DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 11, 2017

Quidel Corporation
Ronald Lollar
Sr. Director, Clinical, Regulatory, Scientific Affairs
2005 East State Street, Suite 100
Athens, Ohio 45701

Re: K170491
Trade/Device Name: Solana C. difficile Assay
Regulation Number: 21 CFR 866.3130
Regulation Name: Clostridium difficile toxin gene amplification assay
Regulatory Class: Class II
Product Code: OZN
Dated: February 16, 2017
Received: February 17, 2017

Dear Ronald Lollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Steven R. Gitterman -S

for Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170491

Device Name
Solana® C. difficile Assay

Indications for Use *(Describe)*
The Solana® C. difficile Assay is an in vitro diagnostic test for the direct, qualitative detection of the Clostridium difficile Toxin A gene (tcdA) in unformed stool specimens of patients suspected of having Clostridium difficile-infection (CDI). The Solana C. difficile Assay is intended for use as an aid in diagnosis of CDI. The assay utilizes helicase-dependent amplification (HDA) for the amplification of a highly conserved fragment of the Toxin A gene sequence. The Solana C. difficile Assay is intended for use only with the Solana® instrument.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Applicant:

Quidel Corporation
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San Diego, California 92130
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Contact Information:

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Ron.Lollar@quidel.com

Date of preparation of 510(k) summary:

May 10, 2017

A. 510(k) Number:

K170491

B. Purpose for Submission:

To obtain substantial equivalence for the Solana® C. difficile Assay when performed on the Solana® instrument

C. Measurand:

A highly conserved region in the 5' end of the *tcdA* gene

D. Type of Test:

Helicase-dependent amplification (HDA)

E. Applicant:

510(k) Summary

Quidel Corporation

F. Proprietary and Established Names:

Solana® C. difficile Assay

G. Regulatory Information:

Table 1. Regulatory Information

Product Code	Classification	Regulation Section	Panel
OZN - Amplification assay for the detection of *Clostridium difficile* toxin genes from stool specimens of symptomatic patients	Class II (Special Controls)	21 CFR 866.3130 - C. difficile Nucleic Acid Amplification Test Assay	Microbiology (83)

H. Intended Use:

1. Intended Use(s):

The Solana® C. difficile Assay is an *in vitro* diagnostic test for the direct, qualitative detection of the *Clostridium difficile* Toxin A gene *(tcdA)* in unformed stool specimens of patients suspected of having *Clostridium difficile*-infection (CDI). The Solana C. difficile Assay is intended for use as an aid in diagnosis of CDI. The assay utilizes helicase-dependent amplification (HDA) for the amplification of a highly conserved fragment of the Toxin A gene sequence. The Solana C. difficile Assay is intended for use only with the Solana® instrument.

2. Indication(s) for Use:

Same as intended Use

3. Special conditions for use statement(s):

- For *in vitro* diagnostic use only
- For prescription use only

510(k) Summary

4. Special instrument requirements:

   Solana® instrument

I. Device Description:

The Solana C. difficile Assay combines simple sample processing and Helicase-Dependent Amplification (HDA) performed in Solana for the detection of toxigenic *Clostridium difficile* directly from CDI-suspected diarrheal specimens.

A small amount of specimen is transferred to a Lysis Tube using a swab. The Lysis Tube is then subjected to heat-treatment at 95°C for 5 minutes. The heat-treated sample is added to a Dilution Tube, and then transferred to a Reaction Tube. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the diluted sample, the Reaction Tube is placed in Solana for amplification and detection of target sequence. In Solana, the target sequence is amplified by specific primers and detected by a specific fluorescence probe included in the Reaction Tube. A competitive process control (PRC) is included in the Lysis Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC is amplified by the target-specific primers and detected by a PRC specific fluorescence probe.

The target and PRC probes are labeled with a quencher on one end and a fluorophore on the other end. Upon annealing to target or PRC amplicons, the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana then report the test results to the user on its display screen, and it can print out the results via a printer.

