DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2016

Quidel Corporation
Ronald H. Lollar
Senior Director, Clinical and Regulatory Affairs
2005 East State Street, Suite 100
Athens, OH 45701

Re: K161182
Trade/Device Name: Solana® Trichomonas Assay
Regulation Number: 21 CFR 866.3860
Regulation Name: *Trichomonas vaginalis* nucleic acid assay
Regulatory Class: II
Product Code: OUY
Dated: July 14, 2016
Received: July 15, 2016

Dear Mr. 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 Parts 801 and 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), 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" (21CFR 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, M.Sc., 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)*
K161182

Device Name
Solana® Trichomonas Assay

Indications for Use *(Describe)*
The Solana® Trichomonas Assay is an *in vitro* diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection of *Trichomonas vaginalis* nucleic acids isolated from clinician-collected vaginal swabs and female urine specimens obtained from symptomatic or asymptomatic females to aid in the diagnosis of trichomoniasis. The Solana® Trichomonas 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
12544 High Bluff Drive, Suite 200
San Diego, California 92130
Telephone: 858-552-7910
Fax: 858-646-8045

Contact Information:

Ronald H. Lollar, Senior Director Clinical and Regulatory Affairs
2005 East State Street, Suite 100
Athens, Ohio 45701
740-589-3300 – Corporate number
740-589-3373 – Desk phone
858-552-6451– Fax
Ron.Lollar@quidel.com

Date of preparation of 510(k) summary:

April 26, 2016

A. 510(k) Number:

K161182

B. Purpose for Submission:

To obtain substantial equivalence for the Solana® Trichomonas Assay when performed on the Solana® instrument

C. Measurand:

Repeated DNA fragment located in *T. vaginalis* genome

D. Type of Test:

Helicase-dependent amplification (HDA)

510(k) Summary

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Solana® Trichomonas Assay

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
OUY – *Trichomonas vaginalis* nucleic acid amplification test system	Class II	21 CFR 866.3860 Trichomonas vaginalis nucleic acid assay	Microbiology (83)

H. Intended Use:

1. Intended Use(s):

   The Solana® Trichomonas Assay is an *in vitro* diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection of *Trichomonas vaginalis* nucleic acids isolated from clinician-collected vaginal swabs and female urine specimens obtained from symptomatic or asymptomatic females to aid in the diagnosis of trichomoniasis. The Solana® Trichomonas 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

4. Special instrument requirements:

   Solana® Instrument

510(k) Summary

I. Device Description:

The Solana® Trichomonas Assay amplifies and detects *Trichomonas vaginalis* nucleic acids present in clinician-collected vaginal swabs and urine specimens from symptomatic and asymptomatic women. The assay targets a conserved multi-copy sequence of the *T. vaginalis* DNA.

The vaginal swab is eluted in a swab lysis tube or a urine specimen is added to a urine lysis tube, and the cells in either specimen type are lysed by simple heat treatment. After heat treatment, an aliquot of the lysed specimen is transferred into a dilution tube. An aliquot of the diluted sample is added 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 *T. vaginalis*-specific target sequence. In Solana, the target sequence is amplified by *T. vaginalis* specific primers and detected by a *T. vaginalis* 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 target is amplified by *T. vaginalis* 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. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to *T. vaginalis* or PRC amplicons, the fluorescence probes are cleaved by RNaseH2 and 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 instrument will then report the test results to the user on its display screen, and the results can be printed via a printer.

Materials Provided:

Solana® Trichomonas Assay Kit: M304.S for swab testing or M304.U for urine testing
48 Tests per kit

Solana® Trichomonas Assay Kit – M304.S		
Component	**Quantity**	**Storage**
Lysis Buffer Tubes	48 tubes/kit, 1.0 mL	2° to 8°C
Dilution Tubes	48 tubes/kit, 1.5 mL	2° to 8°C
Reaction Tubes	48 tubes/kit	2° to 8°C
Solana® Trichomonas Assay Kit – M304.U		
Component	**Quantity**	**Storage**
Lysis Buffer Tubes	48 tubes/kit, 0.2 mL	2° to 8°C
Dilution Tubes	48 tubes/kit, 1.5 mL	2° to 8°C
Reaction Tubes	48 tubes/kit	2° to 8°C

510(k) Summary

Materials required but not provided:

