GI Pathogen Testing, New Guidelines

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Mic 18

Objectives

- IDSA guidelines for diarrheal illnesses
  - Who should be tested
  - What pathogens should be targeted by the tests
  - When we should we test for parasites
  - Treatment
- IDSA guidelines – testing for *C. difficile*
- CIDT's for stool pathogens

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Sutter Health System (SHS)

2nd largest Northern-California health system

- Not-for-profit
- Serving >100 communities
- 24 acute care hospital systems
- 26 clinics, medical foundations
- 40,000 physicians
- 50,000 employees

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Sutter Health Shared Laboratory (SHSL)

- Limited Chemistry, Hematology, Blood Bank, and Serology
  - 3.9 million tests/year
- Major provider of Microbiology tests for the system
  - 1 million tests/year
- Major provider of Molecular Dx (ID, Genetic)
  - 367,000 tests/year

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Gastroenteritis & Diarrheal Illnesses

- 2nd leading cause of infectious diseases morbidity
- 3rd leading cause of mortality
  - 1.4 million deaths in 2010[1]
- 1.7 billion cases/year of childhood diarrhea worldwide[2]
- 179 million cases/year in the US[3]

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1. Mandell's Principals of Infectious Diseases, 2015
2. WHO
3. DuPont, in NEJM 2014

Infectious Diarrhea

- Definition:
  - ≥3 unformed stools within 24 hours **AND**
  - Enteric symptoms (nausea, vomiting, pain, cramps,…)
- Severity:
  - Mild – active
  - Moderate – limited activity
  - Severe – serious disability
- Duration:
  - Acute <14 days
  - Persistent 14-30 days
  - Chronic >30 days – parasitic?

Top 5 Most Frequent Pathogens

Numbers of acute gastroenteritis outbreaks and outbreak-associated outcomes caused by various etiologic agents reported in the National Outbreak Reporting System, United States, 2009–2010*

	No. (%) outbreaks			No. (%) outbreak-associated outcomes		
Outbreak etiology	**Confirmed**	**Suspected**	**Total**	**Illnesses**	**Hospitalizations**	**Deaths**
Single agent†						
Norovirus‡	1,355 (64.2)	553 (78.1)	1,908 (67.7)	69,145 (77.7)	1,093 (45.9)	125 (85.6)
Salmonella spp.	344 (16.3)	11 (1.6)	355 (12.6)	8,590 (9.7)	773 (32.5)	6 (4.1)
Shigella spp.§	99 (4.7)	10 (1.4)	109 (3.9)	2,135 (2.4)	115 (4.8)	1 (0.7)
STEC	88 (4.2)	13 (1.8)	101 (3.6)	1,091 (1.2)	250 (10.5)	9 (6.2)
Campylobacter spp.¶	56 (2.7)	13 (1.8)	69 (2.4)	1,550 (1.7)	52 (2.2)	0

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Emerg Infect Dis. 2013 Aug; 19(8): 1305–1309

Most Frequent Pathogens
- caused **92.7%** of the illnesses

Numbers of acute gastroenteritis outbreaks and outbreak-associated outcomes caused by various etiologic agents reported in the National Outbreak Reporting System, United States, 2009–2010*

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Emerg Infect Dis. 2013 Aug; 19(8): 1305–1309

Most Frequent Pathogens
- caused **96.6%** of deaths

Numbers of acute gastroenteritis outbreaks and outbreak-associated outcomes caused by various etiologic agents reported in the National Outbreak Reporting System, United States, 2009–2010*

