April 17, 2023

Meridian Bioscience Inc.
Heather Planck
Regulatory Affairs Specialist
3471 River Hills Drive
Cincinnati, Ohio 45244

Re: K222829
Trade/Device Name: Curian® Shiga Toxin
Regulation Number: 21 CFR 866.3255
Regulation Name: Escherichia Coli Serological Reagents
Regulatory Class: Class I
Product Code: GMZ
Dated: September 19, 2022
Received: September 19, 2022

Dear Heather Planck:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D.
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222829

Device Name
Curian Shiga Toxin

Indications for Use *(Describe)*

The Curian Shiga Toxin assay, for use with the Curian Analyzer, is a rapid, qualitative, fluorescent immunoassay for the simultaneous detection and differentiation of Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in a single test device. It is intended for use with cultures derived from human stool specimens to aid in the diagnosis of disease caused by Shiga toxin producing Escherichia coli (STEC) infections. Test results are to be used in conjunction with the patient's clinical symptoms and history.

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

510(k) number: K222829 **Date of Preparation:** April 17, 2023

A. 510(k) Number:

K222829

B. Purpose for Submission:

To determine substantial equivalence for the Curian® Shiga Toxin assay used to detect Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in cultures derived from stool samples.

C. Measurand:

Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2)

D. Type of Test:

Lateral flow fluorescent immunoassay

E. Applicant:

Meridian Bioscience, Inc.

F. Proprietary and Established Names:

Curian® Shiga Toxin

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
GMZ	**I**	21 CFR 866.3255 – *Escherichia coli* serological reagents	MI – Microbiology (83)

H. Intended Use:

1. Intended Use:

   The Curian Shiga Toxin assay, for use with the Curian Analyzer, is a rapid, qualitative, fluorescent immunoassay for the simultaneous detection and differentiation of Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in a single test device. It is intended for use with cultures derived from human stool specimens to aid in the diagnosis of disease caused by Shiga toxin producing *Escherichia coli* (STEC) infections. Test results are to be used in conjunction with the patient's clinical symptoms and history.

2. Indications for use:

   Same as Intended Use.

3. Special Conditions for use Statement(s):

   For prescription use only.

4. Special Instrument Requirements:

   Curian Analyzer

I. Device Description:

The Curian® Shiga Toxin assay is a qualitative *in vitro* diagnostic test for the detection of Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in cultures derived from human stool specimens. The Curian® Shiga Toxin assay utilizes fluorescence technology with the cleared Curian® Analyzer (**K192817**) to detect Stx1 and Stx2 in cultures derived from human stool.

Reagents and Test Components:

The Curian® Shiga Toxin assay kit contains the following components:

- Curian® Shiga Toxin Test Card: A test strip enclosed in a plastic frame which is in a foil pouch with a desiccant. The desiccant is pink; if the packaging is compromised, the desiccant will be blue. Supplied ready to use.
- Curian® Shiga Toxin Aioprep™ Sample Preparation Device/ Negative Control: A buffered aqueous protein solution containing blue dye and 0.094% sodium azide. The Aioprep™ device is fitted with a dropper tip. Supplied ready to use.
- Curian® Shiga Toxin Positive Control: Inactivated Shiga toxins 1 and 2 in an aqueous phosphate buffered solution containing 0.094% sodium azide. Supplied ready to use.
- Pipette I: Transfer pipettes graduated to 50 µL and 175 µL.
- Pipette II: Transfer pipettes graduated up to 1.0 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   SHIGA TOXIN QUIK CHEK

