



Culture-Independent Diagnostic Testing: Epidemiological Perspective

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State Epi Perspective: CIDT

- **Clinical vs. public health perspective**
- **FoodNet perspective**
- **Unintended consequences:
surveillance impact, cluster detection,
dual infections, exclusion decisions**
- **Outbreak utility**

Advantages of GI CIDT's

- ▶ Rapid test results
- ▶ Faster and improved diagnosis
- ▶ Assessment of multiple pathogens
- ▶ Reduced media needs
- ▶ Streamlined workflow
- ▶ Does not require trained microbiologist

Clinical Setting

- ▶ Faster detection of potential cases
- ▶ Assessment of multiple pathogens in outbreak specimens
- ▶ Improved detection with molecular testing over culture
- ▶ Potential for improved syndromic surveillance

Public Health

Disadvantages of GI CIDT's

- ▶ False positives result in inappropriate care
- ▶ No susceptibility results
- ▶ Cost
- ▶ Specimen limitations (rectal swabs not approved)
- ▶ What to do with multiple target positives

Clinical Setting

- ▶ Inconsistency among pathogens detected
- ▶ Loss of isolate for surveillance
- ▶ Not useful in assessing PH interventions
- ▶ Shifts the burden of culture to PHLs
- ▶ Potential wasted effort with false positives

Public Health

FoodNet MMWR

- **Bacterial Enteric Infections Detected by Culture-Independent Diagnostic Tests**
 - **FoodNet, United States, 2012–2014**
 - Surveillance data, 2012-2013
 - Clinical laboratory survey, 2014

Surveillance Data, 2012-2013

- **38,666 culture-confirmed and positive CIDT reports**
 - **33,052 (85.5%) Culture-positive only**
 - **3,019 (7.8%) CIDT-pos and culture-pos**
 - **1,251 (3.2%) CIDT-pos and culture-neg**
 - **1,344 (3.5%) CIDT-pos and no culture**

Surveillance Data, Jan 2012-Dec 2013

TABLE. Number of culture-confirmed cases and positive culture-independent diagnostic test (CIDT) reports (N = 38,666), by selected pathogens and culture results — FoodNet, United States, 2012–2013

Pathogen	Culture-positive only		Positive CIDT reports						Total culture-confirmed infections and positive CIDT reports No.
	No.	(%)	CIDT-positive and culture-positive		CIDT-positive and culture-negative		CIDT-positive and no culture		
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.
<i>Campylobacter</i>	12,894	(83.8)	539	(3.5)	1,099	(7.1)	859	(5.6)	15,391
<i>Salmonella</i>	15,034	(98.0)	115	(0.7)	8	(0.1)	185	(1.2)	15,342
<i>Shigella</i>	4,312	(91.8)	160	(3.4)	27	(0.6)	197	(4.2)	4,696
STEC*†	34	(1.4)	2,205	(90.3)	110	(4.5)	94	(3.8)	2,443
<i>Vibrio</i>	446	(98.0)	0	—	5	(1.1)	4	(0.9)	455
<i>Yersinia</i>	332	(98.0)	0	—	2	(0.6)	5	(1.4)	339
Total	33,052	(85.5)	3,019	(7.8)	1,251	(3.2)	1,344	(3.5)	38,666

Abbreviation: STEC = Shiga-toxin-producing *Escherichia coli*.

* Excludes 274 Shiga toxin-positive reports from clinical laboratories that were Shiga toxin-negative at a public health laboratory.

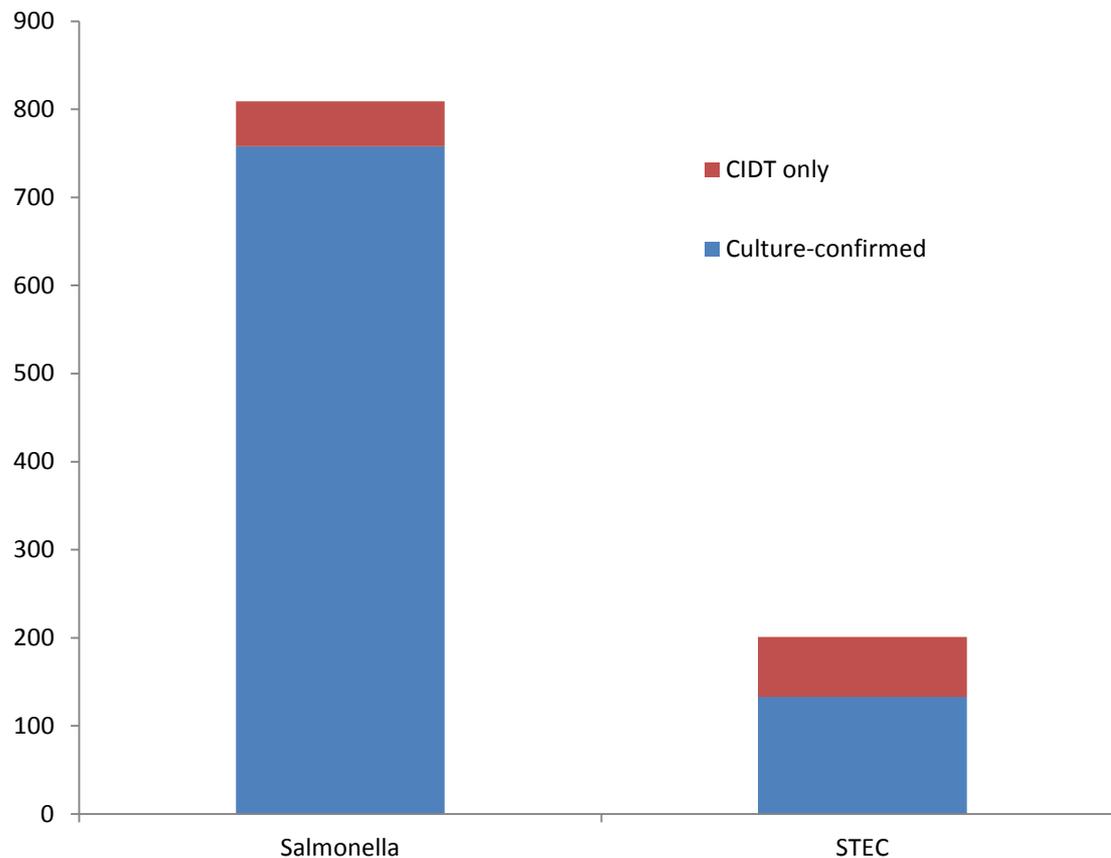
† Excludes 53 positive reports of detection of O157 antigen without testing for Shiga toxin.

