# MULTIPLEX PCR FOR GASTROENTERITIS

**TYLER RADKE, MLS(ASCP)**

**LABORATORY MANAGER**

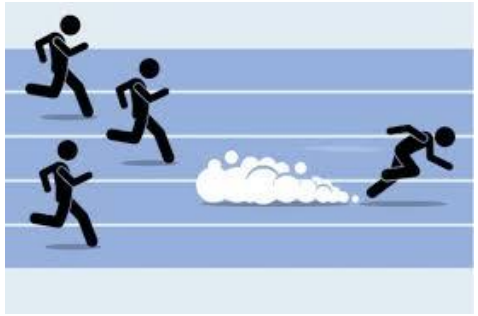
## What are you performing today?

- A – Multiplex NAAT
- B – Stool Culture w/ NAAT
- C – Stool Culture w/ kit testing
- D – Single Assay NAAT
- E – Other

# EXPECTED IMPACT

## GENERAL ASSUMPTIONS

- **COMPARITIVELY EXPIDITIOUS**
  - Equal processing time
  - Less manual interpretation time
  - Less clerical time
  - Faster Turn-Around-Time (TAT)
- **IMPROVED DETECTION**
- **IMPROVED PATIENT OUTCOMES**
- **PHYSICIAN & PATIENT SATISFIER**
- **COST NEUTRAL**




# IMPROVED DETECTION

**What was the most commonly detected organism on the multiplex PCR Panel?**

# Improved Detection

- **A – Enteropathogenic E.coli**
- **B – Campylobacter spp.**
- **C – Salmonella spp.**
- **D – Entamoeba histolytica**
- **E – Norovirus**

# Improved Detection

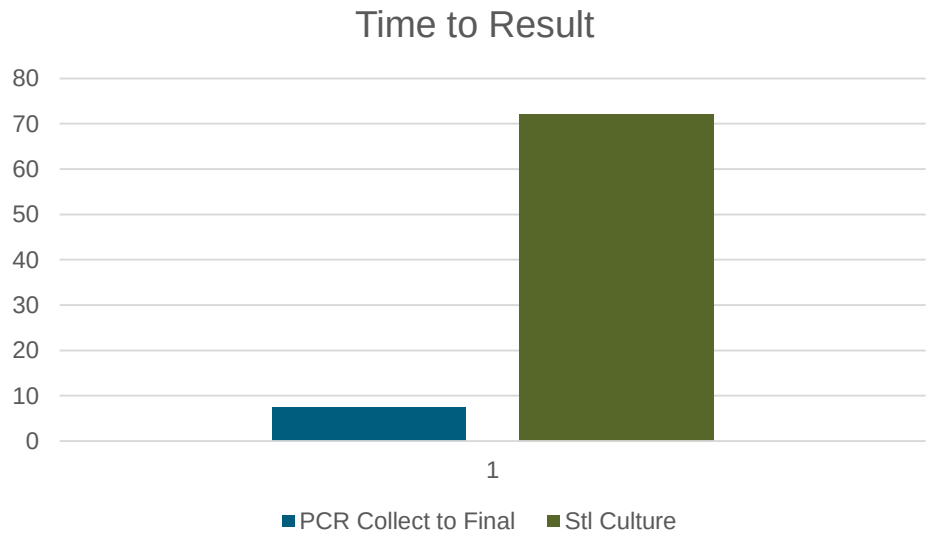
- **> 33% positivity rate on 6311 samples tested (excludes EPEC & C. diff)**
  - 16 cases of Vibrio spp.
  - 15 cases of Plesiomonas shigelloides
  - 21 cases of E. coli 0157
  - 31 cases of Cyclospora
  - 33 cases of Yersinia enterocolitica
  - 89 Adenovirus
  - 110 Astrovirus
  - 119 cases of Cryptosporidium
  - 120 cases of Rotavirus
  - 123 cases of Giardia lamblia
  - 174 Sapovirus

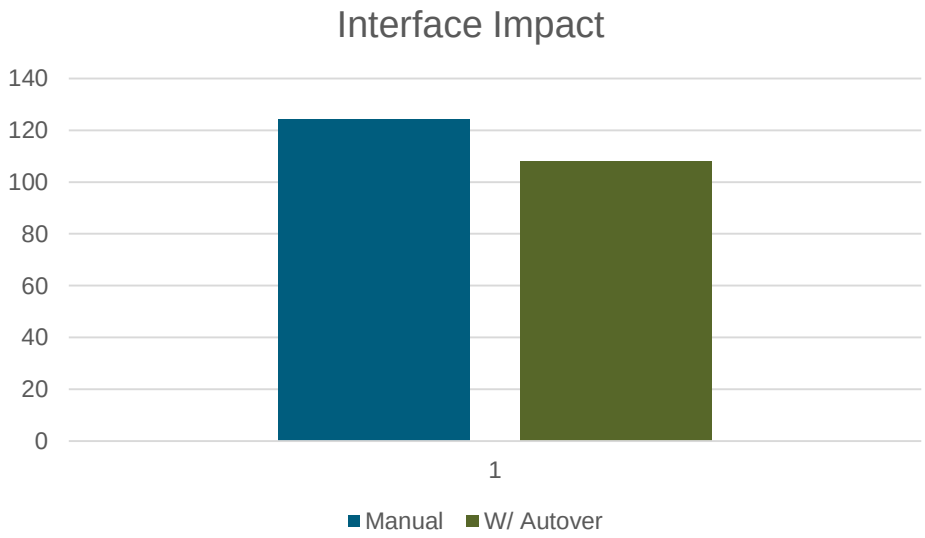

- **Additional Questions!**

# IMPROVED OUTCOMES

# Improved Patient Outcomes

- **Heavily data dependent**
- **Earlier intervention impacting downstream consequences (work days lost)**



# Improved Patient Outcomes

- **Earlier initiation of targeted antimicrobial therapy**
- **Earlier discontinuation of empirical antimicrobial therapy**
- **Less likely to undergo endoscopy or abdominal radiology**
- **Less likely to be prescribed any antibiotic**

Allen Bateman, PhD

- *Clinical Impact of a Multiplex Gastrointestinal Polymerase Chain Reaction Panel in Patients With Acute Gastroenteritis* – Cybulski et al.
- *Impact of Gastrointestinal Panel Implementation on Health Care Utilization and Outcomes* – Axelrad et al.