- External controls for *Trichomonas vaginalis* (e.g. Quidel Molecular Trichomonas Assay Control Kit: M119), which contains positive and negative controls. This positive control contains intact non-viable, trophozoites and has been titered to be near the limit of detection for the assay. This negative control is the same matrix as the positive control, but is trophozoite-free. These controls serve as an external processing and extraction control
- Sterile DNAse-free filter-blocked or positive displacement micropipettor tips
- Micropipettor
- BD BBL™ CultureSwab™ collection and transport device
- Stopwatch or timer
- Scissors or a blade
- Micro tube tray
- Heat block capable of 95° C ± 2° C temperature
- Thermometer
- Solana Instrument

J. Substantial Equivalence Information:

1. Predicate device name(s):

   AmpliVue® Trichomonas Assay

2. Predicate 510(k) number(s):
   K143329

3. Comparison with predicate:

Similarities		
Item	**Solana® Trichomonas Assay (k161182)**	**AmpliVue® Trichomonas Assay (k143329)**
Intended Use	The Solana® Trichomonas Assay is an *in vitro* diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection of *Trichomonas vaginalis* nucleic acids	The AmpliVue® Trichomonas Assay is an *in vitro* diagnostic test, uses isothermal amplification technology (helicase-dependent amplification, HDA) for the qualitative detection of

510(k) Summary

Similarities		
Item	**Solana® Trichomonas Assay (k161182)**	**AmpliVue® Trichomonas Assay (k143329)**
	isolated from clinician-collected vaginal swabs and female urine specimens obtained from symptomatic or asymptomatic females to aid in the diagnosis of trichomoniasis. The Solana® Trichomonas Assay is intended for use only with the Solana® instrument.	*Trichomonas vaginalis* nucleic acids isolated from clinician-collected vaginal swab specimens obtained from symptomatic or asymptomatic females to aid in the diagnosis of trichomoniasis.
Target Sequence Detected	Repeated DNA fragment located in *T. vaginalis* genome	Same
Amplification Technology	Helicase-dependent amplification (HDA)	Same

Differences		
Item	**Solana® Trichomonas Assay (k161182)**	**AmpliVue® Trichomonas Assay (k143329)**
Sample Types	Clinician-collected Vaginal Swabs, Female Urine	Clinician-collected Vaginal Swabs
Self-Contained System Assay after sample preparation	Yes	No
Detection Technique	Automated	Manual
Instrument	Solana	None
Performance	Clinician-collected Vaginal Specimens: Asymptomatic	Clinician-collected Vaginal Specimens: Asymptomatic

510(k) Summary

Differences		
Item	**Solana® Trichomonas Assay (k161182)**	**AmpliVue® Trichomonas Assay (k143329)**
Characteristics	Sensitivity 100% (95% CI 92.9 – 100) Specificity 98.9% (95% CI 97.4 – 99.5) <u>Symptomatic</u> Sensitivity 98.6% (95% CI 92.3 – 99.7) Specificity 98.5% (95% CI 97.0 – 99.3) Female Urine Specimens: <u>Asymptomatic</u> Sensitivity 98% (95% CI 89.5 – 99.6) Specificity 98.4% (95% CI 96.8 – 99.2) <u>Symptomatic</u> Sensitivity 92.9% (95% CI 84.3 – 96.9) Specificity 97.9% (95% CI 96.2 – 98.8)	Sensitivity 100% (95% CI 94.1 – 100) Specificity 98.3% (95% CI 96.9 – 99.1) <u>Symptomatic</u> Sensitivity 100% (95% CI 93.9 – 100) Specificity 97.9% (95% CI 95.5 – 99.0)

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

Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*

L. Test Principle:

The vaginal swab is eluted in a swab lysis tube or a urine specimen is added to a urine lysis tube, and the cells in either specimen type are lysed by simple heat treatment. After heat treatment, an aliquot of the lysed specimen is transferred into a dilution tube. An aliquot of the diluted sample is added 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 *T. vaginalis*-specific target sequence. In Solana, the target sequence is amplified by *T. vaginalis* specific primers

and detected by a *T. vaginalis* 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 target is amplified by *T. vaginalis* 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. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to *T. vaginalis* or PRC amplicons, the fluorescence probes are cleaved by RNaseH2 and 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 instrument will then report the test results to the user on its display screen, and the results can be printed via an attached printer.

