

How Methodist Charlton Medical Center Identified Previously Undetectable Syphilis Cases and Increased Efficiency in the Lab

The Modern Teaching Hospital Adopted the Elecsys® Syphilis Assay and the Reverse Algorithm Model to Benefit Its Community and Organization

Executive Summary

Syphilis rates are rising in the United States, with more than 115,000 cases reported between 2017 and 2018.¹ Texas has been heavily affected, as the state reported the fourth highest rate of congenital syphilis cases in 2017.² **That's why innovative staff at Methodist Charlton Medical Center in Dallas, Texas, were interested in switching to the reverse algorithm model and the Elecsys® Syphilis assay to expedite accurate results, support better patient care and reduce hands-on tech time.**

The traditional diagnostic algorithm for syphilis has been to utilize two types of serologic tests in two steps,³ with the more manual test first. However, it has been shown that detection rates are higher when the tests are performed in the reverse order.^{3,4}

By moving to the reverse algorithm model, there is an opportunity to automate testing, increase efficiency and potentially slow the growth of syphilis by detecting the disease in those who might have previously gone undetected.³ Research has demonstrated that the reverse algorithm initiated with the treponemal test resulted in a **detection rate that was three times higher than the conventional method**.^{3,4}

Methodist Charlton found that the adoption of the Elecsys Syphilis assay and the reverse algorithm greatly benefited the medical center's patients, staff and community, particularly as it **identified 57 positive patients between October 2018 and July 2019 who would not have been detected** using the traditional algorithm.

METHODIST CHARLTON AT A GLANCE



Modern teaching
and community
hospital



2 million
lab tests
per year



One of the
nation's top
performers on key
quality measures,
according to the
Joint Commission



Part of the
Methodist Health
System that serves
a population
of more than 1
million people

Challenge

Historically, the Methodist Charlton lab had run the manual, time-consuming nontreponemal (rapid plasma reagin, or RPR) test during the night shift and then confirmed positive results with a treponemal-specific assay at another lab within the Methodist Health System. This process inhibited timely reporting of results and disproportionately burdened the lab's night shift, which was typically Methodist Charlton's least staffed. Furthermore, lab staff were unable to walk away from the manual test, which took about 18 minutes of hands-on time to perform.

In addition to being labor-intensive and inefficient, the traditional RPR test was not as sensitive as the Elecsys® Syphilis assay. Methodist Charlton Lab Director Tina McNabb, Chemistry Technical Coordinator Kasey Bennett and Vice Chair of Clinical Pathology Dr. Karen Roush believed they could increase accurate identification of positive syphilis patients if Methodist Charlton switched to the Elecsys Syphilis assay, which could be run on the **cobas e 411** analyzer, an instrument already in the Methodist Charlton lab.

Accurate identification of positive patients is paramount, as most people with syphilis are asymptomatic, but if left untreated, the infection can cause significant complications.⁵ However, if diagnosed in the early stages, syphilis can be successfully treated and congenital syphilis prevented.^{5,6}

Reverse Algorithm Adoption Leaders

McNabb, Bennett and Dr. Roush made the decision to bring the assay and the reverse algorithm to Methodist Charlton. **They formalized a five-step process that would ensure successful implementation of the Elecsys Syphilis assay.**

Five-step strategy for implementing the Elecsys Syphilis assay:

1. Validate the test and review proposed implementation.
2. Meet formally with physicians and nurses.
3. Train staff.
4. Go live.
5. Monitor clinical and operational effectiveness.

Actions

From the initial planning to full implementation, it took about eight months for Methodist Charlton to adopt the Elecsys Syphilis assay, though its team believes other organizations could implement the assay even faster by using Methodist Charlton's best practices and steps that follow.



In addition to Methodist Charlton, more than 125 sites around the US have implemented the Elecsys Syphilis assay.

“I had been talking to the Texas State Health Department, and I just happened to mention that we were looking at using the reverse algorithm for syphilis testing and they got very excited. They said, ‘If only more hospitals would start doing this.’”