# Case Study

- **7-year old female with Hx of cerebral palsy presents for vomiting, diarrhea of 5 days, and lethargy.  No signs of fever, cough, dysuria, myalgia, neck pain/stiffness, adenopathy, etc.**
- **Physical exam mostly unremarkable.**
- **WBC 23.6 with 37% bands, remaining components reflective of dehydration.**
- **Creatinine 1.05, Bilirubin 1.4, albumin 2.9**
- **Patient given bolus of fluid, placed on maintenance, and given Zofran.**
- **Pediatric Hospitalist consulted, patient admitted to Peds Unit with impression of gastroenteritis and moderate dehydration.**

**PLAN:**

- **Fluids, electrolytes, and nutrition**
- **Start on Ceftriaxone given elevated bands and wait for Blood/Urine cultures to complete**
- **Continue treatment of seizure disorder**

# Case Study

**Day 2:**

- **Overnight fluid resuscitation did not produced expected outcomes**
- **BUN up to 54, Creatinine up to 2, WBC down to 17, Platelets down to 40**
- **Continued Tachycardia**
- **Stool PCR ordered**

E. Coli 0157

**Discharge Diagnosis:**

- **Gastroenteritis secondary to E. coli 0157**
- **Thrombocytopenia likely secondary to hemolytic uremic syndrome**
- **Renal failure**
- **Admitted to ICU**

# Patient Outcomes – Unintended Consequences

1. **Additional prescribing of antibiotics**
   a) Patient and Insurer Cost
   b) Naïve bacteria exposed to antibiotics → environmental pressure → resistance development
   c) Predisposition to acquire C. difficile
   d) Antibiotic side effects

2. **Unnecessarily prescribing antibiotics**
   a) Pediatric population with dual detections

# PROVIDER & PATIENT SATISFACTION

# Satisfaction

- **Providers**
  - Faster results
  - More detections
  - Earlier interventions

- **Patients**
  - Faster results
  - More answers provided
  - Quicker to treatment

**Have you experienced problems with reimbursement or patient cost?**

# Improved Detection

- **A – YES**
- **B – NO**
- **C – I Don’t Know**
- **D – Other**

# Monetary Satisfaction

- **Spreadsheet of all In-Network Payers and their rate by CPT code**
- **Determine distribution of CPT charge code by Network Payer**
- **Determine amount of money “left on the table”**
- **Get administration approval**

| | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| 1 | HCPCS/MOD | Medicare | | Anthem Priority | | Anthem POS | |
| 2 | | Clinic | Hospital | Clinic | Hospital | Clinic | Hospital |
| 952 | 62355 | $ 253.38 | $ 292.91 | $ 792.54 | $ 792.54 | $ 938.12 | $ 938.12 |
| 953 | 62360 | $ 292.91 | $ 389.15 | $ 929.73 | $ 929.73 | $ 1,100.49 | $ 1,100.49 |
| 954 | 62361 | $ 389.15 | $ 360.49 | $ 983.19 | $ 983.19 | $ 1,163.78 | $ 1,163.78 |
| 955 | 62362 | $ 360.49 | $ 278.26 | $ 1,158.47 | $ 1,158.47 | $ 1,371.26 | $ 1,371.26 |
| 956 | 62365 | $ 278.26 | $ 41.04 | $ 880.76 | $ 880.76 | $ 1,042.52 | $ 1,042.52 |
| 957 | 62367 | $ 41.04 | $ 24.50 | $ 128.18 | $ 76.26 | $ 151.74 | $ 90.27 |
| 958 | 62368 | $ 55.25 | $ 33.89 | $ 173.27 | $ 105.02 | $ 205.08 | $ 124.31 |
| 959 | 62369 | $ 116.57 | $ 33.89 | $ 387.20 | $ 105.02 | $ 458.32 | $ 124.31 |
| 960 | 62370 | $ 123.11 | $ 45.25 | $ 403.61 | $ 141.79 | $ 477.73 | $ 167.84 |
| 961 | 63001 | $ 1,123.13 | $ 1,127.98 | $ 3,577.42 | $ 3,577.42 | $ 4,234.49 | $ 4,234.49 |
| 962 | 63003 | $ 1,127.98 | $ 1,078.61 | $ 3,580.60 | $ 3,580.60 | $ 4,238.26 | $ 4,238.26 |
| 963 | 63005 | $ 1,078.61 | $ 1,013.49 | $ 3,427.99 | $ 3,427.99 | $ 4,057.61 | $ 4,057.61 |
| 964 | 63011 | $ 1,013.49 | $ 1,089.49 | $ 3,202.70 | $ 3,202.70 | $ 3,790.95 | $ 3,790.95 |
| 965 | 63012 | $ 1,089.49 | $ 1,341.09 | $ 3,464.54 | $ 3,464.54 | $ 4,100.88 | $ 4,100.88 |
| 966 | 63015 | $ 1,341.09 | $ 1,386.85 | $ 4,283.11 | $ 4,283.11 | $ 5,069.79 | $ 5,069.79 |
| 967 | 63016 | $ 1,386.85 | $ 1,140.41 | $ 4,382.76 | $ 4,382.76 | $ 5,187.76 | $ 5,187.76 |
| 968 | 63017 | $ 1,140.41 | $ 1,063.15 | $ 3,634.48 | $ 3,634.48 | $ 4,302.02 | $ 4,302.02 |
| 969 | 63020 | $ 1,063.15 | $ 894.37 | $ 3,398.36 | $ 3,398.36 | $ 4,022.54 | $ 4,022.54 |
| 970 | 63030 | $ 894.37 | $ 174.99 | $ 2,822.36 | $ 2,822.36 | $ 3,340.75 | $ 3,340.75 |
| 971 | 63035 | $ 174.99 | $ 1,279.83 | $ 551.41 | $ 551.41 | $ 652.70 | $ 652.70 |
| 972 | 63040 | $ 1,279.83 | $ 1,197.52 | $ 4,059.60 | $ 4,059.60 | $ 4,805.23 | $ 4,805.23 |

**Approximately how much do you charge for a multiplex panel?**

# Improved Detection

- **A $100-$500**
- **B $500-$1000**
- **C $1000-$1500**
- **D >$1500**
- **E – Don’t know**

# CMS LCD Ruling

**Coverage Guidance**

**Coverage Indications, Limitations, and/or Medical Necessity**

This contractor will provide limited coverage for Gastrointestinal Pathogen (GIP) molecular assays identified by multiplex nucleic acid amplification tests (NAATs), and will limit GIP coverage in immune competent beneficiaries up to 5 bacterial targets which represent the top 90-95% of foodborne infections ([incidence of infection per 100,000 population]in decreasing incidence): Salmonella [15.89]; Campylobacter [12.97]; Shigella [5.53]; Cryptosporidium [3.31]; Shiga toxin producing E. coli (STEC) non-O157 [1.64] and STEC O157 [.95].