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility

In order to confirm the reproducibility of the Solana Trichomonas Assay a blinded and randomized study consisting of the following four-member panel containing *Trichomonas vaginalis* positive and negative samples was performed: swab workflow – moderate positive (3x LoD), low positive (1x LoD), high negative (1/54x LoD), and a negative sample; urine workflow - moderate positive (3x LoD), low positive (1x LoD), high negative (1/27x LoD), and a negative sample. The testing was performed using appropriate swab or urine workflows at three (3) test sites (one in-house laboratory and two (2) clinical sites). Each site tested a reproducibility panel and Assay Controls for five (5) days in triplicate. Testing was done by two (2) operators at each site. Each operator ran the panel once a day using one lot of Solana Trichomonas Assay. The testing was performed using both the swab and urine workflows.

Category Swab Workflow	**SITE**									**Overall Percent Agreement**		**95% Confidence Interval**
	Site #1			**Site #2**			**Site #3**					
	#expected results/# tested	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*			
High Negative (1.89 trophozoites /mL)	25/30	83%	66.4% to 92.7%	22/30	73%	55.6% to 85.8%	15/30	50%	33.2% to 66.8%	62/ 90	69%	58.7% to 77.5%

510(k) Summary

Category Swab Workflow	SITE									Overall Percent Agreement		95% Confidence Interval
	Site #1			Site #2			Site #3					
	#expected results/# tested	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*			
Low Positive (102 trophozoites /mL)	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%
Moderate Positive (306 trophozoites /mL)	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%
Negative	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%
Positive Control	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%
Negative Control	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%

Category Urine Workflow	SITE									Overall Percent Agreement		95% Confidence Interval
	Site #1			Site #2			Site #3					
	#expected results/# tested	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*			
High Negative (0.2 trophozoites /mL)	20/30	67%	48.8% to 80.8%	19/30	63%	45.5% to 78.1%	22/30	73%	55.6% to 85.8%	61/ 90	68%	57.6% to 75.5%
Low Positive (4 trophozoites /mL)	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%
Moderate Positive (12 trophozoites /mL)	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%
Negative	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%
Positive Control	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%
Negative Control	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	30/30	100%	88.6% to 100%	90/ 90	100%	95.9% to 100%

The results suggest that there are no significant differences between different users and different sites on different days using either the swab or the urine workflow. Reproducibility studies are acceptable.

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:

A study was performed to determine the stability of swab and urine samples when stored at 2 to 8°C or 30°C ± 2°C. Contrived positive swab and urine samples (2x LoD) were prepared. The testing time points for the specimens stored at 2° to 8°C were 0, 24, 48, 72, 73 hours, 5, 7, 8 days. The testing time points for the specimens stored at 30°C ± 2°C were 0, 2.5, 6.5, 24, 25, 27, 48, and 49 hours.

Based on the data generated by this study, swab specimens may be stored between 2° to 8°C for up to 7 days prior to testing. Swab specimens may be stored at up to 48-hours at 30°C ± 2°C or below prior to testing.

Based on the data generated by this study, urine specimens may be stored between 2° to 8°C for up to 7 days prior to testing. Urine specimens may be stored at up to 24-hours at 30°C ± 2°C or below prior to testing.

Controls:

Controls (Quidel Molecular Trichomonas Control Set #M119, which contains positive and negative controls, serves as an external processing and extraction control) were run on the Solana® Trichomonas Assay each day of testing. These controls are described as follows:

a. The internal control is used to detect HDA inhibitory specimens and to confirm the integrity of assay reagents and the operation of the Solana instrument. The internal control is included in the lysis tube.

b. External assay positive control (e.g. Quidel Molecular Trichomonas Control Set (M119)) serves as the assay positive control. Transfer 50 µL of positive control into a labeled lysis buffer tube and proceed with processing. The external assay positive control is intended to monitor substantial reagent and instrument failure.

c. External assay negative control (e.g. Quidel Molecular Trichomonas Control Set (M119)) serves as the assay negative control. Transfer 50 µL of negative control into a labeled lysis buffer tube and proceed with processing. The external assay negative control is intended to detect reagent or environment contamination or carry-over by either *T. vaginalis* DNA or amplicons.

d. Detection limit:

The analytical sensitivity (limit of detection or LoD) of the Solana® Trichomonas Assay was determined using quantified (trophozoite/mL) strains of two (2) *T. vaginalis* strains, one metronidazole-susceptible G3 and one metronidazole-resistant CDC888 serially diluted in negative clinical matrix. The LOD is defined as the lowest concentration at which 95% of all replicates tested positive.

