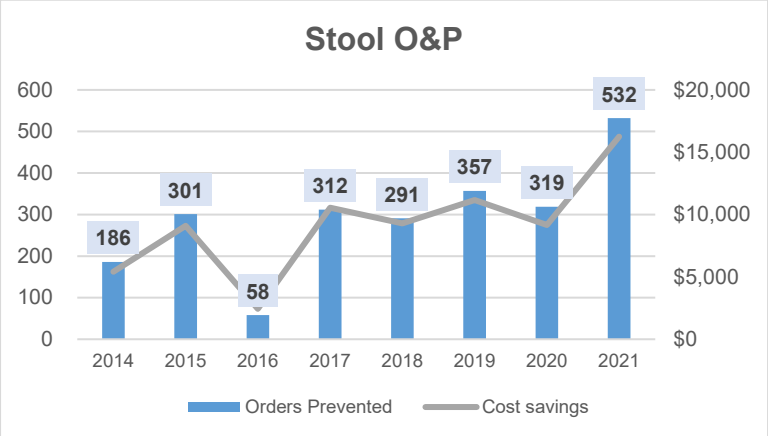
Implemented in 2014, this initiative prevents the ordering of stool cultures and/or O&P exams placed after three days of a patient's hospitalization.

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, the provider can circumvent this intervention by calling RT-PLMI Client Services for an override code.

In 2021, **532 unnecessary stool cultures / O&P exams** were prevented for a **total cost savings of $16,249**.

Since 2014, **2,356 unnecessary tests** were prevented and **saved $73,372**.



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09

Optimizing Blood Culture Ordering

2021 Updates

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

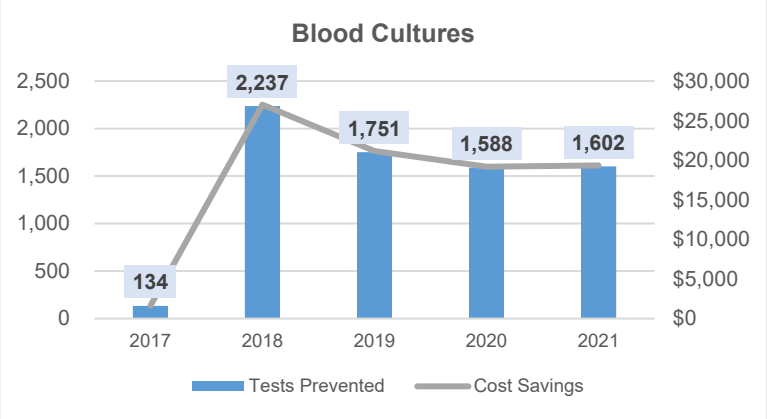
ICU Management raised the issue of potentially excessive blood culture utilization. An investigation disclosed that the test naming convention was likely contributing to inappropriate overutilization.

Consensus between ICU, 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. Providers can override this soft stop at the point of order entry.

We are particularly proud of this intervention, as what began as a project to address potential utilization issues eventually developed into a quality improvement project.

In 2021, **1,602 unnecessary blood cultures** were avoided for a **cost savings of $19,352**.

Since late 2017, **7,312 unnecessary blood cultures** were prevented and **saved $88,326**