In addition, when there is a clinical concern for Clostridium difficile colitis, this contractor will cover up to 11 targets if Clostridium difficile is one of the organisms tested for.

Testing for 12 or more organisms will only be covered in critically ill or immunosuppressed patients.

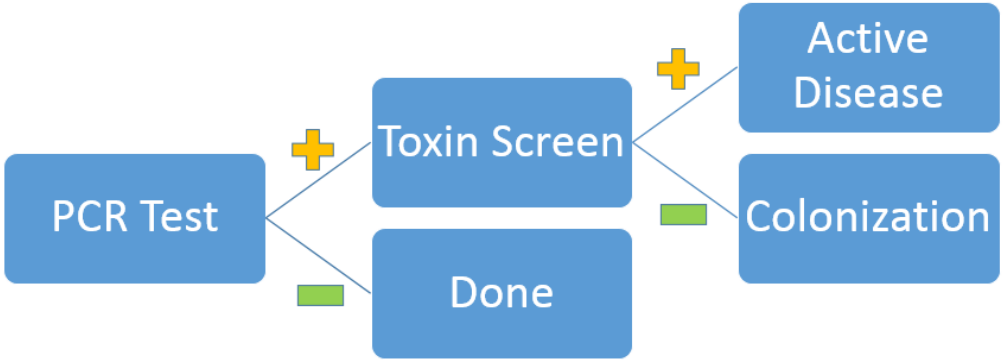
In immune competent individuals, most people with Cryptosporidium, a parasitic disease, will recover without treatment. The pathogens in some of the GIP panels are determined by the manufacturers that make them, and do not represent specific pathogens that cause a common age-based syndrome, or represent organisms that commonly are found in a specific sample type, patient population or reflect community acquired foodborne infections. Because of the unique clinical circumstances of immune compromised patients, ICU patients, and HIV positive patients with diarrhea, GIP testing for bacteria, virus and parasite testing may be indicated, and thus a Medicare benefit.

- https://www.aphl.org/aboutAPHL/publications/Documents/CMS-L37709-20190108-LCD-NAAT.pdf

# Satisfaction – Additional Improvements

- **Ordering Practices**
  - By site & Provider Type
- **Reporting Results**
  - Blind results for C. diff on patients <2 yo
  - Perform Toxin Screen on all positive C. diff results (2-step)
  - Autoverification of negatives
- **Guidelines/Algorithms**
  - Multidisciplinary team developed “best practice guideline”
  - Adapted from available references to be customized to our orderables
  - Notify ordering users of available guideline
- **Ordering Enhancements**
  - Embed guideline hyperlink in orderable
  - Create links to guideline
  - Create “alternative suggestions” during ordering process
  - Apply to acute and ambulatory order sets

# C. Diff 2 Step




**Recommendations**

The interpretation of 2-step testing is as follows:

- A negative PCR test excludes the diagnosis, no treatment is needed
- A positive PCR followed by a positive toxin test will confirm the diagnosis of active C. difficile disease, and treatment is needed.
- A positive PCR followed by a negative toxin test will indicate colonization, and treatment is not needed. Colonized inpatients will still need to be isolated in the hospital.

**How does your lab perform C. diff testing?**

# Panel Question

- **A – NAAT only**
- **B – NAAT followed by Ag/Toxin Screen**
- **C – Ag/Toxin screen followed by NAAT**
- **D – Toxigenic Culture**
- **E – Other**

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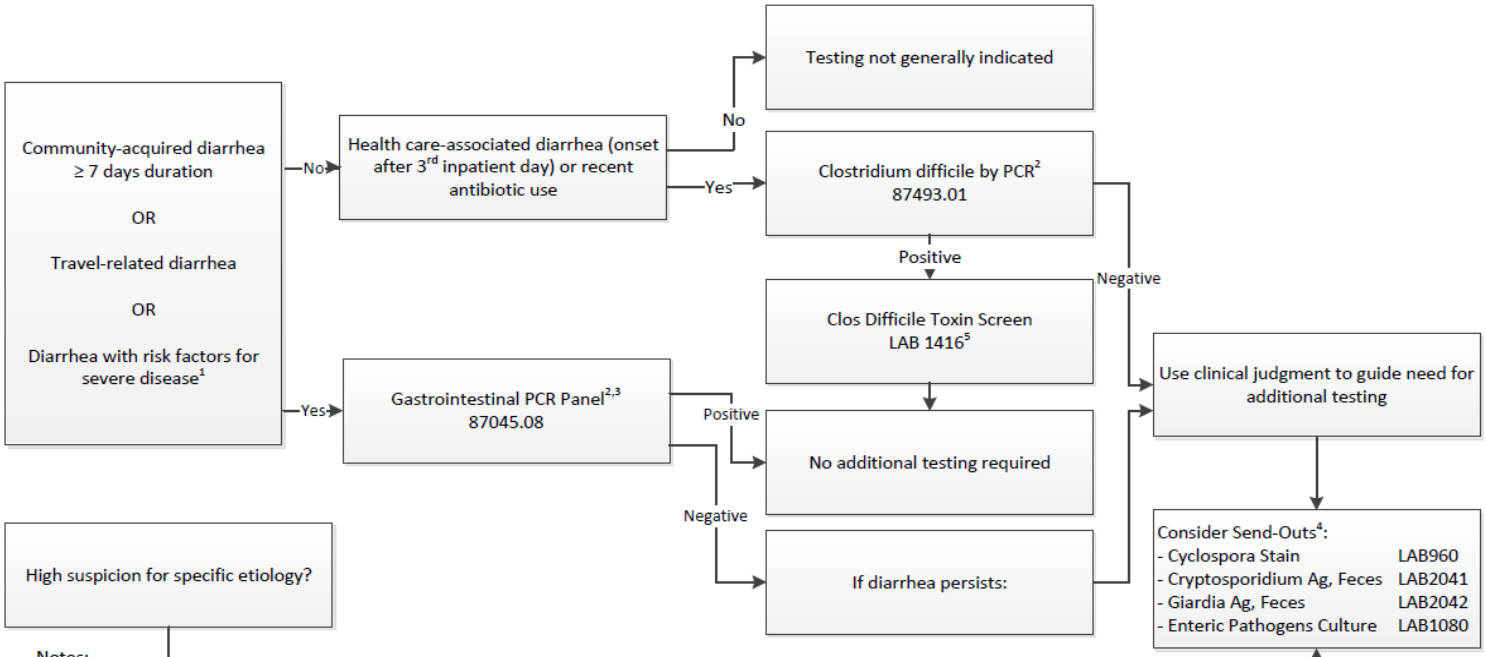
# Laboratory Testing for Infectious Causes of Diarrhea