Tina McNabb
Lab Director



Step 1: Validate the test and review proposed implementation with the clinical director.

- **Begin lab test validation and meet with clinical director.** McNabb and Bennett verified the Elecsys® Syphilis assay would give them the results they needed. When they met with the clinical director, they cited their findings and the strong body of evidence supporting use of the reverse algorithm model for syphilis testing.

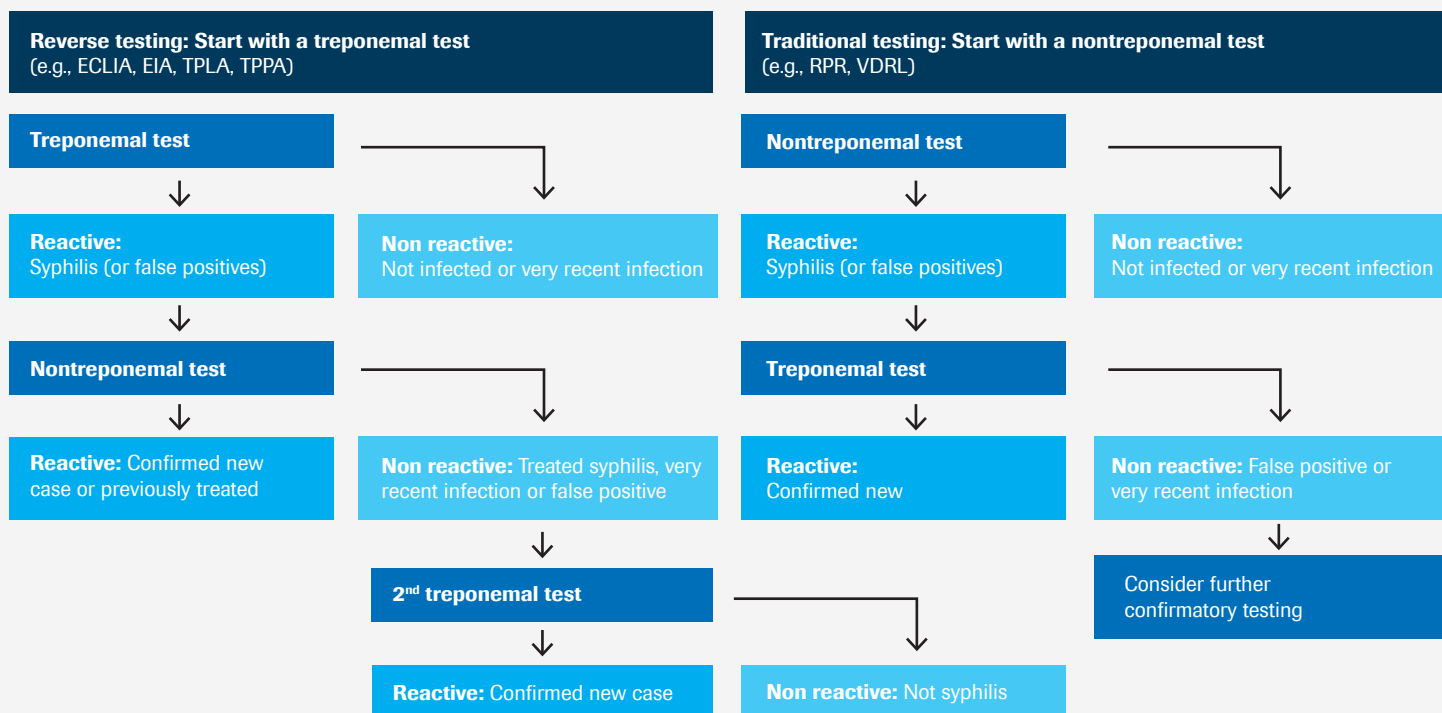
Step 2: Meet formally with physicians and nurses.