Materials Provided:

Cat. #M307
48 Tests per Kit

Table 2. Kit Components

Component	Quantity	Storage
Neonatal flocked swabs	48 tubes/kit	2°C to 30°C
Lysis Buffer	48 tubes/kit 1.0 mL	2°C to 8°C
Dilution Buffer	48 tubes/kit 1.8 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C

Materials required but not provided:

- External controls for *C. difficile* (e.g. Quidel Molecular C. difficile Control Set, which contains positive and negative controls, serves as an external processing and extraction control)
- Sterile DNase-free filter-blocked or positive displacement micropipettor tips
- Micropipettor
- Stopwatch or timer
- Scissors or a blade
- Heat block capable of 95° C ± 2° C temperature
- Solana workflow tray and transfer rack
- Solana Instrument
- Thermometer

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Portrait Toxigenic C. difficile Assay (Great Basin Scientific)

2. Predicate 510(k) number(s):
   K113358 (DEN120013)

3. Comparison with predicate:

Table 3. Similarities

Item	Subject Device Solana® C. difficile Assay	Predicate Device Great Basin Scientific Portrait Toxigenic C. Difficile Assay K113358 (DEN120013)
Intended Use	The Solana® C. difficile Assay is an *in vitro* diagnostic test for the direct, qualitative detection of the *Clostridium difficile* Toxin A gene *(tcdA)* in unformed stool specimens of patients suspected of having *Clostridium difficile*-infection (CDI). The Solana C. difficile Assay is intended for use as an aid in diagnosis of CDI. The assay utilizes helicase-dependent amplification (HDA) for the amplification of a highly conserved	Portrait Toxigenic C. difficile Assay, a prescription device under 21 CFR Part 801.109 that is indicated for the detection of toxigenic Clostridium difficile in human fecal samples collected from patients suspected of having Clostridium difficile infection

510(k) Summary

Table 3. Similarities		
Item	**Subject Device** Solana® C. difficile Assay	**Predicate Device** Great Basin Scientific Portrait Toxigenic C. Difficile Assay K113358 (DEN120013)
	fragment of the Toxin A gene sequence. The Solana C. difficile Assay is intended for use only with the Solana® instrument.	(CDI). The test utilizes automated blocked primer enabled helicase-dependent amplification (bpHDA) to detect toxin gene sequences associated with toxin producing C. difficile. The Portrait Toxigenic C. difficile Assay is intended as an aid in the diagnosis of CDI.
Specimen	Unformed stool	Same
Technological principle	Nucleic acid amplification	Same
Assay technique	Isothermal, helicase-dependent nucleic acid amplification	Same
Assay Results	Qualitative	Same
Extraction Methods	Not required	Same
Detection method	Automated	Same

Table 4. Differences

510(k) Summary

Item	Subject Device Solana® C. difficile Assay	Predicate Device Great Basin Scientific Portrait Toxigenic C. Difficile Assay K113358
Target	Toxin A gene (*tcdA*)	Toxin B gene (*tcdB*)
Amplification and Detection instruments	Solana® instrument	Portrait Analyzer

K. Standard/Guidance Document Referenced (if applicable):

Class II Special Controls Guideline Document: Toxin Gene Amplification Assays for the Detection of *Clostridium difficile*

L. Test Principle:

A small amount of specimen is transferred to a Lysis Tube using a swab. The Lysis Tube is then subjected to heat-treatment at 95°C for 5 minutes. The heat-treated sample is added to a Dilution Tube, and then transferred to a Reaction Tube. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the diluted sample, the Reaction Tube is placed in Solana for amplification and detection of target sequence. In Solana, the target sequence is amplified by specific primers and detected by a specific fluorescence probe included in the Reaction Tube. A competitive process control (PRC) is included in the Lysis Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC is amplified by the target-specific primers and detected by a PRC specific fluorescence probe.