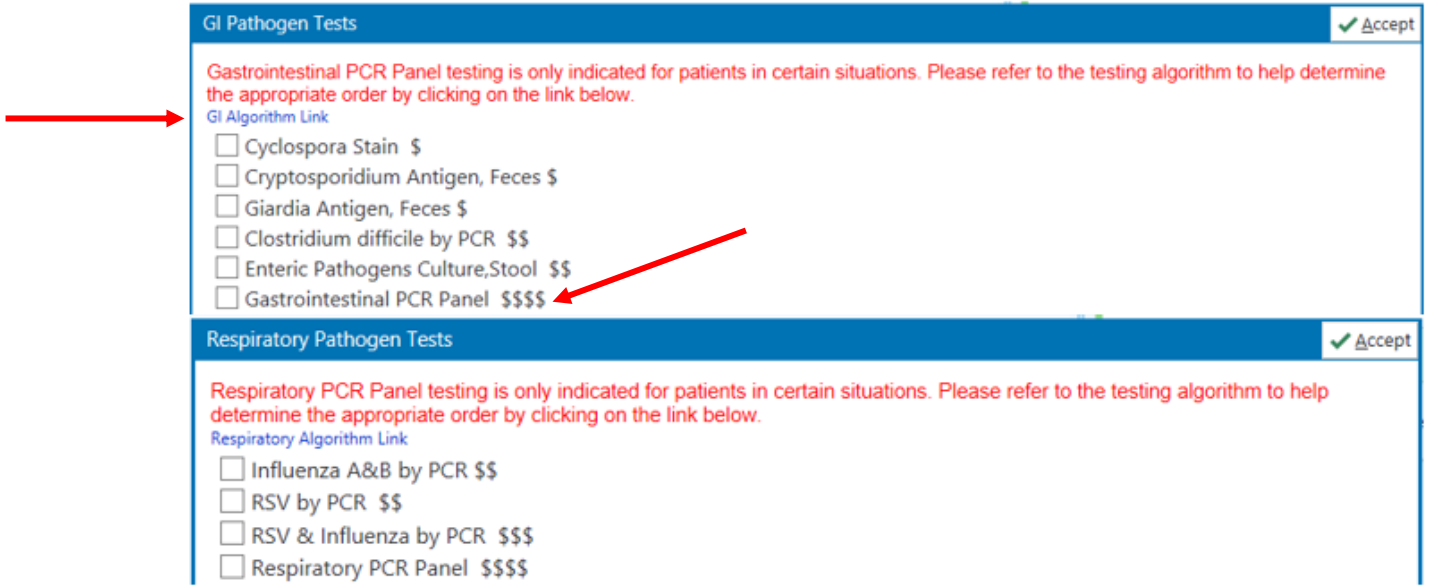

Notes:

1. **Risk factors for severe disease include age, immunocompromised state, bloody diarrhea, dehydration, fever, current or need for hospitalization, and severe abdominal pain.**
2. Detection via molecular methods does not differentiate between viable and non-viable/treated organism; therefore, positive results can persist > 30 days after treatment.
3. Panel detects: Adenovirus, Astrovirus, Campylobacter spp., Clostridium difficile, Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC), E. coli 0157, Shiga-like toxin-producing E. coli (STEC), Shigella/ Enteroinvasive E. coli (EIEC), Giardia lamblia, Norovirus, Plesiomonas shigelloides, Rotavirus, Salmonella spp., Sapovirus, Vibrio parahaemolyticus, Vibrio vulnificus, Vibrio cholera, and Yersinia enterocolitica.
4. Send-outs to a reference lab may require ≥ 72 hours before results are available.
5. Positive Toxin Screen indicates active disease. Negative T… …ent is usually not indicated.

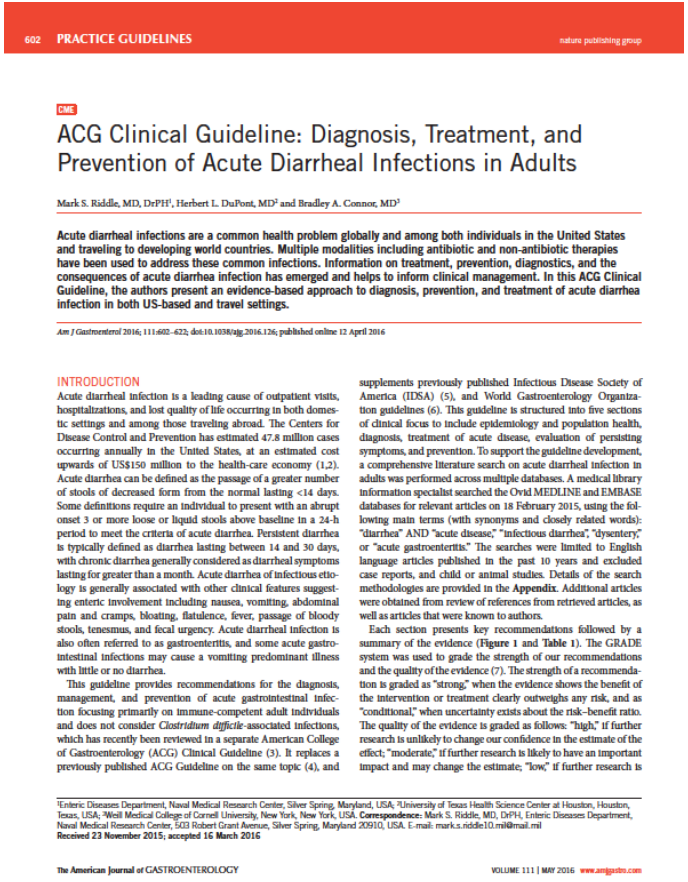
# Ordering Enhancements

## After the Change:

The original order displays optional procedures and relative cost information. The appropriate procedure(s) can be selected. An Algorithm Link to best practice guidelines also displays.