2. Predicate 510(k) number:

   K121364

3. Comparison with predicate:

	NEW DEVICE **Curian® Shiga Toxin**	**PREDICATE DEVICE** ***SHIGA TOXIN QUIK CHEK*** **K121364**
Similarities		
Intended Use/ Indications for Use	The Curian Shiga Toxin assay, for use with the Curian Analyzer, is a rapid, qualitative, fluorescent immunoassay for the simultaneous detection and differentiation of Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in a single test device. It is intended for use with cultures derived from human stool specimens to aid in the diagnosis of disease caused by Shiga toxin producing *Escherichia coli* (STEC) infections. Test results are to be used in conjunction with the patient's clinical symptoms and history.	The SHIGA TOXIN QUIK CHEK test is a rapid membrane enzyme immunoassay for the simultaneous qualitative detection and differentiation of Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in a single test device. It is intended for use with human fecal samples from patients with gastrointestinal symptoms to aid in the diagnosis of disease caused by Shiga toxin producing *Escherichia coli* (STEC). It may be used with fecal specimens, or broth or plate cultures derived from fecal specimens. The test results should be considered in conjunction with the patient history.
Classification	Class I	Same
Product Code	GMZ	Same
Regulation	21 CFR 866.3255	Same

	NEW DEVICE Curian® Shiga Toxin	PREDICATE DEVICE *SHIGA TOXIN QUIK CHEK* K121364
Measured Analyte	Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2)	Same
Antibody Format	Monoclonal/Polyclonal	Same
Target Population	Persons suspected of having disease caused by Shiga toxin producing *E. coli* (STEC) infections	Same
Type of Test	Qualitative	Same
Specimen Type	Human Stool Specimen	Same
Sample Matrix	Broth and Plate Cultures Derived from Human Stool Specimens	Same
Controls	Positive and negative control included in the kit. Internal Control line.	Same
Read Result Time	< 30 minutes	Same
Format	Single Use Cassette	Same
Storage	Refrigerated (2-8 ºC)	Same
Differences		
Sample Matrix	Not for use with Direct Human Stool Specimen	Direct Human Stool Specimen
Technology	Lateral flow fluorescent immunoassay	Rapid membrane enzyme immunoassay
Interpretation of Results	Results interpretation automated by Curian® Analyzer	Visual Reading

K. Test Principle:

The Curian Shiga Toxin assay is a lateral flow-based fluorescent immunoassay for the direct detection of Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in cultures derived from human stool specimens. The Curian Shiga Toxin assay is based on standard immunoassay sandwich technology utilizing two detector antibodies (*E. coli* monoclonal antibodies specific to Stx1 or Stx2, which are conjugated to Europium as a fluorescent tag), and three capture antibodies: (a) anti-*E. coli* monoclonal antibodies specific to Stx1 or Stx2, which are affixed at the "Stx1 Test Line" or "Stx2 Test Line" positions of the test strip, and (b) a polyclonal goat anti-mouse IgG antibody, which is affixed at the "Control Line" position of the test strip.

The Aioprep sampling device (the "Aioprep") is pre-filled with blue tinted Sample Diluent / Negative Control and contains a filter and a dropper tip. A sample of the patient's culture enriched stool specimen is transferred from the enrichment media to the Aioprep, using either the included transfer pipettes (Pipette II) or a swab (not provided with the kit) to add the sample directly into the Sample Diluent / Negative Control. The diluted sample is mixed directly in the Aioprep barrel and then dispensed drop-wise into the sample port of the Curian Shiga Toxin test card.

If Stx1 and/or Stx2 antigens are present in the sample, they bind to the respective monoclonal detector antibodies conjugated to fluorescent particles, forming a complex. As the complex moves through the test strip, the anti-Shiga toxin 1 and/or 2 monoclonal capture antibodies, each bound to the assay membrane at their respective Stx1 and Stx2 test positions of the strip, bind the complexes to yield the respective test lines. When antigen is not present, a complex is not formed, and therefore, test lines do not form. As the sample continues to move further up the test strip, the polyclonal capture antibody, bound to the assay membrane at the control position of the strip, binds the conjugated antibodies and

yields the control line. A line at the control position of the test strip should be present each time a sample or external control is tested. If the control line is not generated, adequate sample flow has not occurred, and the Curian Analyzer will consider the test invalid. The output is a reported test result produced by the Curian Analyzer, indicating if Stx1 and/or Stx2 has been detected. The assay detects and differentiates between Stx1 and Stx2 in a single test device.

L. Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility

The reproducibility of the Curian Shiga Toxin assay was determined by testing contrived cultured broth samples across three independent laboratories. Samples were created with Stx1 and/or Stx2 spiked into pooled negative cultured broth matrix at high negative, low positive, and moderate positive concentrations, along with a true negative cultured broth sample. Ten panels consisting of 30 blinded samples comprising of various combinations of Stx1 and Stx2 concentrations were provided to each of the three laboratories for a total of 900 samples. Testing was conducted at each laboratory over 5 different days. Each day two separate operators tested each one a separate panel while alternating between kit lots. Testing included three different kit lots (2 lots per site). In addition, positive and negative controls were run daily.

For Stx1, the overall agreement between the Curian Shiga Toxin assay result and the expected assay result was 99.6% (95% CI: 98.9% - 99.8%) with 100% for all sample types except for combined Stx1 and Stx2 high negative samples, which showed an agreement of 95.6% (95% CI: 89.1% - 98.3%). For Stx2, the overall agreement between the Curian Shiga Toxin assay result and the expected assay result was 99.7% (95% CI: 99.0% - 99.9%) with 100% for all sample types except for Stx2 high negative samples, which showed an agreement of 97.8% (95% CI: 92.3% - 99.4%), and combined Stx1 and Stx2 high negative samples, which showed an agreement of 98.9% (95% CI: 94.0% - 99.8%). Results are summarized in the table below.

Panel Sample	% Agreement (n)	
	Stx1 Results	Stx2 Results
Shiga Toxin 1 Sample Types		
True Negative	100% (90/90)	100% (90/90)
High Negative	100% (90/90)	100% (90/90)
Low Positive	100% (90/90)	100% (90/90)
Moderate Positive	100% (90/90)	100% (90/90)
Shiga Toxin 2 Sample Types		
True Negative	100% (90/90)	100% (90/90)
High Negative	100% (90/90)	97.8% (88/90)
Low Positive	100% (90/90)	100% (90/90)
Moderate Positive	100% (90/90)	100% (90/90)
Shiga Toxin 1 and 2 Sample Types		
True Negative	100% (90/90)	100% (90/90)
High Negative	95.6% (86/90)	98.9% (89/90)
Low Positive	100% (90/90)	100% (90/90)
Moderate Positive	100% (90/90)	100% (90/90)

b. Linearity/reportable range:

Not applicable as this is a qualitative test.

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

Specimen Stability:
The specimen stability claims include storage of up to 7 days at refrigerated temperature (2-8 C) or for up to 21 days frozen (-20°C and/or -80°C) for clinical broth culture enriched stool specimens prior to testing with the Curian® Shiga Toxin assay.
Freeze/Thaw:
The specimen freeze/thaw stability claims for clinical broth culture enriched stool specimens include freezing and thawing specimens for up to two (2) freeze/thaw cycles when specimens are stored frozen (≤ -20 C) prior to testing with the Curian® Shiga Toxin assay.

Reagent Stability:
Accelerated Stability testing produced acceptable results to support up to eighteen (18) months expiry date at 2-8 C for the Curian® Shiga Toxin assay and kit components (i.e., test cards, Aioprep and Positive Control).

d. Analytical Sensitivity

Analytical sensitivity studies were performed to determine the analytical limit of detection (LoD) of quantified Stx1 and Stx2 in broth culture matrix derived from human stool for the Curian Shiga Toxin assay. Three lots of the Curian Shiga Toxin assay were evaluated. For each kit lot, an LoD was established and confirmed in separate studies for each target toxin (Stx1 and Stx2). The LoD was defined as the lowest concentration of the target toxin that produced positive results ≥ 95% of the time.