	No. (%) outbreaks			No. (%) outbreak-associated outcomes		
Outbreak etiology	**Confirmed**	**Suspected**	**Total**	**Illnesses**	**Hospitalizations**	**Deaths**
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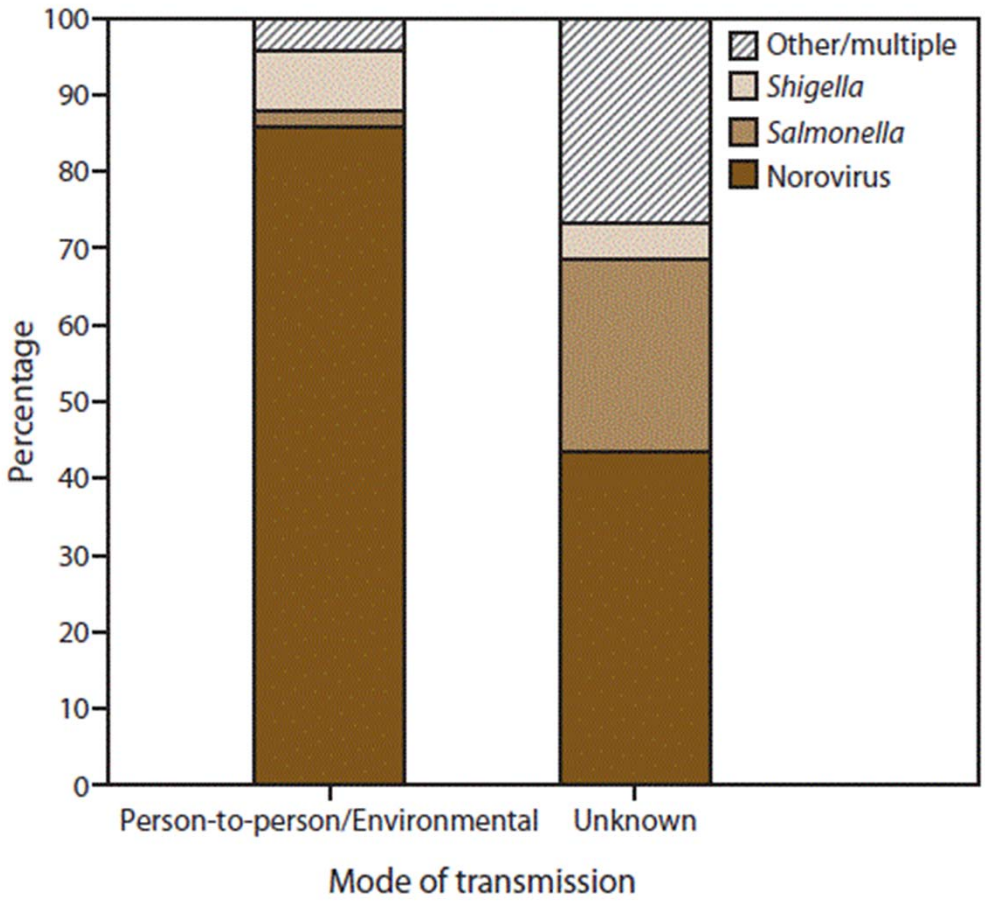
Emerg Infect Dis. 2013 Aug; 19(8): 1305–1309

Most Frequent Pathogens

Percentage of outbreaks of acute gastroenteritis transmitted by person-to-person contact, environmental contamination, and unknown mode of transmission by confirmed etiology — National Outbreak Reporting System, United States, **2009–2013**

[MMWR, Dec. 11 2015 / 64]



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https://www.cdc.gov/mmwr/preview/mmwrhtml/ss6412a1.htm?s_cid=ss6412a1_w#Tab1

IDSA – Infectious Diarrhea Diagnosis

Clinical Infectious Diseases

IDSA GUIDELINE

2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea

Andi L. Shane, MD[1] Rajal K. Mody, MD[2] John A. Crump, MD[3] Phillip I. Tarr,[4] Theodore S. Steiner, MD[5] Karen Kotloff, MD[6] Joanne M. Langley, MD[7] Christine Wanke, MD[8] Cirle Alcantara Warren, MD[9] Allen C. Cheng, PhD[10] Joseph Cantey, MD[11] and Larry K. Pickering, MD[12]

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

Who Should be Tested?