# Additional Guidelines



602 PRACTICE GUIDELINES nature publishing group

CME

## ACG Clinical Guideline: Diagnosis, Treatment, and Prevention of Acute Diarrheal Infections in Adults

Mark S. Riddle, MD, DrPH[1], Herbert L. DuPont, MD[2] and Bradley A. Connor, MD[3]

**Acute diarrheal infections are a common health problem globally and among both individuals in the United States and traveling to developing world countries. Multiple modalities including antibiotic and non-antibiotic therapies have been used to address these common infections. Information on treatment, prevention, diagnostics, and the consequences of acute diarrhea infection has emerged and helps to inform clinical management. In this ACG Clinical Guideline, the authors present an evidence-based approach to diagnosis, prevention, and treatment of acute diarrhea infection in both US-based and travel settings.**

*Am J Gastroenterol* 2016; 111:602–622; doi:10.1038/ajg.2016.126; published online 12 April 2016

INTRODUCTION

Acute diarrheal infection is a leading cause of outpatient visits, hospitalizations, and lost quality of life occurring in both domestic settings and among those traveling abroad. The Centers for Disease Control and Prevention has estimated 47.8 million cases occurring annually in the United States, at an estimated cost upwards of US$150 million to the health-care economy (1,2). Acute diarrhea can be defined as the passage of a greater number of stools of decreased form from the normal lasting <14 days. Some definitions require an individual to present with an abrupt onset 3 or more loose or liquid stools above baseline in a 24-h period to meet the criteria of acute diarrhea. Persistent diarrhea is typically defined as diarrhea lasting between 14 and 30 days, with chronic diarrhea generally considered as diarrheal symptoms lasting for greater than a month. Acute diarrhea of infectious etiology is generally associated with other clinical features suggesting enteric involvement including nausea, vomiting, abdominal pain and cramps, bloating, flatulence, fever, passage of bloody stools, tenesmus, and fecal urgency. Acute diarrheal infection is also often referred to as gastroenteritis, and some acute gastrointestinal infections may cause a vomiting predominant illness with little or no diarrhea.

This guideline provides recommendations for the diagnosis, management, and prevention of acute gastrointestinal infection focusing primarily on immune-competent adult individuals and does not consider *Clostridium difficile*-associated infections, which has recently been reviewed in a separate American College of Gastroenterology (ACG) Clinical Guideline (3). It replaces a previously published ACG Guideline on the same topic (4), and supplements previously published Infectious Disease Society of America (IDSA) (5), and World Gastroenterology Organization guidelines (6). This guideline is structured into five sections of clinical focus to include epidemiology and population health, diagnosis, treatment of acute disease, evaluation of persisting symptoms, and prevention. To support the guideline development, a comprehensive literature search on acute diarrheal infection in adults was performed across multiple databases. A medical library information specialist searched the Ovid MEDLINE and EMBASE databases for relevant articles on 18 February 2015, using the following main terms (with synonyms and closely related words): "diarrhea" AND "acute disease," "infectious diarrhea", "dysentery," or "acute gastroenteritis." The searches were limited to English language articles published in the past 10 years and excluded case reports, and child or animal studies. Details of the search methodologies are provided in the **Appendix**. Additional articles were obtained from review of references from retrieved articles, as well as articles that were known to authors.

Each section presents key recommendations followed by a summary of the evidence (**Figure 1** and **Table 1**). The GRADE system was used to grade the strength of our recommendations and the quality of the evidence (7). The strength of a recommendation is graded as "strong," when the evidence shows the benefit of the intervention or treatment clearly outweighs any risk, and as "conditional," when uncertainty exists about the risk–benefit ratio. The quality of the evidence is graded as follows: "high," if further research is unlikely to change our confidence in the estimate of the effect; "moderate," if further research is likely to have an important impact and may change the estimate; "low," if further research is

[1]Enteric Diseases Department, Naval Medical Research Center, Silver Spring, Maryland, USA; [2]University of Texas Health Science Center at Houston, Houston, Texas, USA; [3]Weill Medical College of Cornell University, New York, New York, USA. **Correspondence:** Mark S. Riddle, MD, DrPH, Enteric Diseases Department, Naval Medical Research Center, 503 Robert Grant Avenue, Silver Spring, Maryland 20910, USA. E-mail: mark.s.riddle10.mil@mail.mil

**Received 23 November 2015; accepted 16 March 2016**



MAYO CLINIC LABORATORIES

Laboratory Testing for Infectious Causes of Diarrhea[1]

*ACG Clinical Guideline: Diagnosis, Treatment, and Prevention of Acute Diarrheal Infections in Adults – Riddle et al.*

# COST NOT NEUTRAL

| | 1,948-GI PCR | 1,948 - Combo |
|---|---|---|
| Cost of Goods Sold | $ 318,233.33 | $ 226,787.78 |
| Labor | $ 7,187.73 | $ 64,690.87 |
| Supplies | $ 301,940.00 | $ 158,119.16 |
| Contract/Maint | $ 8,034.60 | $ 2,835.00 |
| Depreciation | $ 1,071.00 | $ 1,142.75 |
| Cost per Test | $ 163.36 | $ 116.42 |

Labor rate 1 min = 0.73797

Labor rate 5 min = 3.6898

Labor rate 1 hr = 44.278493

# IMPACT

## GENERAL ASSUMPTIONS

- **COMPARITIVELY EXPIDITIOUS**
  - Equal processing time
  - Less manual interpretation time
  - Less clerical time
  - Faster Turn-Around-Time (TAT)
- **IMPROVED DETECTION**
- **IMPROVED PATIENT OUTCOMES**
- **PHYSICIAN & PATIENT SATISFIER**
- **COST NEUTRAL**