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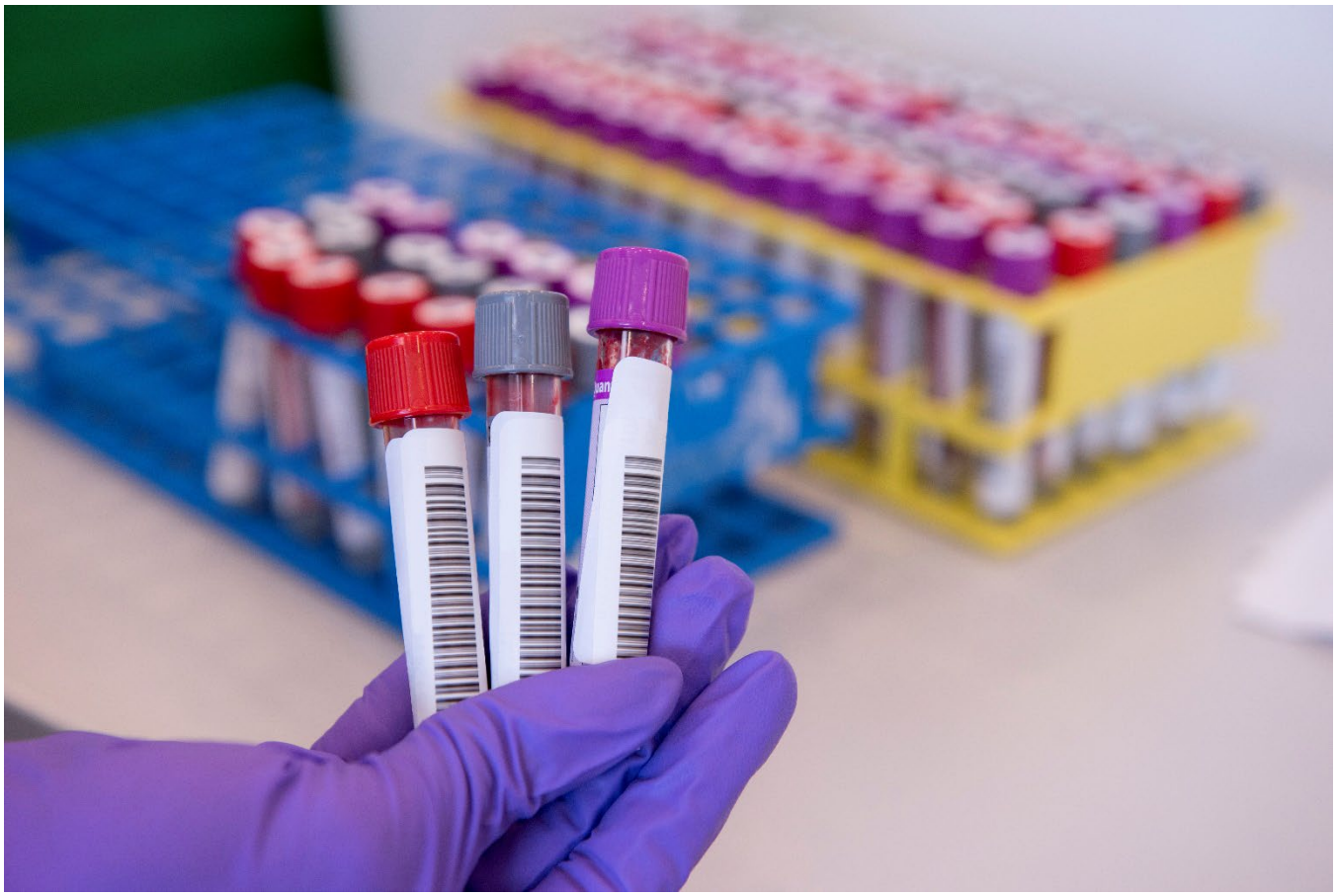