- Test based on:
  - History of illness
    - Travel
    - Long-term care
    - Childcare
    - Healthcare Associated (HCA)
  - Immunocompromised
  - Zoonoses, Outbreak-associated, or Public Health risk
  - Severe Diarrhea
    - Fever, dehydration, dysentery
    - > 7 Days[1,2] or persistent

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1. Riddle MS, in AJG April 2016
2. *Clin Infect Dis*. 2017 Nov 29;65(12):e45-e80. IDSA guidelines

IDSA – What Specimens Should be Tested?

- "The optimal specimen for laboratory diagnosis of infectious diarrhea is a diarrheal stool sample (i.e., a sample that takes the shape of the container). For detection of bacterial infections, if a timely diarrheal stool sample cannot be collected, a rectal swab may be used (weak, low)."

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

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  - Diarrheal Stool
  - Rectal Swab

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

IDSA – Target Oriented Testing

- Organism detection depends on what pathogens are tested and which tests are used
- Factors that determine tests and targets are:
  - History (exposure)
  - Clinical presentation (signs and symptoms)
  - Immune status

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

IDSA – Test For Which Pathogens?

Condition	Target
Severe Cramping/Tenderness, Fever, Bloody or Mucoid stool, Sepsis? • Children w/ persistent abdominal pain, exposure to pork products • Travel to endemic region or Shellfish consumption	*Salmonella*, *Shigella*, *Campylobacter*, *Yersinia*, STEC, *C. difficile** • *Yersinia enterocolitica* • *Vibrio*
Possibility of Outbreaks	Broad Panel (bacterial, viral, parasitic)
Immunocompromised	Broad Panel (bacterial, viral, parasitic)
Uncomplicated Traveler's Diarrhea, which treatment is not indicated	Testing not recommended
Traveler's Diarrhea >14 days	Parasites

* usually not bloody.

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

IDSA – Who Should be Treated?

- "In immunocompetent children and adults, empiric antimicrobial therapy for bloody diarrhea while waiting for results of investigations is **not** recommended (strong, low)."

Clin Infect Dis. 2017 Nov 29;65(12):e45-e80.

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IDSA – Who Should be Empirically Treated?

- "In immunocompetent children and adults, empiric antimicrobial therapy for bloody diarrhea while waiting for results of investigations is **not** recommended (strong, low)."
- Exceptions:
  - <3 months old
  - High severity
    - Fever
    - Abdominal pain
    - Dysentery (bloody stool, cramps, tenesmus, fever …)
  - Recent travel history
    - Fever
    - Signs of sepsis
  - Immunocompromised

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

IDSA – Who Should be Treated?

- Usually has fever and bloody diarrhea
- Any signs or symptoms of sepsis
- Epidemiological or travel link
- Immunocompromised with severe illness
- *Shigella*
- Some *Campylobacter* and *Salmonella*

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

IDSA – Testing for Parasites
[Exposure or Condition Associated with Pathogens]

Swimming in recreational water facility with treated water	*Cryptosporidium* and other potentially waterborne pathogens when disinfectant concentrations are inadequately maintained
Healthcare, long-term care, prison exposure, or employment	Norovirus, *Clostridium difficile*, *Shigella*, *Cryptosporidium*, *Giardia*, STEC, rotavirus
Child care center attendance or employment	Rotavirus, *Cryptosporidium*, *Giardia*, *Shigella*, STEC
Recent antimicrobial therapy	*C. difficile*, multidrug-resistant *Salmonella*
Travel to resource-challenged countries	*Escherichia coli* (enteroaggregative, enterotoxigenic, enteroinvasive), *Shigella*, Typhi and nontyphoidal *Salmonella*, *Campylobacter*, *Vibrio cholerae*, *Entamoeba histolytica*, *Giardia*, *Blastocystis*, *Cyclospora*, *Cystoisospora*, *Cryptosporidium*
Exposure to house pets with diarrhea	*Campylobacter*, *Yersinia*
Exposure to pig feces in certain parts of the world	*Balantidium coli*
Contact with young poultry or reptiles	Nontyphoidal *Salmonella*
Visiting a farm or petting zoo	STEC, *Cryptosporidium*, *Campylobacter*
Exposure or condition	
Age group	Rotavirus (6–18 months of age), nontyphoidal *Salmonella* (infants from birth to 3 months of age and adults >50 years with a history of atherosclerosis), *Shigella* (1–7 years of age), *Campylobacter* (young adults)
Underlying immunocompromising condition	Nontyphoidal *Salmonella*, *Cryptosporidium*, *Campylobacter*, *Shigella*, *Yersinia*
Hemochromatosis or hemoglobinopathy	*Y. enterocolitica*, *Salmonella*
AIDS, immunosuppressive therapies	*Cryptosporidium*, *Cyclospora*, *Cystoisospora*, microsporidia, *Mycobacterium avium*–intercellu-