## REALIZATIONS

- **EXPIDITIOUS**
  - Clerical time about the same
- **IMPROVED PATIENT OUTCOMES**
  - Mixed results
- **SATISFIER**
  - Mixed results
- **COST NEUTRAL**
  - Supply expense increased

# Panel Discussion

Allen Bateman, PhD

Eric Beck, PhD

Blake Buchan, PhD

Tyler Radke, MLS(ASCP)

Tyler Tschanz, CLS(ASCP)

**Does your lab run a molecular GI panel that has *Vibrio cholerae on it*?**

# Panel Question

- **A – Yes**
- **B – No**

**For labs running *Vibrio cholerae,* how do you treat positive specs?**

# Panel Question

- **A – Report positive, send to WSLH**
- **B – Report as positive PCR w/ culture confirmation to follow (either in house or at WSLH).**
- **C – Mask the result (don’t report) until culture performed for confirmation. Report culture result.**
- **D – Mask the result (don’t report) and don’t do anything else.**
- **E – Other**

**How does your lab handle positive C. diff on Multiplex panels?**

# Panel Question

- **A – No additional testing**
- **B – Chart validation**
- **C – Reflex additional testing**
- **D – Leave for next shift**
- **E – Other**

**How do you gain approval of a new multiplex assay?**

# Panel Question

- **A – Bring to Pathology Committee**
- **B – Bring to AMS Committee**
- **C – Bring to Value Analysis**
- **D – Bring to Laboratory Stewardship**
- **E – Other**

# Panel Questions

- **Is it time to bring back Stool Culture?**
- **How do you handle overutilization?**
- **Are providers asking for lower cost options?**
- **Do you have population exclusions for testing?**
- **What size multiplex panel are you using or interested in?**
- **Added cost improving care or just detections?**

# Thank You!

If additional time, review of study from Allen Bateman, PhD

OXFORD ACADEMIC

Clinical Infectious Diseases

ACCEPTED MANUSCRIPT

# Clinical impact of a Multiplex Gastrointestinal PCR Panel in Patients with Acute Gastroenteritis

Robert J Cybulski, Jr, Allen C Bateman, Lori Bourassa, Andrew Bryan, Barb Beail, Jason Matsumoto, Brad T Cookson, Ferric C Fang ✉ Author Notes

*Clinical Infectious Diseases*, ciy357, https://doi.org/10.1093/cid/ciy357

**Published:** 25 April 2018 **Article history** ▾

# Objectives

Assess the clinical relevance and utility of BioFire FilmArray GI panel

1. Determine whether patients detected by multiplex PCR have comparable clinical features to those diagnosed with conventional methods
    - Clinical features of patients positive by
        - FilmArray and stool culture (concordant) vs
        - FilmArray only (discordant)

2. Measure the impact of more rapid diagnosis on clinical decision-making and therapy
    - Compare to stool culture
        - Sensitivity
        - TAT
        - Antimicrobial treatment
            - Initiation, empiric vs targeted, discontinuation

# Study design

- Parallel testing
  - Jan 1 – Sep 30, 2017
- Historical control, stool culture
  - Jan 1 – Sep 30, 2016
- Eligible subjects
  - Outpatients
  - Newly-admitted (<3d) inpatients
  - From 17 outpatient clinics, UWMC, and HMC

**1,887 stool specimens**

**Stool culture**

- *Salmonella*
- *Shigella*
- *Campylobacter*
- *E. coli* O157:H7
- *Yersinia*
- *Vibrio*
- *Aeromonas*
- *Plesiomonas*

**FilmArray™ Gastrointestinal Panel**

**1 Test. 22 Targets. All in about an hour.**

**Bacteria**

*Campylobacter (jejuni, coli and upsaliensis)*
*Clostridium difficile* (toxin A/B)
*Plesiomonas shigelloides*
*Salmonella*
*Yersinia enterocolitica*
*Vibrio (parahaemolyticus, vulnificus and cholerae)*
*Vibrio cholerae*
***Diarrheagenic E. coli/Shigella***
Enteroaggregative *E. coli* (EAEC)
Enteropathogenic *E. coli* (EPEC)
Enterotoxigenic *E. coli* (ETEC) *lt/st*
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*
*E. coli* O157
*Shigella*/Enteroinvasive *E. coli* (EIEC)

**Parasites**

*Cryptosporidium*
*Cyclospora cayetanensis*
*Entamoeba histolytica*
*Giardia lamblia*

**Viruses**

Adenovirus F 40/41
Astrovirus
Norovirus GI/GII
Rotavirus A
Sapovirus (I, II, IV and V)

# Testing and reporting

- Stool culture orderable replaced with ‘Enteric Pathogens by PCR’ test (Jan 1, 2017)
- Clinicians informed
  - in-person presentations
  - institution-wide memorandum from medical directors
- Stool in Cary-Blair medium, FilmArray GI tested/reported on receipt
  - 11pm-7am, tested/reported following morning
- Stool culture results not reported
- Parasite and virus tests performed as ordered
  - O&P, modified acid-fast smear, Giardia antigen, LDT viral PCR
- Results reported in LIS
  - STEC, called to clinicians