- **Sit down with the right clinicians and staff (including nurses), armed with data from the CDC that supports the reverse algorithm.** To minimize pushback that typically occurs when protocols change, discuss the reasons for the change in protocol, including test accuracy, so stakeholders can understand it better. Let them know that automated syphilis testing can be run 24/7.
- **Discuss the difference of the new reverse algorithm versus the traditional algorithm.**
- **Identify clinical champions.** Champions outside of the lab are critical for go-live success and socialization of the new process. McNabb recommends finding champions in OB/GYN and infectious disease.

General representation of the reverse and traditional syphilis testing algorithms

Algorithms: Indications for testing

Skin lesions, suggestive history of sexually transmitted diseases (STDs), current STDs, pregnancy



ECLIA, electrochemiluminescence immunoassay; EIA, enzyme immunoassay; RPR, rapid plasma reagin; TPLA, treponema pallidum latex agglutination; VDRL, Venereal Disease Research Laboratory test, adapted from Binnicker (2012)³ and Katz (2010)⁷

“Our biggest champion was an infectious disease doctor. They held a lot of weight as a voice outside of the laboratory and as someone who had a lot of knowledge about treating infections and about the rate of syphilis infections in our community.

“There’s obviously a lot of cynicism about why the lab is doing this. Is it purely for the efficiencies? And an infectious disease physician can say, ‘There are clinical reasons to do this and get better clinical outcomes. Get an infectious disease person in your corner; they almost all are with this reverse algorithm.’”

Karen Roush, MD
Vice Chair, Clinical Pathology



Step 3: Train staff.

- **Administer competency testing.**
- **Meet with the IT department.** Discuss the change in order sets and investigate any other necessary changes.
- **Update billing codes.**

Step 4: Go live.

- **Logistics: Set the go-live date and put the rollout plan in place.** Make sure the lab has enough reagents for your testing needs.
- **Ensure the test is configured correctly in the electronic health records (EHR).**
- **Add a statement to test results for at least 30 days after implementation.** Alert clinicians and staff that it’s a new test and include the potential impact on how they would treat patients and why they’re seeing something different than they’d typically see.
- **Further communicate the change.** Methodist Charlton recommends planning how to communicate the change across your organization via grand rounds, department meetings, hospital medical staff meetings, emails and EHR broadcast (final communication, released a few days prior to going live).

Communications should focus on:

- Clinical advantage of reverse algorithm
- Reduced wait time for test results (if applicable for your organization)
- Differences between the reverse algorithm and the traditional algorithm they’d been using
- Addressing any staff concerns

Step 5: Monitor clinical and operational effectiveness of the Elecsys® Syphilis assay.

- **Continue to communicate with physicians.** They may be seeing positive results for patients with previously negative results, so it's best to be proactive in communicating with clinicians who may have questions.

“If we’d been doing traditional testing, some patients — new mothers and their infants among them — could’ve been discharged with no additional follow-up. The clinical outcomes of untreated syphilis, including congenital syphilis, can be devastating.”

Karen Roush, MD
Vice Chair, Clinical Pathology



Results

Change Made Possible Through Accuracy and Efficiency

Based on the successful implementation of the Elecsys® Syphilis assay at Methodist Charlton Medical Center in Dallas, the Methodist Health System plans to roll out implementation of the assay at other labs within its organization.

Methodist Charlton was able to accomplish several objectives and measure significant results:



Identified positive patients, including pregnant mothers, who would not have been detected using the traditional testing.

- Between October 2018 and July 2019, Methodist Charlton identified 57 positive patients **who would not have been detected using the traditional algorithm.**⁸
- The medical center measured a 6.3 percent positive rate using the reverse algorithm, versus a 2.7 percent positive rate the prior year using the traditional algorithm.⁸



Decreased wait time for test results, since automated syphilis testing could be performed 24/7 instead of exclusively during the night shift.



Reduced overall lab costs through efficiencies such as bringing all primary and secondary syphilis testing in-house.