The LoD values determined for the Curian Shiga Toxin assay for each toxin detected by the assay in culture matrix derived from human stool are 0.185 ng/mL for Stx1 and 0.125 ng/mL for Stx2.

e. Prozone / Hook Effect

A study was performed to determine the potential for a high dose prozone/hook effect with the Curian Shiga Toxin assay. Dilutions of quantified Stx1 and Stx2 were prepared in negative broth culture matrix to create contrived positive samples containing known concentrations of the target toxin. Individual reactions were prepared such that the concentration in each replicate was that of a high positive specimen, approximately 5xLoD - 377xLoD for Stx1 samples (ranging from 0.932 to 69.78 ng/mL) and 7xLoD - 558xLoD for Stx2 samples (ranging from 0.932 to 69.78 ng/mL). A total of n=7 dilutions were prepared for each toxin (Stx1 and Stx2), with an additional dilution prepared for a contrived combined Stx1 and Stx2 positive sample representing the highest concentration of Stx1 and Stx2 tested individually (69.78 ng/mL, approximately 377X LoD for Stx1 and 558X LoD for Stx2). Therefore, n=15 total dilutions were evaluated for this study. Each sample dilution was tested in replicates of five to determine whether a hook/prozone effect was observed with the Curian Shiga Toxin assay. A prozone/ hook effect was not observed with the Curian Shiga Toxin assay when testing samples containing high concentrations of Stx1 and/or Stx2.

f. Cross-Reactivity:

A cross-reactivity and microbial interference study was performed to determine if potential co-contaminants of broth culture derived from human stool specimens would non-specifically react with the Curian Shiga Toxin assay, or interfere with detection of Stx1 or Stx2 when present at high concentrations. The specificity of Curian Shiga Toxin was evaluated by testing bacteria, fungi, and viral strains. Each organism was tested with a true negative sample and two contrived low positive samples (3xLoD; one for each of Stx1 and Stx2) at a minimum concentration of $1.2x10^7$ CFU/mL (for bacteria/fungi, with the exception of *Shigella dysenteriae*) or $1.0x10^5$ $TCID_{50}$/mL (for viruses).

No cross-reactivity or microbial interference with the Curian Shiga Toxin assay was observed except for *S. dysenteriae* (strain ATCC 9361), which was found to be Stx1 positive at concentrations greater than 1.25×10^6 CFU/mL in the Curian Shiga Toxin assay. The organisms evaluated for cross-reactivity are listed below.

Microorganism	Strain ID	Microorganism	Strain ID
Aeromonas hydrophila	ATCC 35654	*Helicobacter pylori*	CCUG 39500
Bacillus subtilis	ATCC 6051	*Klebsiella pneumoniae*	ATCC BAA-1900
Bacteroides fragilis	ATCC 23745	*Lactobacillus acidophilus*	ATCC 4356
Campylobacter coli	ATCC 43482	*Proteus vulgaris*	ATCC 6380
Campylobacter concisus	ATCC 33237	*Providencia stuartii*	ATCC 33672
Campylobacter fetus	ATCC 25936	*Pseudomonas aeruginosa*	ATCC 10145
Campylobacter hyointestinalis	ATCC 35217	*Pseudomonas fluorescens*	ATCC 13525
Campylobacter jejuni	ATCC 33292	*Salmonella enterica susb. enterica serovar Hilversum*	ATCC 15784
Candida albicans	ATCC 18804	*Salmonella enterica susb. enterica serovar Typhimurium*	ATCC 13311
Citrobacter freundii	ATCC 43864	*Salmonella minnesota*	ATCC 9700
Clostridium difficile	ATCC 43255	*Serratia liquefaciens*	ATCC 27592
Clostridium perfringens	ATCC 12915	*Serratia marcescens*	ATCC 43862
Enterobacter cloacae	ATCC 15337	*Shigella boydii*	ATCC 9207
Enterococcus faecalis	ATCC 49532	*Shigella dysenteriae*	ATCC 9361
Escherichia coli (non-toxigenic)	ATCC BAA-2190	*Shigella flexneri*	ATCC 12022
Escherichia coli EIEC	ATCC 43893	*Shigella sonnei*	ATCC 25931
Escherichia coli EPEC	ATCC 33780	*Staphylococcus aureus*	ATCC 51153
Escherichia coli ETEC	ATCC 35401	*Staphylococcus aureus (Cowan's)*	ATCC 12598
Escherichia coli O157:H7 (non-toxigenic)	ATCC 700728	*Staphylococcus epidermidis*	ATCC 49134
Escherichia fergusonii	ATCC 35469	*Streptococcus equisimilis subsp. dysgalactiae*	ATCC 12388
Escherichia hermanii	ATCC 33650	*Yersinia enterocolitica*	ATCC 23715
Gardnerella vaginalis	ATCC14019	Human Coxsackievirus A9	VR-1311
Human Adenovirus 2	Type 2; Species C	Human Coxsackievirus B1	VR-687
Human Adenovirus 14	VR-15	Human Enterovirus 69	Tolouca-1
Human Adenovirus 40	Dugan	Human Rotavirus	RV4
Human Adenovirus 41	Tak	Feline calicivirus	VR-782