The target and PRC probes are labeled with a quencher on one end and a fluorophore on the other end. Upon annealing to target or PRC amplicons, the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana then report the test results to the user on its display screen, and it can print out the results via a printer.

M. Performance Characteristics:

1. <u>Analytical performance:</u>

510(k) Summary

a. Precision/Reproducibility:

Reproducibility

The reproducibility of the Solana C. difficile Assay was evaluated at three laboratory sites. A blinded and randomized study panel containing *Clostridium difficile* negative and positive samples were tested at three (3) test sites (two (2) clinical sites). Each site tested a reproducibility panel and Assay Controls for five (5) days in triplicate. Testing was done by two operators at each site. Each operator ran the panel once a day. A total of 540 specimens were tested (including controls).

Table 5. Reproducibility Summary

Category	SITE						Overall Percent Agreement		95% Confidence Interval
	Site #1		Site #2		Site #3				
	#expected results/# tested	*% Agreement*	*#expected results/# tested*	*% Agreement*	*#expected results/# tested*	*% Agreement*			
C. difficile High Negative (4.8×10^2 CFU/mL)	12/30	40%	19/30	63.3%	12/30	40%	43/90	47.8%	37.8% - 58.0%
C. difficile Low Positive (1.7×10^3 CFU/mL)	30/30	100%	30/30	100%	29/30	96.7%	89/90	98.9%	94% - 99.8%
C. difficile Moderate Positive (3.4×10^3 CFU/mL)	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%
Negative	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%
C. difficile Positive Control	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%
Assay Negative Control	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%

The results suggest that there are no significant differences between different users using different instruments at different sites on different days.

510(k) Summary

b. Linearity/assay reportable range:

Not applicable – This assay is qualitative.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:

Not applicable. This assay is qualitative.

Specimen Stability:

An analytical study was conducted to determine the potential specimen storage capabilities of the Solana® C. difficile Assay by testing contrived stool samples that have been stored to mimic what may happen in a clinical setting. Specimen stability was also assessed in the prospective clinical study that tested 854 specimens that were stored for up to 3 days at 2° to 8°C.The results of clinical and analytical studies supported the storage of stool specimens at 2 to 8^{o}C for up to 3 days before testing.

Controls:

- External controls for *C. difficile* (e.g. Quidel Molecular C. difficile Control Set, which contains positive and negative controls, serves as an external processing and extraction control) were run on the Solana C. difficile Assay each day of testing. The external controls produced the expected results in all analytical and clinical testing.

- The process control monitored sample processing, HDA inhibitory specimens and confirmation of the integrity of assay reagents and Solana instrument functionality throughout the clinical and analytical testing. The process control identified two (2) specimens in the clinical testing as invalid (2/854, 0.2%). The process control was detected in all analytical testing.

d. Detection limit:

The analytical sensitivity (limit of detection or LOD) of the Solana C. difficile Assay was determined using serial dilutions of two (2) toxigenic C. difficile strains, ATCC BAA-1805 and CCUG 20309 spiked in negative matrix, and also quantified C. difficile genomic DNA, BAA-1382DQ™ spiked in lysis buffer. Analytical sensitivity (LOD) is defined as the lowest concentration at which 95% of all replicates tested positive.

510(k) Summary

Table 6. LOD Values		
Stool Matrix	*C. difficile* Strains	Strain LOD
Unpreserved Stool	**ATCC BAA-1805**	9.13E+03 CFU/mL
	CCUG 20309	4.90E+03CFU/mL
N/A	**Genomic DNA: ATCC® BAA-1382DQ™**	15 copy/assay

e. Analytical specificity:

Cross Reactivity and Microbial Interference:

The analytical specificity of the Solana C. difficile Assay was evaluated by testing a panel consisting of sixty-eight (68) bacterial, viral and yeast microorganisms and human DNA representing common enteric pathogens, flora or nucleic acid commonly present in the intestine. Microorganisms or nucleic acid was mixed with pooled negative matrix and tested directly or in the presence of 1.83E+04 CFU/mL of *C. difficile* for cross-reactivity and microbial interference, respectively.