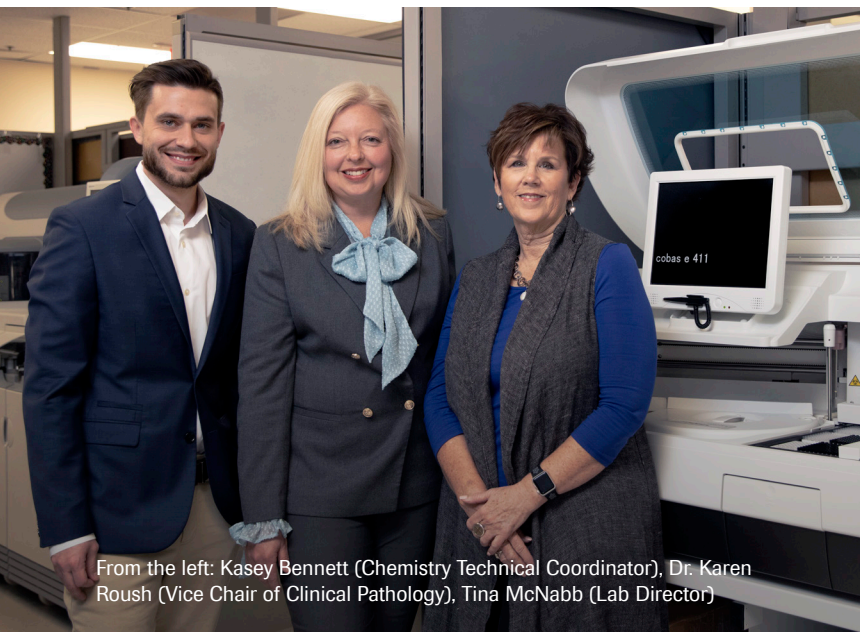
Reduced hands-on time for lab staff via automation so they could focus on value-added tasks instead.

“It frees you up, even if it’s just a phone call, calling criticals. You don’t have to put anything on a delay. You’re able to run tests and walk away instead of standing in front of a manual test.”

Kasey Bennett
Chemistry Technical Coordinator



Helped increase job satisfaction for lab personnel and enable them to improve support for physicians and patients.



“I could afford to pay a little bit extra per test to save on tech time and get the outcome that we did. We found so many more positive patients that it was a no-brainer.”

Tina McNabb
Lab Director

Implement the Elecsys® Syphilis assay to support better care for patients and help improve laboratory efficiency.

Learn more about the Elecsys Syphilis assay at go.roche.com/syphiliscasestudy

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¹Centers for Disease Control and Prevention. “New CDC Report: STDs Continue to Rise in the U.S.” October 8, 2019. <https://www.cdc.gov/nchhstp/newsroom/2019/2018-STD-surveillance-report-press-release.html> (accessed October 31, 2019).

²Texas Department of State Health Services. “Congenital Syphilis in Texas.” 2017. <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwiKp42bycbIAhVDUt8KHYcPCUUQFjAAegQIBBAC&url=https%3A%2F%2Fwww.dshs.state.tx.us%2Fhivstd%2Finfo%2Fedmat%2FCongenitalSyphilis.pdf&usg=AOvVaw01syKyz05RMZLh-CRUJHFhF> (accessed October 31, 2019).

³Binnicker, M.J. (2012). “Which algorithm should be used to screen for syphilis?” *Curr Opin Infect Dis* 25:79–85.

⁴Natesan, T. and V. Sudha. (2014). “Usefulness of reverse screening algorithm in the diagnosis of syphilis.” *Apollo Medicine* 11(4):264–266.

⁵Workowski, K.A. and S. Berman. CDC. (2010). Sexually transmitted diseases treatment guidelines, 2010. *MMWR Recomm Rep* 59:1–110.

⁶World Health Organization. (2012). Investment case for eliminating mother-to-child transmission of syphilis. Available from http://apps.who.int/iris/bitstream/10665/75480/1/9789241504348_eng.pdf (accessed September 2013).

⁷Katz, K. (2010). “Newer laboratory testing algorithms for syphilis begin with EIA.” *MLO Med Lab Obs* 42:18–20.

⁸Bennett, K., T. McNabb and K. Roush. (2019). Methodist Charlton Medical Center. “Reverse Algorithm Syphilis Testing: What Are We Missing?”