The strains were freshly grown and quantified using a hemocytometer. The cells were serially diluted in negative clinical matrix to three (3) concentrations at 3×, 1×, and 1/3× in the preliminary LOD determination study.

LoD was confirmed by testing each reference strain with 20 replicates on three reagent lots in the negative vaginal swab and negative urine matrixes.

***Trichomonas vaginalis* reference strain**	Swab Workflow LoD	Urine Workflow LoD
G3	102 trophozoite /mL	4 trophozoite /mL
CDC888	306 trophozoite /mL	108 trophozoite /mL

e. Analytical specificity:

Cross Reactivity:

A study was performed to evaluate the cross-reactivity of the Solana® Trichomonas Assay in the presence of forty-seven (47) microorganisms (37 bacteria, 4 yeast, 4 viruses, 2 parasite) potentially found in specimens collected to test for *Trichomonas*

vaginalis infection. Each microorganism was diluted in either swab negative matrix or negative urine matrix to the desired concentration (10^6 or higher CFU/mL or copies/mL for bacteria, yeast or DNA/RNA and 10^5 or higher pfu/mL or $TCID_{50}$/mL for viruses). The strains included in the cross-reactive study are shown in the table below.

Microorganism	Stock Concentration	Microorganism	Stock Concentration
Acinetobacter lwoffi	1.0×10^6 CFU/mL	Herpes simplex virus I	1.0×10^5 $TCID_{50}$/mL
Actinomyces israelii	1.0×10^6 CFU/mL	Herpes simplex virus II	1.0×10^5 $TCID_{50}$/mL
Atopobium vaginae	1.0×10^6 CFU/mL	*Klebsiella oxytoca*	1.0×10^6 CFU/mL
Bacteroides fragilis	1.0×10^6 CFU/mL	*Lactobacillus acidophilus*	1.0×10^6 CFU/mL
Bifidobacterium adolescentis	1.0×10^6 CFU/mL	*Lactobacillus jensenii*	1.0×10^6 CFU/mL
Campylobacter jejuni	1.0×10^6 CFU/mL	*Lactobacillus vaginalis*	1.0×10^6 CFU/mL
Candida albicans	1.0×10^6 CFU/mL	*Listeria monocytogenes*	1.0×10^6 CFU/mL
Candida glabrata	1.0×10^6 CFU/mL	*Mobiluncus curtisii*	1.0×10^6 CFU/mL
Candida parapsilosis	1.0×10^6 CFU/mL	*Mycoplasma hominis*	1.0×10^6 CFU/mL
Candida tropicalis	1.0×10^6 CFU/mL	*Neisseria gonorrhoeae*	1.0×10^6 CFU/mL
Chlamydia trachomatis	1.0×10^6 CFU/mL	*Pentatrichomonas hominis*	1.0×10^6 CFU/mL
Clostridium difficile	1.0×10^6 CFU/mL	*Prevotella bivia*	1.0×10^6 CFU/mL
Clostridium perfingens	1.0×10^6 CFU/mL	*Propionibacterium acnes*	1.0×10^6 CFU/mL
Corynebacterium genitalium	1.0×10^6 CFU/mL	*Proteus mirabilis*	1.0×10^6 CFU/mL
Cryptococcus neoformans	1.0×10^6 CFU/mL	*Pseudomonas aeruginosa*	1.0×10^6 CFU/mL
Enterobacter aerogenes	1.0×10^6 CFU/mL	*Staphylococcus aureus* (MRSA)	1.0×10^6 CFU/mL
Enterococcus faecalis	1.0×10^6 CFU/mL	*Staphylococcus epidermidis*	1.0×10^6 CFU/mL
Escherichia coli	1.0×10^6 CFU/mL	*Streptococcus pyogenes*	1.0×10^6 CFU/mL
Fusobacterium nucleatum	1.0×10^6 CFU/mL	*Streptococcus agalactiae*	1.0×10^6 CFU/mL
Gardnerella vaginalis	1.0×10^6 CFU/mL	*Trichomonas tenax*	1.0×10^6 CFU/mL

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Microorganism	Stock Concentration	Microorganism	Stock Concentration
Haemophilus ducreyi	1.0×10^6 copies/mL	*Enterobacter cloacae*	1.0×10^6 CFU/mL
HIV-1 Subtype B RNA	1.0×10^5 RNA copies/mL	HPV 16 (SiHa)	1.0×10^5 copies/mL
Peptostreptococcus anaerobius	1.0×10^6 copies/mL	*Ureaplasma urealyticum* DNA	1.23 $x10^8$ cp/mL
Synthetic *Mycoplasma genitalium* DNA*	1.0×10^6 copies/mL		

* Preparation includes fragments from the 16S gene, mgpA, and gap.