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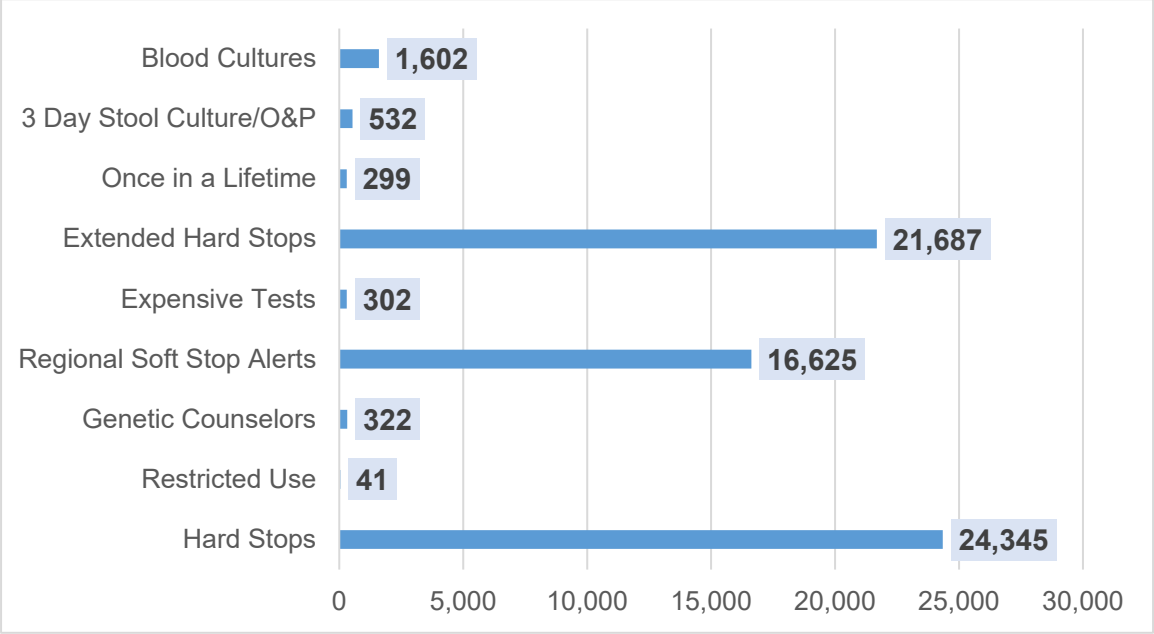
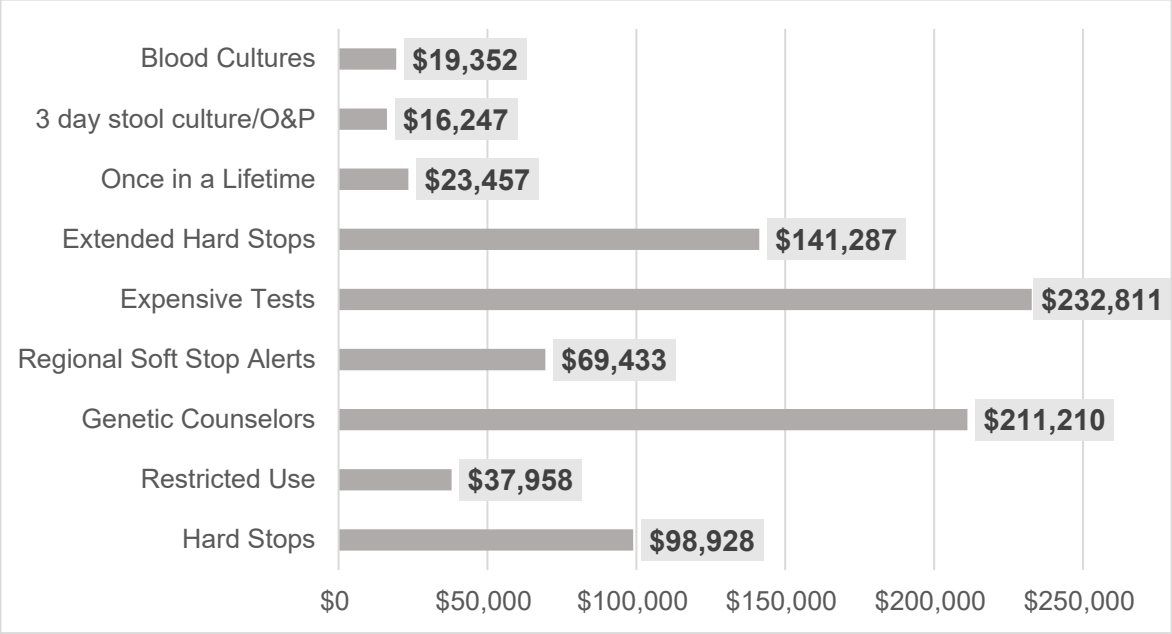
2021 Financial Summary