The table below lists the bacterial, viral and yeast microorganisms used in these studies. There was no evidence of cross reactivity or interference with any of the panel members and the Solana C. difficile Assay.

Microorganism	
Abiotrophia defective	ATCC 49176
Acinetobacter baumannii	ATCC 19606
Aeromonas hydrophila	ATCC 7966
Alcaligenes faecalis subsp. *faecalis*	ATCC 15554
Bacillus cereus	ATCC 13472
Bacteroides fragilis	ATCC 25285
Campylobacter coli	ATCC 43479
Campylobacter jejuni sub sp *.jejuni*	ATCC 33292
Candida albicans	ATCC 10231
Citrobacter freundii	ATCC 8090
Clostridium bifermentans	ATCC 638
Clostridium botulinum	In silico analysis
Clostridium butyricum	CCRI-11128

510(k) Summary

Microorganism	
Clostridium haemolyticum	ATCC 19398
Clostridium novyi	ATCC 19402
Clostridium orbiscindens	ATCC 49531
Clostridium perfringens	ATCC 13124
Clostridium scindens	ATCC 35704
Clostridium septicum	ATCC 12464
Clostridium sordellii	ATCC 9714
Clostridium sordellii	Z077
Clostridium sordellii	CCUG 6329
Clostridium sordellii	CCUG 9284
Clostridium sordellii	CCUG 33098
Clostridium sordellii	CCUG 36938
Clostridium sordellii	CCUG 43123
Clostridium sordellii	CCUG 47545
Clostridium sordellii	CCUG 59819
Clostridium difficile (non-toxigenic)	ATCC 43593
Clostridium difficile (non-toxigenic)	ATCC 43601
Clostridium sporogenes	ATCC 15579
Edwardsiella tarda	ATCC 15947
Enterobacter aerogenes	ATCC 13048
Enterobacter cloacae	ATCC 13047
Enterococcus faecalis vanB	ATCC 51299
Escherichia coli	ATCC 23511
Escherichia coli O157:H7	ATCC 700927
Helicobacter pylori	ATCC 43504
Klebsiella oxytoca	ATCC 33497
Lactobacillus acidophilus	ATCC 4356
Listeria monocytogenes	ATCC BAA-389
Peptostreptococcus anaerobius	ATCC 27337
Plesiomonas shigelloides	ATCC 14029
Porphyromonas asaccharolytica	ATCC 25260
Prevotella melaninogenica	ATCC 25845
Proteus mirabilis	ATCC 25933
Providencia alcalifaciens	ATCC 9886
Pseudomonas aeruginosa	ATCC 35554
Salmonella choleraesuis (typhimurium)	ATCC 14028
Salmonella enterica subsp. *arizonae*	ATCC 13314
Salmonella enterica subsp. *enterica*	ATCC 7001

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Microorganism	
Serratia liquefaciens	ATCC 27592
Serratia marcescens	ATCC 13880
Shigella boydii	ATCC 9207
Shigella dysenteriae	ATCC 11835
Shigella sonnei	ATCC 29930
Staphylococcus aureus	ATCC 43300
Staphylococcus epidermidis	ATCC 14990
Streptococcus agalactiae	ATCC 12973
Vibrio parahaemolyticus	ATCC 17802
Adenovirus	
Rotavirus	
Norovirus	
Enterovirus	
Echovirus	
Coxsackie virus	
Cytomegalovirus	
Human DNA	

Interference:

The performance of Solana C. difficile Assay was evaluated with potentially interfering substances that may be present in stool specimens. A panel composed of thirty-two (32) substances was tested in the absence or presence of *C. difficile* at 1.83E+04 CFU/mL in the Solana C. difficile Assay. There was no evidence of interference caused by the substances tested at the concentrations shown below.