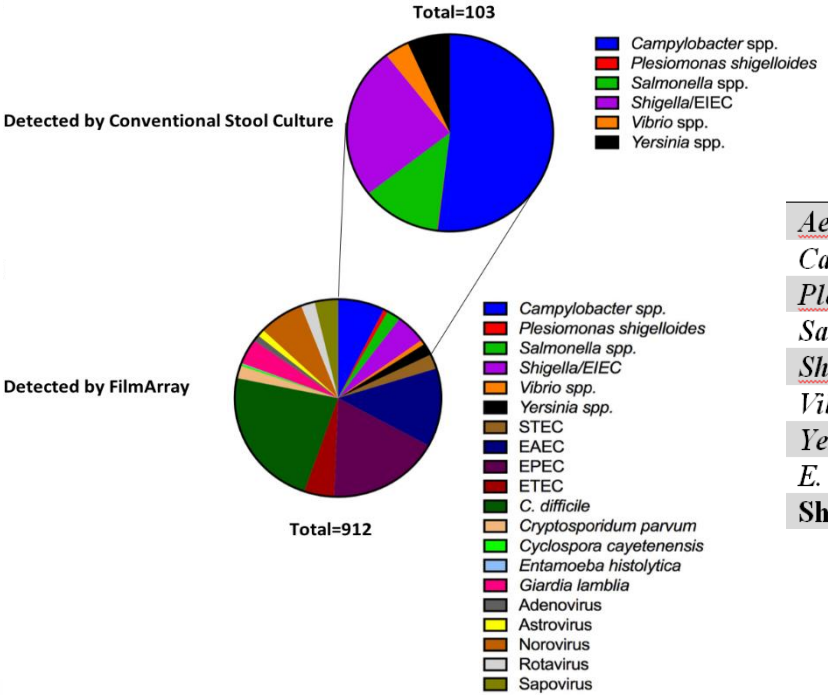
# Chart review

- Chart review on all stool culture positives and FilmArray™ positives (n=579)
  - Demographics
  - Signs and symptoms of gastroenteritis
  - Antimicrobial treatment

- Times obtained from LIS
  - Sample collection
  - Arrival in lab
  - Result reported

- Empiric therapy = therapy initiated prior to the release of results
- Targeted therapy = therapy initiated after results released AND clinician prescribed agent with predicted activity against microbe detected

# Pathogen Detection




| | Stool Culture (n=1,887) | | FilmArray (n=1,887) | | p |
|---|---|---|---|---|---|
| | POS | % | POS | % | |
| *Aeromonas* spp. | 8 | 0.4 | | | n/a |
| *Campylobacter* spp. | 51 | 2.7 | 68 | 3.6 | n.s. |
| *Plesiomonas shigelloides* | 0 | 0.0 | 6 | 0.3 | 0.0142 |
| *Salmonella* spp. | 13 | 0.7 | 19 | 1 | n.s. |
| *Shigella*/EIEC | 28 | 1.4 | 43 | 2.2 | n.s. |
| *Vibrio* spp. | 4 | 0.2 | 7 | 0.4 | n.s. |
| *Yersinia* spp. | 7 | 0.4 | 17 | 0.9 | 0.0414 |
| *E. coli* O157:H7 | 3 | 0.2 | 4 | 0.2 | n.s. |
| Shiga-like toxin producing *E. coli* | | | 21 | 1.1 | 0.0002 |

# Clinical Features

- Patients with classic enteric bacterial pathogens by FilmArray

- Concordant = identified by FilmArray and stool culture
- Discordant = identified by FilmArray only

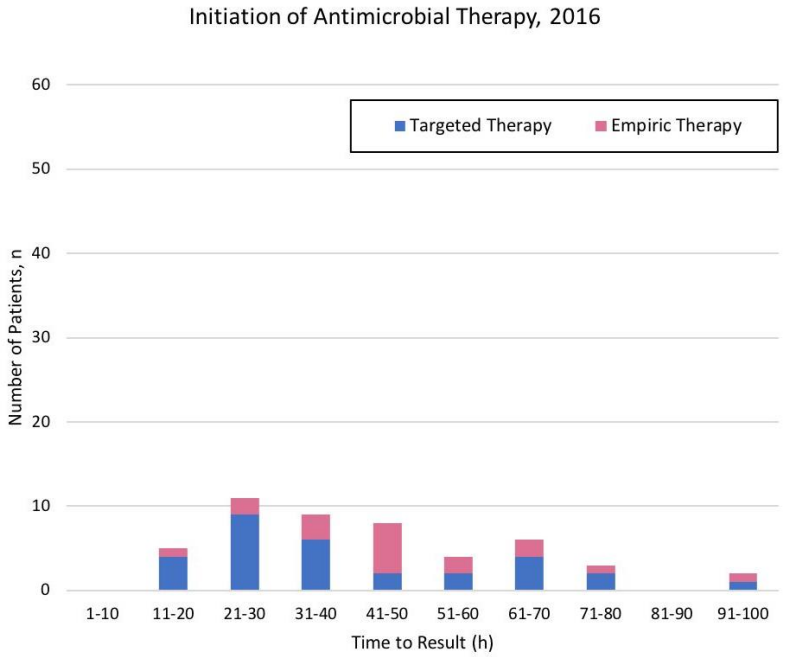
- Patients with concordant results: nonsignificant trend toward greater symptom severity
- Patients with discordant results: longer symptom duration