No cross-reactivity was seen with the Solana® Trichomonas Assay with any of forty-seven (47) microorganisms (37 bacteria, 4 yeast, 4 viruses, 2 parasite) tested.

Interference:

Vaginal Swab Specimens

A study was conducted to determine if the Solana® Trichomonas assay is inhibited in the presence of a panel of fourteen (14) substances potentially present in vaginal swab specimens collected to test for *Trichomonas vaginalis* infection. Each of the potential interfering substances was tested in three (3) replicates in the presence and absence of near LOD (2x) levels of two (2) strains of *Trichomonas vaginalis* in the Solana® Trichomonas Assay. Substances were introduced into the assay at concentrations which were medically relevant.

Class	Substances	Concentration Tested
Blood	Whole blood with EDTA	10% (v/v)
Seminal fluid	Seminal fluid	1% (v/v)
Mucus	Mucin from Porcine Stomach	1% (w/v)
Over the counter (OTC) vaginal products and contraceptives	K-Y Personal Lubricant Jelly	1% (w/v)
	Ortho Options Gynol II Extra Strength Vaginal Contraceptive Jelly	1% (w/v)
	Summer's Eve Ultra Extra Strength Feminine Deodorant Spray	1% (w/v)
	Vagisil Creme Maximum Strength	1% (w/v)

510(k) Summary

Class	Substances	Concentration Tested
	CVS Vinegar & Water Extra Cleansing Disposable Douche (Glacial acetic acid)	1% (v/v)
	Summer's Eve Douche, Medicated	1% (v/v)
Intravaginal Hormones	Estradiol	1% (w/v)
Hemerrhoidal Cream	Preparation H	1% (w/v)
Leukocytes	Leukocytes	10^6 cells/mL
Prescription vaginal treatments	Acyclovir (Acycloguanosine)	0.05% (w/v) (1% of active ingredient of Zovirax cream with Acyclovir at 5%)
	Metronidazole	0.0075% (w/v) (1% of active ingredient of Vandazole gel with Metronidazole at 0.75%)

None of the substances tested interfered with the detection of either strain of 2x LoD *Trichomonas vaginalis*, or the detection of the internal control in negative specimens.

Urine Specimens

A study was conducted to determine if the Solana® Trichomonas assay is inhibited in the presence of a panel of seventeen (17) substances potentially present in urine specimens collected to test for *Trichomonas vaginalis* infection. Each of the potential interfering substances was tested in three (3) replicates in the presence and absence of near LoD (2x) levels of two (2) strains of *Trichomonas vaginalis* in the Solana® Trichomonas Assay. Substances were introduced into the assay at concentrations which were medically relevant.

Class	Substances	Concentration Tested
Blood	Whole blood with EDTA	1% (v/v)
Seminal fluid	Seminal fluid	5% (v/v)
Mucus	Mucin from Porcine Stomach	1% (w/v)
	AZO Standard Urinary Relief Tablets (Phenazopyridine Hydrochloride)	1.0 mg/mL

510(k) Summary

Class	Substances	Concentration Tested
Analgesics & Antibiotics	Acetylsalicylic Acid	8 mg/mL
	Acetaminophen	3.2 mg/mL
	Azithromycin	1.0 mg/mL
	Doxycycline	0.5 mg/mL
Over the counter deodorant spray and powder	Summer's Eve Feminine Deodorant Powder	1% (w/v)
	Summer's Eve Feminine Deodorant Spray	1% (w/v)
Albumin	Human Albumin	10 mg/ml
Glucose	Glucose	10 mg/ml
Bilirubin	Bilirubin	1 mg/ml
Acidic Urine (pH 4.0)	Urine + N-Acetyl-L-Cysteine	pH 4.0
Alkaline Urine (pH 9.0)	Urine + Ammonium Citrate & Sodium hydroxide	pH 9.0
Leukocytes	Leukocytes	10^6 cells/mL
Intravaginal Hormones	Estradiol	1% (w/v)

None of the substances tested interfered with the detection of either strain of 2x LOD *Trichomonas vaginalis*, or the detection of the internal control in negative specimens.