g. Interfering Substances:

Interference testing was performed in the presence of chemical and biological substances introduced directly into contrived Stx1 and Stx2 low positive and negative cultured broth samples. Substances and their respective test concentrations evaluated are listed below. Interference was not observed with the Curian Shiga Toxin assay for any of the substances evaluated at their respective test concentrations.

Substance (active ingredient(s))	**Test Concentration**
Barium Sulfate	5% w/v
Ciprofloxacin	0.25% w/v (2.500 mg/mL)
Hog gastric mucin	3.5% w/v (35 mg/mL)
Human blood (whole)	40% v/v
Human hemoglobin	10.0% w/v (100 mg/mL)
Human urine	5% v/v
Imodium AD (Loperamide HCl, 1 mg/7.5 mL)	5% v/v
Kaopectate (Bismuth subsalicylate 262 mg/15 mL)	5% v/v
Leukocytes	0.05% v/v

Mylanta (per 10 mL: Aluminum hydroxide 800 mg, Magnesium hydroxide 800 mg, Simethicone 80 mg)	5% v/v (8.400 mg/mL)
Palmitic acid (fecal fat)	40% w/v (400 mg/mL)
Pepto-bismol (Bismuth subsalicylate 525 mg/30 mL)	5% v/v
Prilosec OTC (Omeprazole 20 mg/tablet)	5 µg/mL
Stearic acid (fecal fat)	40% w/v (400 mg/mL)
Tagamet (Cimetidine 200 mg/tablet)	5 µg/mL
TUMS	50 µg/mL
Naproxen sodium	0.5% w/v (5 mg/mL)
Metronidazole	0.25% w/v (2.500 mg/mL)
Vancomycin	0.25% w/v (2.500 mg/mL)

h. Assay Reactivity/ Inclusivity:

Various Shiga toxin-producing *Escherichia coli* strains (STEC) were evaluated in the Curian Shiga Toxin assay by the Sorbitol MacConkey Agar (SMAC) plate, Gram Negative (GN) broth, and MacConkey (MAC) broth culture enrichment methods. Each strain was a clinical isolate tested by an FDA-cleared commercial assay and a cytotoxin assay to confirm the presence of the Shiga toxin gene(s). All strains representing various serotypes and toxin combinations tested showed reactivity with the Curian Shiga Toxin assay, detailed below:

STX1 Type Strains: O26:H11 (6), O111:H8 (3), O45:H2 (3), O103:H25 (2), O145 (2), O103:H11 (2), O157:H7, O103:H2, O111

STX2 Type Strains: O121:H19 (4), O145 (3), O104:H21 (2), O113:H21 (2), O157:H7, O157:NM, O145:H25, O145:H28, O91:H21

STX1+2 Type Strains: O111:H8 (3), O157:H7 (2), O111 (2), O145, O113:H21, O26:H11

i. Assay Cut-Off:

Not Applicable

2. Comparison Studies

a. Method Comparison with Predicate Device:

See Clinical Studies Section below.

b. Matrix Comparison:
Not applicable.