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80.

IDSA – Testing for Parasites

- **Travel to resource-challenged area**
- **AIDS and immunosuppressive therapy**

- Swimming in treated water
  - *Cryptosporidium*
- Childcare related
  - *Cryptosporidium, Giardia*
- Underlying immunocompromised condition
  - *Cryptosporidium*
- Anal-genital, oral-anal, digital-anal contact
  - *E. histolytica*, *Giardia*, *Cryptosporidium*

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80.

IDSA – Testing for Parasites

- **Travel to resource challenged area**
  - *"… Entamoeba histolytica, Giardia, Blastocystis, Cyclospora, Cystoisospora, Cryptosporidium …"*

"Travelers with diarrhea lasting 14 days or longer should be evaluated for intestinal parasitic infections (strong, moderate)."

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80.

IDSA – Testing for Parasites

- Travel to resource challenged area

- **AIDS and Immunosuppressive Therapy**
  - *"Cryptosporidium*, *Cyclospora*, *Cystoisospora*, microsporidia …"

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80.

IDSA – *C. difficile* Testing

Clinical Infectious Diseases

IDSA GUIDELINE

IDSA Infectious Diseases Society of America

hivma hiv medicine association

OXFORD

Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA)

L. Clifford McDonald,[1] Dale N. Gerding,[2] Stuart Johnson,[2,3] Johan S. Bakken,[4] Karen C. Carroll,[5] Susan E. Coffin,[6] Erik R. Dubberke,[7] Kevin W. Garey,[8] Carolyn V. Gould,[1] Ciaran Kelly,[9] Vivian Loo,[10] Julia Shaklee Sammons,[6] Thomas J. Sandora,[11] and Mark H. Wilcox[12]

[1]Centers for Disease Control and Prevention, Atlanta, Georgia; [2]Edward Hines Jr Veterans Administration Hospital, Hines, and [3]Loyola University Medical Center, Maywood, Illinois; [4]St Luke's Hospital, Duluth, Minnesota; [5]Johns Hopkins University School of Medicine, Baltimore, Maryland; [6]Children's Hospital of Philadelphia, Pennsylvania; [7]Washington University School of Medicine, St Louis, Missouri; [8]University of Houston College of Pharmacy, Texas; [9]Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts; [10]McGill University Health Centre, McGill University, Montréal, Québec, Canada; [11]Boston Children's Hospital, Massachusetts; and [12]Leeds Teaching Hospitals NHS Trust, United Kingdom

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Clin Infect Dis. 2018 Mar 19:66(7)

IDSA - *C. difficile* Infection (CDI) Definition

- **Symptoms**:
  - Diarrhea (usually)
    - Unexplained (e.g., exclude laxative)
    - New-onset
    - ≥3 within 24 hours
    - Unformed stool
- **Tests**:
  - Detection of *C. difficile* toxins
  - Detection of Toxigenic *C. difficile*
  - Colonoscopy
  - Histopathology

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Clin Infect Dis. 2018 Mar 19:66(7)

IDSA – When Should We Test for *C. difficile*?