Analytical Reactivity (Inclusivity):

A study was performed to verify the *in silico* inclusivity results with functional testing of the Solana® Trichomonas Assay using twenty (20) additional strains of *Trichomonas vaginalis* tested in triplicate at concentrations at or near the 1x LoD levels of the assay in both the swab and urine workflows.

Bacterial Strain	Strain Detected (Yes/No)	Strain Detected (Yes/No)
CDC899	Yes	Yes
CDC938	Yes	Yes
CDC963	Yes	Yes
CDC1031	Yes	Yes

Bacterial Strain	Strain Detected (Yes/No)	Strain Detected (Yes/No)
CDC1256	Yes	Yes
PMGH25	Yes	Yes
BUSH20	Yes	Yes
CDC911	Yes	Yes
MOR31	Yes	Yes
CDC1080	Yes	Yes
B7708/1839	Yes	Yes
F1623	Yes	Yes
CDC1095	Yes	Yes
SD1	Yes	Yes
SA-384	Yes	Yes
CDC948	Yes	Yes
SD10	Yes	Yes
SA-A53	Yes	Yes
CDC1230	Yes	Yes
SA-A19	Yes	Yes

The twenty (20) additional strains of *Trichomonas vaginalis* tested in triplicate at concentrations near the LoD levels of the assay were detected in both the swab and urine workflows of the Solana® Trichomonas assay.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

510(k) Summary

a. Clinical Sensitivity:

A multi-center study was performed to evaluate Solana® Trichomonas Assay using one thousand forty-four (1044) clinician-collected vaginal swab and urine specimens obtained from asymptomatic (n=501) or symptomatic (n=543) patients. The clinician categorized the patients as symptomatic or asymptomatic at the time of specimen collection. The study was performed November 2015 through March 2016 at four (4) locations in the United States. Specimens were obtained from each subject after informed consent was obtained. The study was conducted in accord with the Health Insurance Portability and Accountability Act (HIPAA).

Vaginal Swab

For each subject, three (3) vaginal specimens were collected using polyester or rayon Swabs w/ liquid Stuart's, and one (1) vaginal specimen was collected with a collection swab from a FDA-cleared molecular device. The four (4) clinician collected vaginal swabs were used for reference and Solana testing. The first two (2) polyester/rayon swabs were randomized, one swab was tested for the Wet Mount (reference method) and the other swab was used for the InPouch TV Culture (reference method). The third swab was used for testing the Solana® Trichomonas Assay**.** The FDA-cleared molecular device collection swab was used for discordant testing.

All sensitivity and specificity calculations were based on a composite reference method of Wet Mount and InPouch TV culture. A specimen was considered positive if either test was positive.

One thousand forty-four (1044) clinician-collected vaginal swab specimens obtained from asymptomatic (n=501) or symptomatic (n=543) patients were tested by the composite reference method and the Solana® Trichomonas Assay. Ten (10) specimens generated invalid results upon initial testing with the Solana® Trichomonas Assay (0.96%). These specimens were re-tested according to the instructions provided in the package insert. Nine (9) of these specimens generated valid results upon re-testing (6 negative and 3 positive results), and one (1) specimen generated a second invalid result (0.1%). The table below shows the sensitivity, specificity, PPV, and NPV of the Solana® Trichomonas Assay and the prevalence of *T. vaginalis* (by asymptomatic, symptomatic clinician designations and combined) for the remaining one thousand forty-three (1043) subjects.

Performance Characteristics of the Solana® Trichomonas Assay with Vaginal Swabs by Symptom Status compared to the Composite Reference Method											
Site Number	Symptom Status	N	TP	FP	TN	FN	Prev%	Sensitivity% (95% CI)	Specificity% (95% CI)	PPV % (95% CI)	NPV % (95% CI)