2021 Prevented Tests: 65,755



2021 Cost Savings: $850,685



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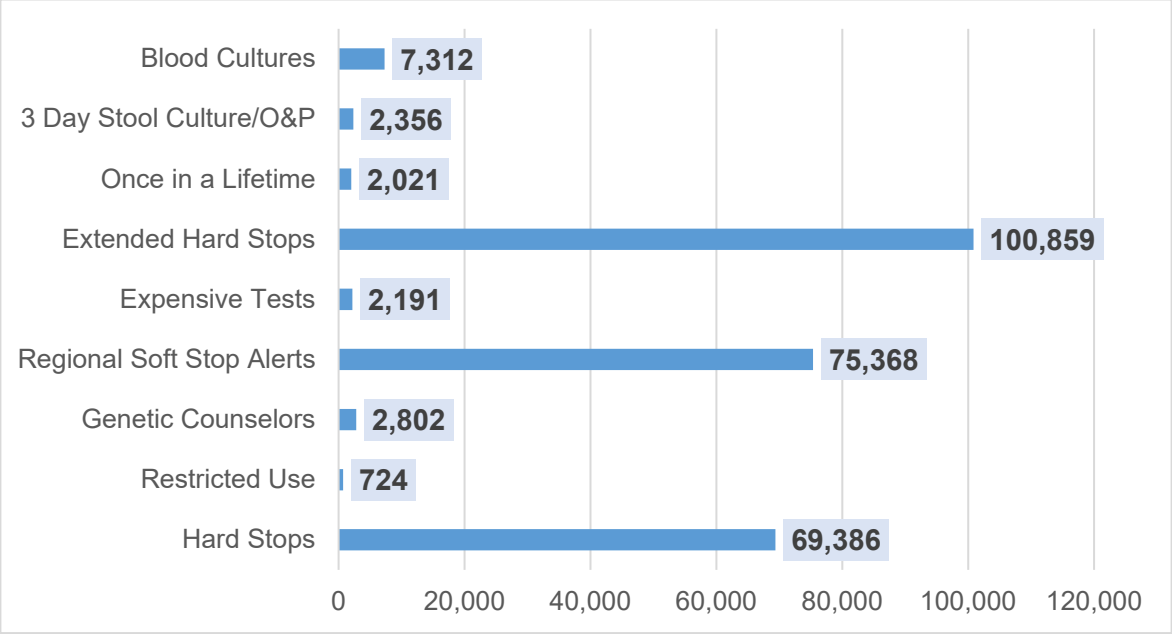
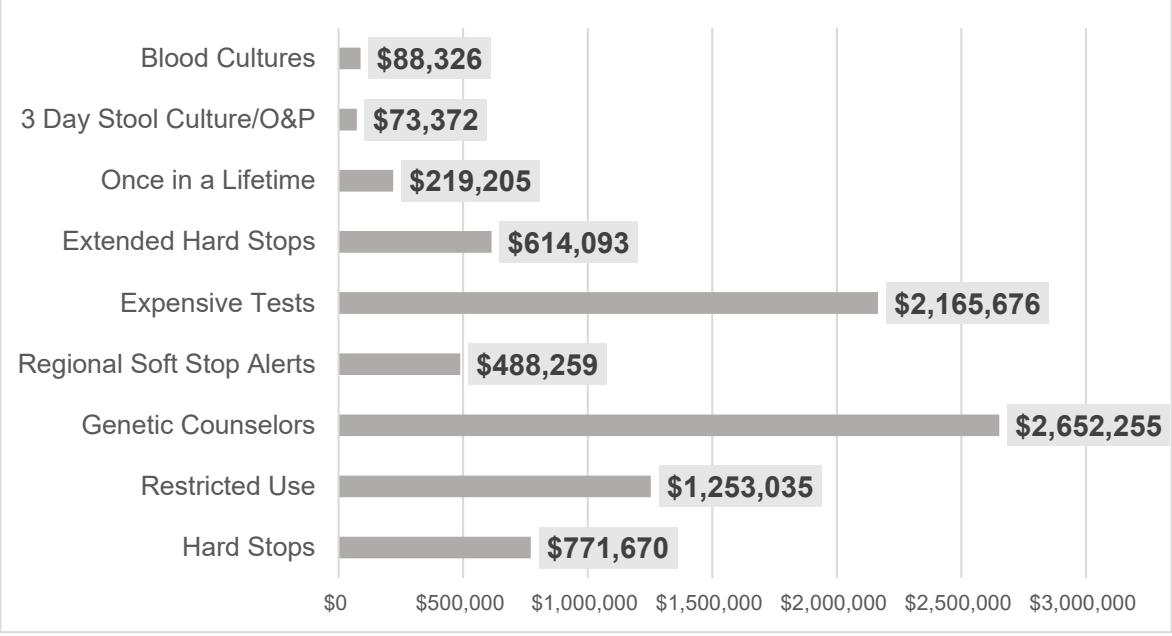
2011 – 2021 Accumulated Totals

LSC Total Prevented Tests: 302,641



LSC Total Cost Savings: $8,567,421



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2022 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 Ohio hospitals in partnership with clinical leaders.
3.	Refresh 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.	Implement new Epic Beaker and Haemonetics SafeTrace Tx® (blood bank) laboratory information systems and monitor correct functioning of LSC interventions and BPAs after go-live.
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.	Optimizing efforts surrounding automated prior authorization of lab tests.

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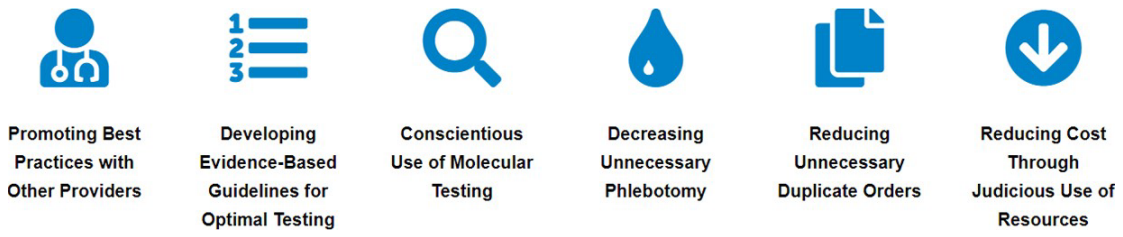
Acknowledgements

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.

LSC appreciates the support and guidance of Dr. Robert Wyllie, Medical Operations, Chief of Staff, and other members of Cleveland Clinic's senior leadership.

We would also like to thank Dr. Brian Rubin and RT-PLMI leadership for their assistance and counsel. We are especially appreciative of the collaborations we have developed with 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, particularly the productive and well-managed CSO/RT-PLMI/ITD standing meeting. 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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9500 Euclid Ave., Cleveland, OH 44195

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clevelandclinic.org