1. ***"VI. When should testing be performed for Clostridium difficile? Recommendation.***

   18. Testing may be considered for *C. difficile* in people >2 years of age who have a history of diarrhea following antimicrobial use and in people with healthcare-associated diarrhea." [1]

2. "Patients with unexplained and new-onset ≥3 unformed stools in 24 hours are the preferred target population for testing for CDI." [2]

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1. *Clin Infect Dis*. 2017 Nov 29;65(12):e45-e80.
2. *Clin Infect Dis*. 2018 Mar 19:66(7)

IDSA – When Should We Test for *C. difficile*?

- >2 years old
- History of antimicrobial use
- Healthcare-associated diarrhea
- Persistent with no apparent etiology or risk factor
- Test only once
- Testing either toxin (EIA?) or toxigenic strain (NAAT) are acceptable

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Clin Infect Dis. 2018 Mar 19:66(7)

SHSL Gastroenteritis Testing

Bacterial cult. (19K 4.4% POS)	Viral (2,500)	Parasites (EIA 5,300)
Campylobacter (407)	Rotavirus-EIA (6.5%)	*Cryptosporidium* (1.2%)
Salmonella (259)	Norovirus-PCR (**10.7%**)	*Giardia* (0.9%)
Shigella (30)		
Aeromonas (78)		**Other parasites (50K) !?**
Plesiomonas (13)		
E. coli 0157, STEC (36)		
*Vibrio** (5)		
*Yersinia** (4)		
C. difficile (12,000) EIA (5.9%) – PCR (25.2%)		

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* Needs special request & media

Stool Bacterial Culture

- GN-Broth (only if Shiga-toxin ordered)
- BAP
- MAC
- MAC/Sorb
- *Salmonella, Shigella* (SS)
- Hektoen Enteric (HE)
- Campy-CVA agar

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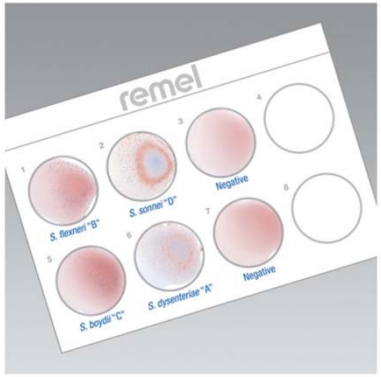
- https://www.google.com/search?q=gn+broth&safe=active&rlz=1C1GGRV_enUS751US751&source=lnms&tbm=isch&sa=X&ved=0ahU
- https://www.tuyenlab.net/2018/02/microbiology-hektoen-enteric-agar.html
- https://www.google.com/search?q=macconkey+agar&safe=active&rlz=1C1GGRV_enUS751US751&source=lnms&tbm=isch&sa

Stool Bacterial Culture (Confirmation)

- Shiga-toxin – EIA

- *E. coli* O157, H7 – EIA
- Latex agglutination: Wellcolex® Color
  - *Shigella*
  - *Salmonella*



