EVALUATION OF VERIGENE ENTERIC PATHOGENS TEST IN A SMALL VOLUME LABORATORY

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INTRODUCTION

Current state at Prairie Ridge Health for Enteric Pathogens consists of a 5 separate orders for bacterial and parasitic pathogens and 1-3 samples. This includes the following:

- Stool culture for bacterial pathogens
- Enzyme immunoassay (EIA) for Shigatoxin 1 and Shigatoxin 2
- Enzyme immunoassay for Campylobacter
- No viral pathogens unless ordered separately

These methods are labor-intensive and lack specificity and/or sensitivity. EIA requires staff to set timers and read results at 20 minutes. Stool culture takes up to 3 days and workup may require a bacterial identification using the Vitek 2 system if suspicious colonies are present.

Syndromic panels are now available. These incorporate extraction, amplification, and detection in closed system.

Benefits	Disadvantages
Less hands-on time	Increased false positives in asymptomatic individuals
Improved sensitivity	
Multiple targets on one panel	Pathogen detection does not prove cause of disease
Improved turnaround time	
Fewer samples required	No isolate for public health follow-up

The objectives of this study are as follows:

1. Perform a labor study to determine labor savings. It is predicted that the Enteric Pathogens (EP) test will result in less hands-on time for the technologists, resulting in labor savings.
2. Evaluate the order process for providers
3. Perform a cost analysis of the EP panel compared to current methods. This includes analyzer, reagent, and staff cost as well as reimbursement costs.
4. Evaluate the turnaround time including time from collection to result as well as time to treatment when applicable
5. Investigate the impact this new method will have on public health. This includes investigating positive samples to develop a workflow that allows the public health department to obtain maximum recovery.

METHODS

Verigene Enteric Pathogens test (EP). This method was selected for cost-conscious ordering and reporting. It currently offers flexible order and report options for respiratory panel. This will be available for enteric pathogens in the future on the next Verigene platform.

Labor study was be performed by staff self-recording time including pre-analytic, analytic, and post-analytic phase as well as training time for Verigene. A process map was created to document workflow.

Cost analysis was performed including analyzer, maintenance and reagent cost (actual) vs reimbursement cost from 2020 CMS fee schedule. Staff cost was determined using average hourly wage from payroll and tech time from labor study.

Turnaround time (collection to result) was obtained from Laboratory Information System (LIS).

Public Health impact was evaluated using a list of positive results to obtain turnaround time for public health reports and telephone conversations with Public Health to obtain feedback regarding sample quality and downstream effects.

RESULTS

Table 1: Labor Study (Tech time per test)

Current methods	40 minutes + 10 minutes for each Vitek ID required
PCR method	15 minutes
Training for Verigene	12 total hours

Labor study. Time per test including pre-analytic, analytic, and post-analytic phase.

Order process and Samples required
Current methods (5 orders 3 samples)
PCR method (2 orders 2 samples)

Cost analysis included implementation costs and cost per test.
Table 2: Implementation Cost

	Validation reagents	Staff validation time	Staff Training	Validation samples	Total
Verigene Enteric Pathogens	$0	$527.85	$368.16	$0	$896.01

Implementation costs. Cost analysis including reagent, sample, and staff cost for Verigene EP test.

Table 3:Cost per test

	Reagents	Staff wages	Mainten-ance	Proficiency Testing	CMS reimbur-sement	Total cost per test	Variance
Current methods	$25.52	$14.17	$8.14	$2.55	$65.59	$50.38	$15.21
PCR	$76.10	$7.67	$65.50	$7.06	$262.99	$156.33	$106.66

Cost Analysis. Cost analysis per test including reagent cost, staff cost, proficiency testing, standard reimbursement, and variance for traditional culture method (n=92) and molecular testing (n=67).

Table 4: Turnaround time

	Mean TAT	Median TAT	Minimum TAT	Maximum TAT
Traditional culture	2.98 days	3 days	2 days	4 days
Enteric Pathogen PCR	7.5 hours	6 hours	3 hours	26 hours

Turnaround time analysis. Turnaround time analysis based on time of collection to time of result for traditional culture method (n=57) and molecular testing (n=43).

CONCLUSIONS

Clinical laboratories are experiencing a workforce shortage. Laboratory administrators have been tasked with developing ways to increase testing capacity with reduced personnel. The reduced hands-on time with the Verigene aids with this.

While there was an implementation cost for the Verigene, the significant change in variance per test quickly compensates for that initial startup expense. CMS reimbursement for molecular testing is currently significantly higher than traditional culture methods. CMS reimbursement rates vary over time. While molecular testing is currently covered, this could change in subsequent years. At this point in time, molecular testing shows a positive variance.

Public health impact could not be assessed, as there were no positive results during the time period. This low positivity rate is normal. The established workflow for positive samples is to send the preserved sample to the Public Health laboratory for surveillance testing. This workflow is acceptable with the local Public Health laboratory due to the small volume of positive samples.

This study demonstrated benefits in reduced hands-on time for staff, improved ordering process for providers, faster turnaround time, and larger positive fiscal variance. It is concluded that the transition to molecular testing for enteric pathogens is beneficial for the providers, patients, finance, and laboratory productivity. It is also concluded that these benefits apply to both small volume and large volume laboratories.