Substance Name	Active Ingredients	Test Concentration
Nystatin	Nystatin	1% (w/v)
Cortizone 10	Hydrocortisone	1% (w/v)
Fleet Glycerin Suppositories	Glycerin	1% (w/v)
Desitin	Zinc Oxide	1% (w/v)
Anusol Plus	pramoxine hydrochloride and zinc sulfate monohydrate	1% (w/v)
Preparation H	Phenylephrine	1% (w/v)
Nystatin	Nystatin	1% (w/v)
Cortizone 10	Hydrocortisone	1% (w/v)
Fleet Glycerin Suppositories	Glycerin	1% (w/v)
Desitin	Zinc Oxide	1% (w/v)

510(k) Summary

Substance Name	Active Ingredients	Test Concentration
Anusol Plus	pramoxine hydrochloride and zinc sulfate monohydrate	1% (w/v)
Preparation H	Phenylephrine	1% (w/v)
Tums	Calcium Carbonate	10% (w/v)
Equate Antacid Max Strength	Aluminum hydroxide, Magnesium hydroxide	10% (w/v)
Mesalazine Rectal Suspension Enema	Mesalazine	10% (w/v)
Fleet Mineral Oil Enema	Mineral Oil	10% (w/v)
Gynol II Vaginal Contraceptive	Nonoxynol-9	1% (w/v)
Imodium AD	Loperamide HCl	10% (w/v)
Pepto Bismol	Bismuth subsalicylate	10% (w/v)
Ex-Lax	Sennosides	1% (w/v)
Metronidazole	Metronidazole	12.5 mg/ml
Vancomycin	Vancomycin	12.5 mg/ml
Polysporin	Bacitracin and Polymyxin B	1% (w/v)
Naproxen sodium	Naproxen sodium	12.5 mg/ml
Tucks personal cleaning pads	Witch hazel	10% (v/v)
Benzalkonium Chloride Towelettes	Benzalkonium Chloride	10% (v/v)
Ethanol	Ethanol	10% (v/v)
Mucus	Immunoglobulins, Lysozyme, Polymers, etc.	3.5%
Whole Blood	Glucose, Hormones, Enzymes, Ions, Iron, etc.	10%
Palmitic acid	Palmitic acid	12.5 mg/ml
Steric Acid	Steric Acid	12.5 mg/ml
Triglyceride Mix (C2 – C10)	Triglyceride	10%

Analytical Reactivity (Inclusivity):

The inclusivity of the Solana C. difficile Assay was further evaluated by functional testing of toxigenic *C. difficile* in addition to those strains used in the LOD study. Twenty-three (23) additional strains of toxigenic *C. difficile*, representing at least five different toxinotypes, were tested in triplicate at the 2X LOD concentration (1.83E+04 CFU/mL as determined for ATCC BAA-1805) with Solana C. difficile Assay, in addition to the strains used for the LOD study. All twenty-three additional strains were detected in all replicates by the Solana C. difficile Assay in this study.

Strain	Toxinotype
ATCC BAA-1805*	III

510(k) Summary

Strain	Toxinotype
CCUG 20309*	X
ATCC BAA-1870	IIIb
CCUG 37770	IV
ATCC BAA-1875	V
ATCC 43598	VIII
ATCC 37774	XXIII
CCUG 9004	Unknown
ATCC BAA-1874	0
ATCC 43600	0
ATCC BAA-1871	0
ATCC BAA-1803	IIIc
ATCC BAA-1872	0
ATCC 700792	0
ATCC 43599	0
CCUG 60276	Unknown
CCUG 60275	Unknown
CCUG 37778	Unknown
CCUG 37777	Unknown
CCUG 37776	Unknown
CCUG 37773	Unknown
ATCC 17857	0
ATCC 43594	0
ATCC 43596	0
ATCC 43255	0

3. Clinical studies:

Performance characteristics of the Solana C. difficile Assay were established during a prospective study conducted November 2016 to February 2017. Eight hundred fifty-four (854) specimens used for this study were collected from patients suspected of having *Clostridium difficile* infection (CDI) at three distinct geographical sites across the United States. These specimens were tested with the Solana Assay at the sites. The Solana results were compared to an enhanced toxigenic bacterial culture (sensitivity/specificity) and a FDA-cleared molecular device (positive/negative percent agreement).