Campy and STEC

- **Campylobacter**
 - **12,894 (83.8%) Culture-positive only**
 - **1,099 (7.1%) CIDT-pos and culture-neg**
- **STEC**
 - **34 (1.4%) Culture-positive only**
 - **2,205 (90.3%) CIDT-pos and culture-pos**

2015 Year-To-Date: Salmonella and STEC

CIDT-only and Culture-confirmed Cases, Salmonella and STEC, Tennessee 1/1/2015-11/13/2015



Laboratory Survey, 2014

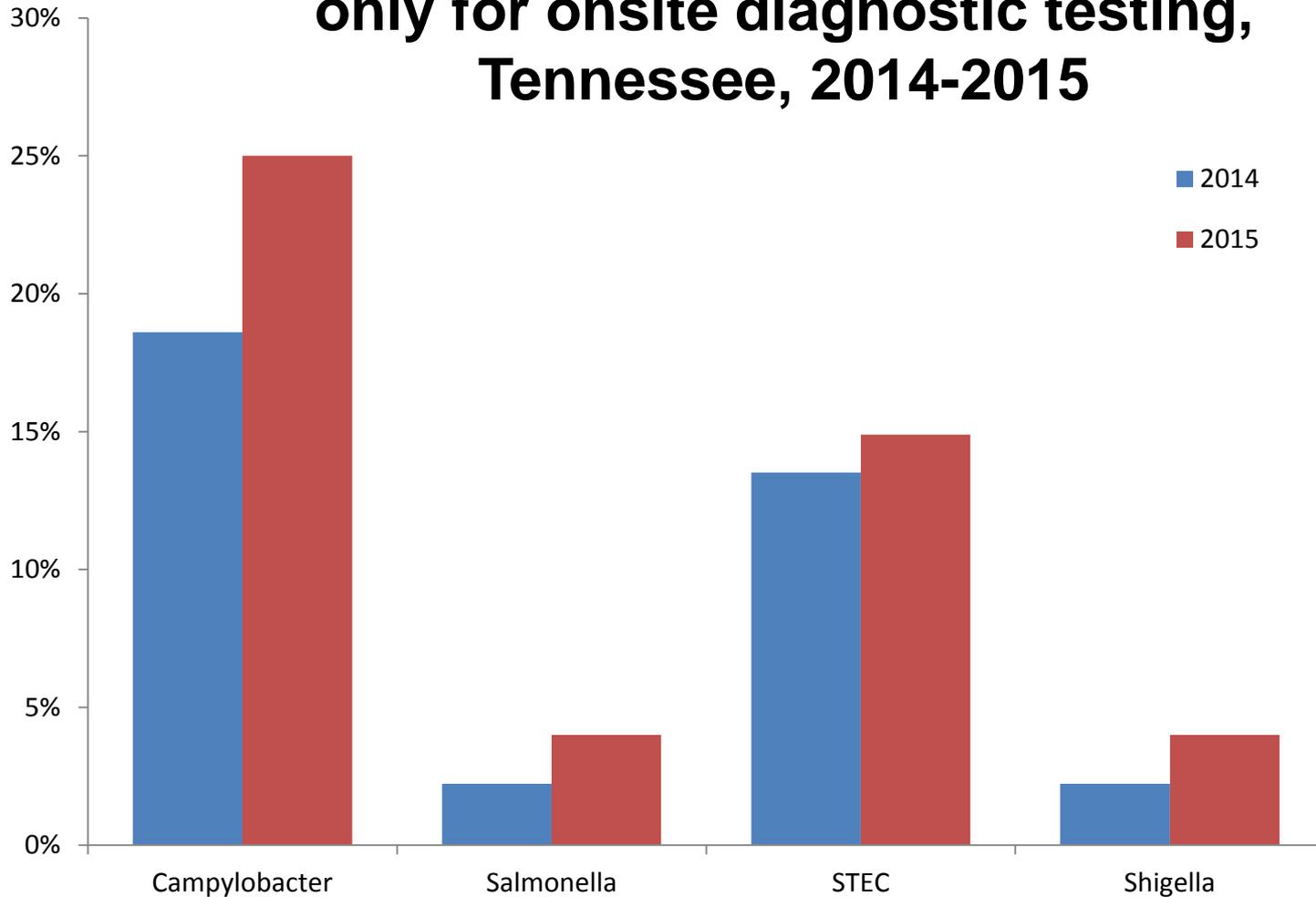
664 FoodNet Clinical Laboratories...