3. Clinical Performance

a. Clinical Sensitivity:

Prospective:

The Curian Shiga Toxin assay was evaluated from September 2021 to June 2022 at five clinical study sites representing geographically distinct regions throughout the United States. There were 1,627 stool specimens from patients suspected of having a Shiga toxin-producing *Escherichia coli* (STEC) infection for whom a diagnostic *E. coli* test had been ordered by a practicing physician. Specimens were prospectively collected and tested with the Curian Shiga Toxin assay using stool specimens inoculated into appropriate broth. Of those 1,627, evaluable reference data was available for 1,538, all of which were evaluable prospective specimens. All specimens were tested at the study sites with the Curian Shiga Toxin assay and in a central laboratory with the reference method, the Vero cell Cytotoxin Assay (with neutralization) performed on the broth culture obtained from the stool specimen. Clinical performance (sensitivity and specificity) for prospective specimens against the reference method (Vero cell Cytotoxin Assay) for both Stx1 and Stx2 are

presented in the following tables. There were no observable differences in performance of the Curian Shiga Toxin assay with respect to study site, broth type, kit lot, or patient gender or age.

Curian Shiga Toxin Overall Performance for Prospective Specimens versus Vero Cell Cytotoxin Assay

		Reference Method: Vero cell Cytotoxin Assay					
		Stx1 Positive	Stx1 Negative	Total	Parameter	Estimate	95% CI
Curian Shiga Toxin Assay	Stx1 Positive	5	9	14	Sensitivity	100.0%	[56.6% - 100.0%]
	Stx1 Negative	0	1524	1524	Specificity	99.4%	[98.9% - 99.7%]
	Total	5	1533	1538			

		Reference Method: Vero cell Cytotoxin Assay					
		Stx2 Positive	Stx2 Negative	Total	Parameter	Estimate	95% CI
Curian Shiga Toxin Assay	Stx2 Positive	4	7	11	Sensitivity	100.0%	[51.0% - 100.0%]
	Stx2 Negative	0	1527	1527	Specificity	99.5%	[99.1% - 99.8%]
	Total	4	1534	1538			

Archived:

To further estimate sensitivity and specificity of the Curian Shiga Toxin assay, 140 archived stool samples were retrospectively tested for Stx1 and Stx2 using the Curian Shiga Toxin assay at all five study sites. The clinical performance (sensitivity and specificity) for archived samples against the reference method (Vero cell Cytotoxin Assay) are presented in the table below. Of the 140 eligible samples enrolled, 5 were excluded due to inconclusive Vero cell Cytotoxin results, leaving a total of 135 evaluable archived specimens. There were no observable differences in performance of the Curian Shiga Toxin assay with respect to study site, broth type, kit lot, or patient gender or age.

Curian Shiga Toxin Overall Performance for Archived Samples versus Vero Cell Cytotoxin Assay

		Reference Method: Vero cell Cytotoxin Assay					
		Stx1 Positive	Stx1 Negative	Total	Parameter	Estimate	95% CI
Curian Shiga Toxin Assay	Stx1 Positive	46	2	48	Sensitivity	100.0%	[92.3% - 100.0%]
	Stx1 Negative	0	87	87	Specificity	97.8%	[92.2% - 99.4%]
	Total	46	89	135			

		Reference Method: Vero cell Cytotoxin Assay					
		Stx2 Positive	Stx2 Negative	Total	Parameter	Estimate	95% CI
Curian Shiga Toxin Assay	Stx2 Positive	32	2	34	Sensitivity	97.0%	[84.7% - 99.5%]
	Stx2 Negative	1	100	101	Specificity	98.0%	[93.1% - 99.5%]
	Total	33	102	135			

b. Clinical Specificity:

See section L.3.a. above.

c. *Other clinical supportive data (when a. and b. are not applicable):*

Not applicable.

4. Clinical Cut-off:

Not applicable.

5. Expected values/Reference Range:

Not applicable.

M. Proposed Labeling:

The labeling is sufficient, and it satisfies the requirements of 21 CFR Part 809.10.

N. Conclusion:

The Curian® Shiga Toxin assay, as supported by the information submitted in this premarket submission, is substantially equivalent to the predicate device (*SHIGA TOXIN QUIK CHEK*; K121364).