Performance in Comparison to Enhanced toxigenic bacterial culture

510(k) Summary

Eight hundred fifty-four (854) raw specimens were tested by both the Solana C. difficile Assay and enhanced toxigenic culture. For the toxigenic culture method, samples were inoculated into chopped-meat glucose (CMG) broth and sub-cultured after 48-hours onto CCFA-HB plates. Suspicious colonies were further characterized and *C. difficile* identified colonies were sub-cultured in CMG broth for subsequent cytotoxin testing. Two (2) specimens (0.2%) were invalid in the Solana C. difficile Assay when tested according to the Solana C. difficile Assay draft instructions for use. Both specimens remained invalid upon repeat testing. These specimens were removed from further analysis. The data below is for the remaining eight hundred fifty-two (852) specimens.

Combined Sites – Raw Specimen								
	Enhanced Toxigenic Culture						95% CI	
		POS	NEG	Total	Sensitivity	93.0%	86.9%	96.4%
Solana C. difficile Assay	POS	107	6*	113	Specificity	99.2%	98.2%	99.6%
	NEG	8**	731	739				
	Total	115	737	852				

* Three (3) of the six (6) specimens were positive for *C. difficile* toxin gene DNA by an alternate FDA cleared molecular device, three (3) were negative.
** Six (6) of eight (8) specimens were found positive for *C. difficile* toxin gene DNA by an alternate FDA cleared molecular device., and two (2) were negative

Performance in Comparison to FDA-cleared molecular device

Eight hundred fifty-four (854) specimens were tested by both the Solana C. difficile Assay and FDA-cleared molecular device. Two (2) specimens (0.2%) were invalid in the Solana C. difficile Assay when tested according to the Solana C. difficile Assay draft instructions for use. Both specimens remained invalid upon repeat testing. These specimens were removed from further analysis. The data below is for the remaining eight hundred fifty-two (852) specimens.

Combined Sites – Raw Specimen								
	FDA-cleared molecular device						95% CI	
		POS	NEG	Total	Positive Percent	97.0%	91.59%	99.0%

510(k) Summary

					Agreement			
Solana C. difficile Assay	POS	97	16*	113	Negative Percent Agreement	97.9%	96.6%	98.7%
	NEG	3**	736	739				
	Total	100	752	852				

* Twelve (12) of the sixteen (16) specimens were positive for *C. difficile* toxin gene DNA by an alternate FDA cleared molecular device, four (4) were negative.

** Two (2) of three (3) specimens were found positive for *C. difficile* toxin gene DNA by an alternate FDA cleared molecular device, and one (1) was negative

5. Expected values:

The expected values of the Solana C. difficile Assay were established during a prospective study conducted between November 2016 to February 2017. Eight hundred fifty-four (854) specimens used for this study were collected from patients suspected of having *Clostridium difficile*-infection (CDI) at three distinct geographical sites across the United States. A single specimen was collected per patient. The specimens were processed and tested with Solana C. difficile Assay on the Solana instrument at the sites.

Patient age and gender for the combined sites are presented below.

Combined Sites – Age and Gender Distribution				
Sex	F	M	Total	Total percent positive with the Solana C. difficile Assay in Raw specimens
≤ 2 years	3	3	6	16.7% (1/6)
3 to 11 years	4	6	10	20.0% (2/10)
12 to 17 years	4	10	14	7.1% (1/14)
18 to 21 years	11	14	25	24.0% (6/25)
22 to 59 years	206	132	338	14.2% (48/337*)
≥ 60 years	268	193	461	12.0% (55/460*)
Total	496	358	854	13.3% (113/852**)

* One (1) specimen was invalid

** Two (2) total specimens were invalid