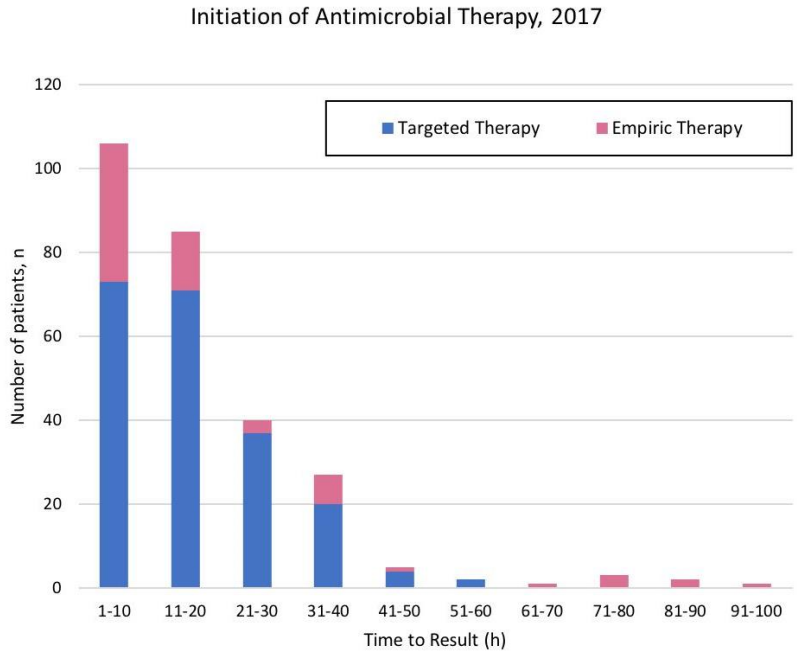
| | Concordant Results | Discordant Results | p |
|---|---|---|---|
| Patients, n | 98 | 68 | |
| Age, years | | | |
| Mean (range) | 40.3 (1-91) | 39.6 (1-82) | n.s. |
| Median (range) | 34.0 (1-91) | 36.0 (1-82) | n.s. |
| Percent Female | 35.60% | 53.60% | n.s. |
| Ordering location, n (%) | | | |
| Outpatient | 80 (79) | 55 (80%) | n.s. |
| ED | 17 (17) | 9 (13%) | |
| Inpatient | 4 (4) | 5 (7%) | |
| Mean # of symptoms per patient (range) | 3.8 (0-8) | 3.4 (0-8) | n.s. |
| Patients with Headache, n (%) | 9 (9) | 5 (7) | n.s. |
| Patients with Abdominal pain, n (%) | 73 (75) | 49 (72) | n.s. |
| Patients with Tenesmus, n (%) | 2 (2) | 1 (2) | n.s. |
| Patients with Nausea, n (%) | 42 (43) | 30 (44) | n.s. |
| Patients with Vomiting, n (%) | 19 (19) | 14 (21) | n.s. |
| Patients with Diarrhea, n (%) | 96 (98) | 62 (91) | n.s. |
| Patients with Watery Diarrhea, n (%) | 53 (54) | 36 (53) | n.s. |
| Patients with Blood in Stool, n (%) | 22 (22) | 8 (12) | n.s. |
| Patients with Chills, n (%) | 28 (29) | 14 (21) | n.s. |
| Patients with Fatigue, n (%) | 27 (28) | 13 (19) | n.s. |
| Patients with Fever, n (%) | 17/97 (18) | 10/65 (15) | n.s. |
| Patients with Leukocytosis, n (%) | 20/48 (42) | 5/30 (17) | n.s. |
| Patients with Fecal Leukocytes, n (%) | 5/12 (42) | 1/9 (11) | n.s. |
| Median duration of symptoms at presentation, days (range) | 7 (1-90) | 8.5 (1-240) | <0.0001 |
| Patients with international travel history, n (%) | 33 (34) | 31 (46) | n.s. |
| Patients with bacteria/parasite receiving antibiotic, n (%) | 79 (81) | 47 (68) | n.s. |
| Patients receiving empirical antibiotic therapy, n (%) | 27 (34) | 10 (21) | n.s. |
| Median duration of antibiotics, days (range) | 4.5 (1-10) | 5 (1-28) | n.s. |
| Patients hospitalized, n (%) | 12 (12) | 8 (12) | n.s. |
| Cases with apparent resolution of symptoms, n (%) | 88 (90) | 62 (91) | n.s. |

# Turnaround time and clinical decision-making

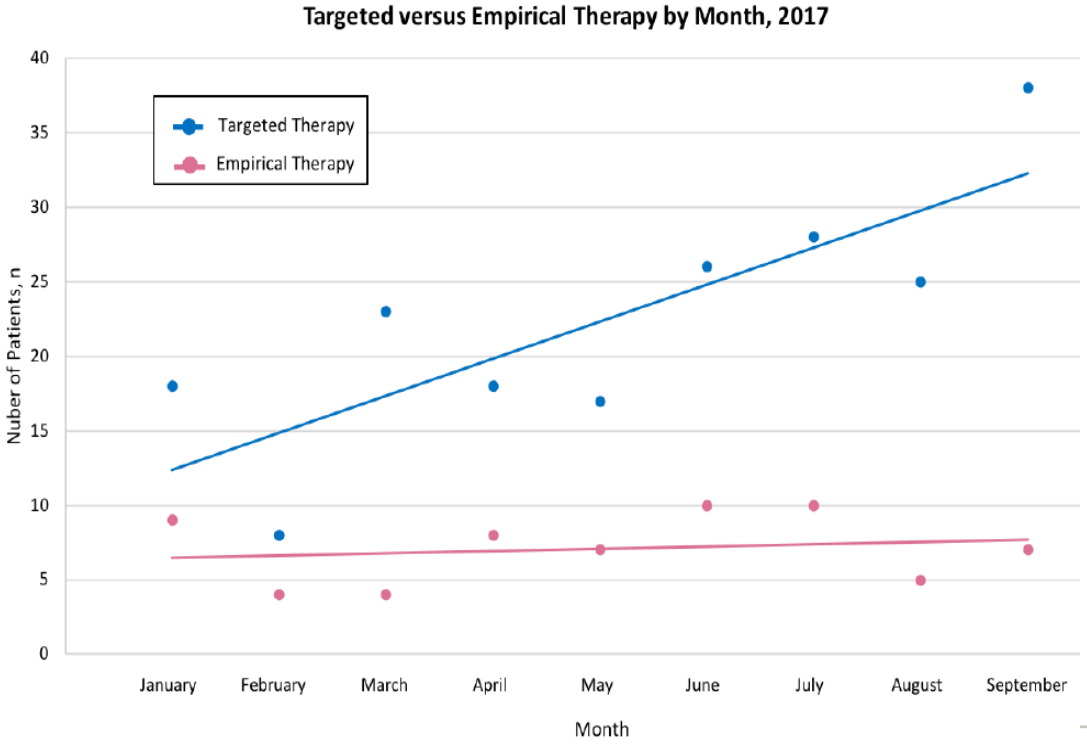
| | 2016 Culture | 2017 FilmArray™ | p |
|---|---|---|---|
| **Cases Reviewed, n** | 83 | 496 | n/a |
| **Median Time Collection to First Report (h)** | 47.0 | 18.0 | <0.0001 |
| **Patients with bacteria/parasite identified, n** | 83 | 420 | n/a |
| **Eligible patients prescribed antimicrobials, n (%)** | 50 (60.3) | 272 (63.8) | ns |
| **Empirical antimicrobial prescription, n (%)** | 20 (40.0) | 64 (23.5) | 0.0148 |
| **Median Time Collection to Antimicrobial (h)** | 72.0 | 26.0 | <0.0001 |

# Turnaround time and clinical decision-making



# Turnaround time and clinical decision-making



# STEC infections

| | # STEC identified | TAT |
|---|---|---|
| FilmArray | 21 (4 O157:H7) | 18h |
| Stool culture + Shiga toxin immunoassay | 3 O157:H7 | 60h (positive)<br>75h (negative) |

- 9 of 21 patients with STEC empirically prescribed ABX
- 8 of 9 cases, discontinued after STEC reported
  - Median of 8h from results to discontinuation

# Pathogen Detection