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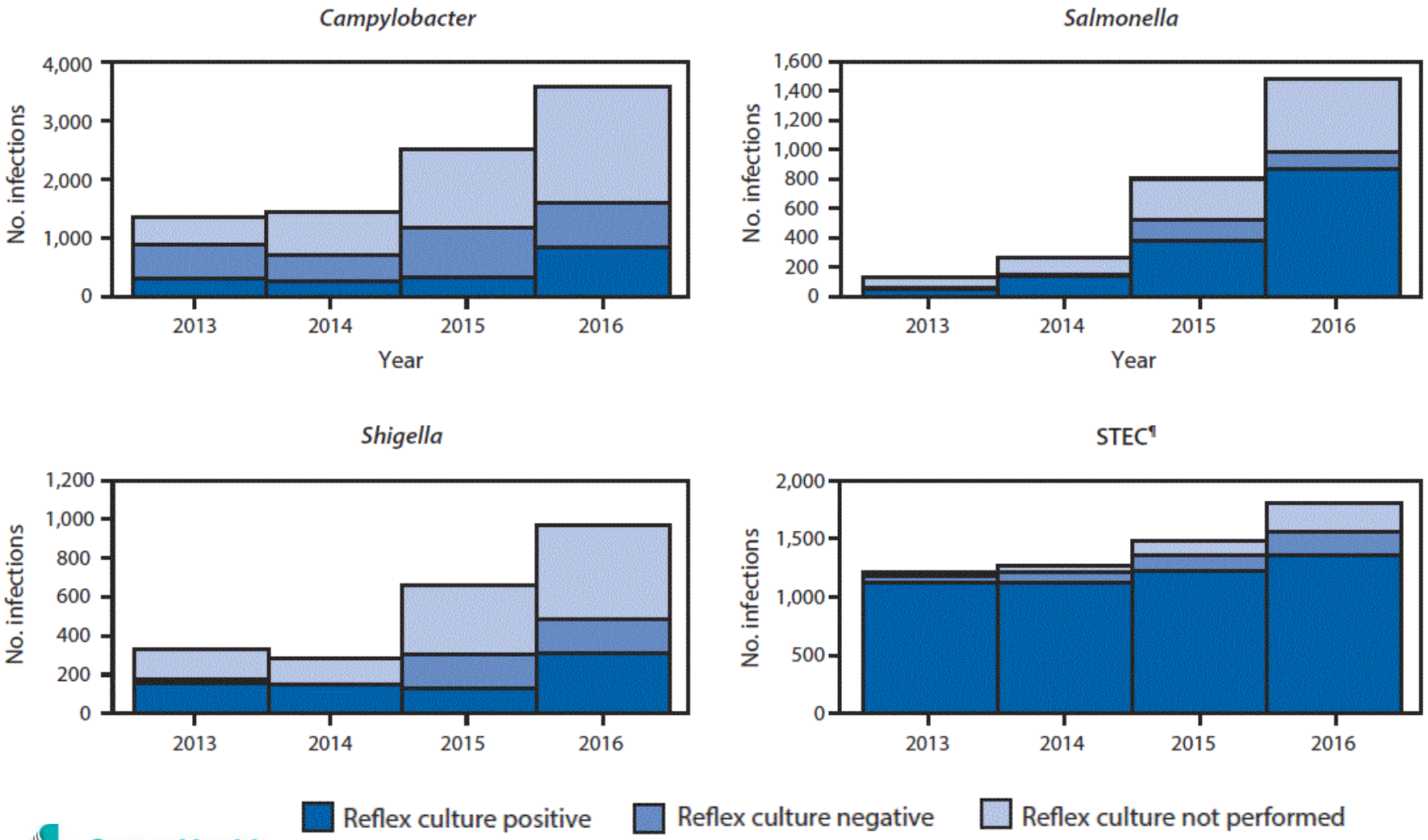
- https://www.google.com/search?q=wellcolex+shigella&safe=active&rlz=1C1GGRV
- http://www.meridianbioscience.com/diagnostic-products/foodborne/immunocard-stat/immunocard-stat-ehec.aspx
- https://www.thermofisher.com/order/catalog/product/R24250

Culture Independent Diagnostic Tests (CIDT)
[Marder EP, et al. MMWR 2017]



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https://www.cdc.gov/mmwr/volumes/66/wr/mm6615a1.htm

IDSA – Culture-Independent Diagnostic Test

"V. Which diagnostic tests should be performed when enteric fever or bacteremia is suspected? Recommendation.

17. Culture-independent, including panel-based multiplex molecular diagnostics from stool and blood specimens, and, when indicated, culture-dependent diagnostic testing should be performed when there is a clinical suspicion of enteric fever (diarrhea uncommon) or diarrhea with bacteremia (strong, moderate)."