Pathogen tested N (%)	Culture only n (%)	CIDT only* n (%)	Culture + CIDT n (%)
Campylobacter 446 (67%)	379 (85%)	45 (10%)	22 (5%)
STEC 395 (60%)	135 (34%)	73 (19%)	187 (47%)

* Only 6 labs reported using CIDT for Salmonella

Tennessee Laboratory Surveys, 2014-2015

Proportion of laboratories reporting CIDT only for onsite diagnostic testing, Tennessee, 2014-2015



Unintended Consequences

- **Surveillance impacts:**
 - **Challenges in monitoring trends**
 - **Variability in test characteristics may lead to different presentation of result**
 - **FoodNet surveillance working group**

2014 FOOD SAFETY PROGRESS REPORT

Pathogen	Healthy People 2020 target rate	2014 rate*	Change compared with 2006-2008†	
<i>Campylobacter</i>	 8.5	13.45	 13% increase	
<i>E. coli</i> O157 [§]	 0.6	0.92	 32% decrease	
<i>Listeria</i>	 0.2	0.24	No change	
<i>Salmonella</i>	 11.4	15.45	No change	
<i>Vibrio</i>	 0.2	0.45	 52% increase	
<i>Yersinia</i>	 0.3	0.28	 22% decrease	



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

*Culture-confirmed infections per 100,000 population
†2006-2008 were the baseline years used to establish Healthy People 2020 targets

§ Shiga toxin-producing *Escherichia coli* O157

For more information, visit www.cdc.gov/foodnet

Unintended Consequences

- **Cluster detection: fewer isolates available for PFGE / WGS**
- **Dual infections:**
 - *Clostridium difficile*
- **Exclusion decisions:** All positive test results using CIDT should have a follow-up culture for confirmation.

Unintended Consequences

Amy Woron, “If you cant beat ‘em, join ‘em!”

- **Early adoption of Biofire platform for outbreak investigations**
 - **Faster identification of etiology to direct public health actions**
 - **Novel outbreak pathogens**

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

Enterohaggative *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)



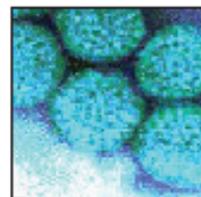
Parasites

Cryptosporidium

Cyclospora cayetanensis

Entamoeba histolytica

Giardia lamblia



Viruses

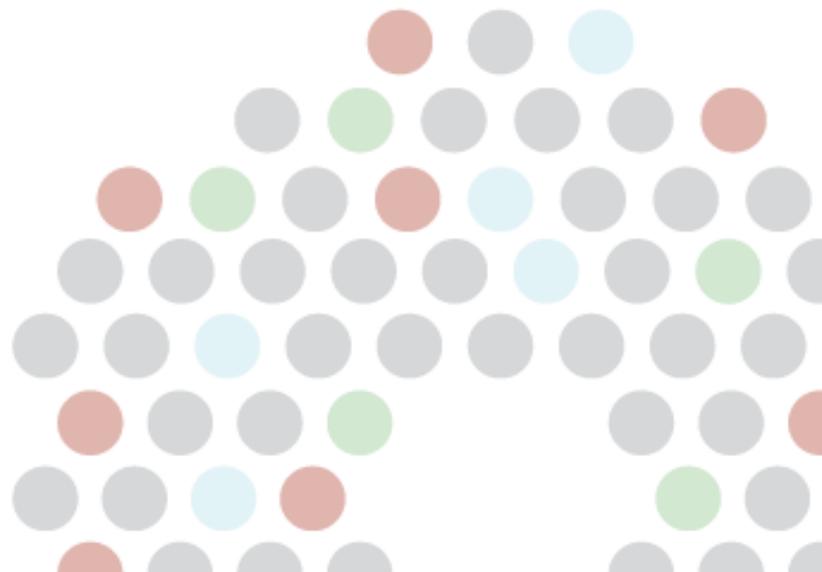
Adenovirus F 40/41

Astrovirus

Norovirus GI/GII

Rotavirus A

Sapovirus (I, II, IV and V)



Summary

- **Clinicians want faster, wider array of diagnostic testing...CIDT here to stay**
- **Test characteristics and uptake will influence reporting of trends**
- **Variety of unintended consequences**
- **Benefits to public health**