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

IDSA – Culture-Independent Diagnostic Tests

- Now CIDT's are recommended when:
  - Suspected sepsis
  - Immunocompromised patients
- Results should be interpreted with cautions and/or be confirmed by culture if:
  - non-viable organisms are suspected
  - susceptibility testing is indicated
  - outbreak investigation at Public Health level required
- CIDT's should not be used for patient management or test-of-cure

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Clin Infect Dis. 2017 Nov 29;65(12):e45-e80

CIDT (Continued)

- Advantages:
  - Turnaround time (Days vs. Hours)
  - Easy to perform (Moderate complexity)
  - Reliability (higher sensitivity) [1, 3]
  - Reduces ER admission[2]
  - Reduces length of stay[2]
  - Less dependent on the specimen quality, viability[3]
  - Recommended by IDSA latest guidelines[4]

1. Marder EP, et al MMWR Vol 66 No 15, 2017
2. McNabb, K. 2017
3. Alexander J, 2018
4. *Clin Infect Dis*. 2017 Nov 29;65(12):e45-e80. IDSA guidelines

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CIDT (Continued)

- Disadvantages:
  - $ Cost **??**
  - May detect nonviable organisms; not the best fit for follow-up or treatment monitoring[1]
    - Public Health studies
    - Susceptibility
      - Rarely indicated
      - Ciprofloxacin resistance in 2015[2]
        - » *Salmonella*= 4%
        - » *Shigella*= 2.5%

1. *Clin Infect Dis*. 2017 Nov 29;65(12):e45-e80
2. https://wwwn.cdc.gov/narmsnow

FDA-cleared GI Panels

Test	Instrument	Manufacturer	Targets	Time (h)
Enteric Panel (EP)	VERIGENE®	Luminex	9	2
GI Pathogen	xTAG®	Luminex	14	~5
FilmArray® GI Panel	Torch®	BioFire Dx	22	1
EBP	BD Max®	BD	4	~3
ProGastro	GenProbe®	Hologic	4	4

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BioFire FilmArray® - GI Panel

Bacteria	Parasites	Virus
Campylobacter *C. difficile* *Plesiomonas* *Salmonella* *Y. enterocolitica* *Vibrio* STEC, ETEC, EPEC, EAEC *Shigella*/EIEC	*Cryptosporidium* *Cyclospora* *E. histolytica* *Giardia*	Adenovirus Astrovirus Norovirus Rotavirus Sapovirus

https://www.biofiredx.com/wp-content/uploads/2016/03/IS-FLM1-MKT-0158-FilmArray-Brochure-Insert.pdf

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VERIGENE® - Enteric Panel

Bacteria
Campylobacter Group
Salmonella spp.
Shigella spp.
Vibrio Group
Y. enterocolitica
Toxins
Shiga Toxin 1
Shiga Toxin 2
Viruses
Norovirus
Rotavirus

https://www.luminexcorp.com/clinical/our-technology/verigene-nanogrid-technology/

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Factors to Consider CIDT's

- Reliability
  - Results accuracy, analytical specificity, and sensitivity
  - Vulnerability to contamination
- Ease-of-use
- Ability to detect **major pathogens**
- Flexibility to match the right-patient/right-test concept
- Avoid over-diagnosis, not matching the clinical picture such as *C. difficile*
- Cost:
  - Capital
  - Per test

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Summary

- Testing should be based on history, severity, duration, epidemiological links of the disease, and immune status of the patient
- Utilization and value of **CIDT**'s for diarrheal illnesses
- Over-diagnosis has to be dealt with by choosing the right **patient**, the right **test**, and the right **specimen**
- Consider testing for **parasites** when the clinical features (lack of fever, chronicity…) and exposure links (travel, daycare …) are established or patient is immunocompromised
- Consider testing for ***C. difficile*** when there is a history of antimicrobial use or healthcare association of diarrhea
- There are indications for broad syndromic panels, but they're **rare**

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