510(k) Summary

Performance Characteristics of the Solana® Trichomonas Assay with Vaginal Swabs by Symptom Status compared to the Composite Reference Method											
Site Number	Symptom Status	N	TP	FP	TN	FN	Prev%	Sensitivity% (95% CI)	Specificity% (95% CI)	PPV % (95% CI)	NPV % (95% CI)
Combined	Asymptomatic	501	50	5	446	0	10.0	100 (92.9 to 100)	98.9 (97.4 to 99.5)	90.9 (80.4 to 96.1)	100 (99.1 to 100)
	Symptomatic	542	69	7	465	1	12.9	98.6 (92.3 to 99.7)	98.5 (97.0 to 99.3)	90.8 (82.2 to 95.5)	99.8 (98.8 to 100)
	All	1043	119	12*	911	1*	11.5	99.2 (95.4 to 99.9)	98.7 (97.7 to 99.3)	90.8 (84.7 to 94.7)	99.7 (99.4 to 100)
Site 1	Asymptomatic	77	7	0	70	0	9.1	100 (64.6 to 100)	100 (94.8 to 100)	100 (64.6 to 100)	100 (94.8 to 100)
	Symptomatic	27	2	1	24	0	7.4	100 (34.2 to 100)	96.0 (80.5 to 99.3)	66.7 (20.8 to 93.9)	100 (86.2 to 100)
	All	104	9	1	94	0	8.7	100 (70.1 to 100)	98.9 (94.3 to 99.8)	90.0 (59.6 to 98.2)	100 (96.1 to 100)
Site 2	Asymptomatic	108	13	0	95	0	12.0	100 (77.2 to 100)	100 (96.1 to 100)	100 (77.2 to 100)	100 (96.1 to 100)
	Symptomatic	213	37	2	174	0	17.4	100 (90.6 to 100)	98.9 (80.5 to 99.3)	94.9 (83.1 to 98.6)	100 (97.8 to 100)
	All	321	50	2	269	0	15.6	100 (92.9 to 100)	99.3 (97.3 to 99.8)	96.2 (87.0 to 98.9)	100 (98.6 to 100)
Site 3	Asymptomatic	146	19	1	126	0	13.0	100 (83.2 to 100)	99.2 (95.7 to 99.9)	95.0 (76.4 to 99.1)	100 (97.0 to 100)
	Symptomatic	67	9	1	57	0	13.4	100 (70.1 to 100)	98.3 (90.9 to 99.7)	90.0 (59.6 to 98.2)	100 (93.7 to 100)
	All	213	28	2	183	0	13.1	100 (87.9 to 100)	98.9 (96.1 to 99.7)	85.9 (76.0 to 92.2)	100 (99.3 to 100)
Site 4	Asymptomatic	170	11	4	155	0	6.5	100 (74.1 to 100)	97.5 (93.7 to 99.0)	73.3 (48.0 to 89.1)	100 (97.6 to 100)
	Symptomatic	235	21	3	210	1	9.4	95.5 (78.2 to 99.2)	98.6 (95.9 to 99.5)	87.5 (69.0 to 95.7)	99.5 (97.4 to 99.9)
	All	405	32	7	365	1	8.1	97.0 (84.7 to 99.5)	98.1 (96.2 to 99.1)	82.1 (67.3 to 91.0)	99.7 (98.5 to 100)

*Of the one thousand forty-three 1043 specimens evaluated a total of thirteen (13) specimens were discordant. Of the twelve (12) discordant (Solana Positive/Composite Reference Method Negative) specimens, four (4) were positive by a FDA-cleared *Trichomonas vaginalis* molecular assay. The one (1) discordant (Solana Negative/Composite Reference Method Positive) specimen was negative by a FDA-cleared *Trichomonas vaginalis* molecular assay.

Urine

One thousand forty-four (1044) first catch urine specimens obtained from asymptomatic (n=501) or symptomatic (n=543) patients were tested by the Solana® Trichomonas Assay. Five (5) specimens generated invalid results upon initial testing with the Solana® Trichomonas Assay (0.5%). These specimens were re-tested according to the instructions provided in the package insert. All five (5) of these specimens generated valid results upon re-testing (four (4) negative and one (1) positive result). The table below shows the sensitivity, specificity, PPV, and NPV of the Solana® Trichomonas Assay and the prevalence of *T. vaginalis* (by asymptomatic, symptomatic clinician designations and combined) for the one thousand forty-four (1044) subjects when compared to the corresponding Wet Mount and the InPouch TV Culture results.

510(k) Summary

Performance Characteristics of the Solana® Trichomonas Assay with Urine Specimens by Symptom Status compared to the Composite Reference Method											
Site Number	Symptom Status	N	TP	FP	TN	FN	Prev%	Sensitivity% (95% CI)	Specificity% (95% CI)	PPV % (95% CI)	NPV % (95% CI)
Combined	Asymptomatic	501	49	7	444	1	10.0	98.0 (89.5 to 99.6)	98.4 (96.8 to 99.2)	87.5 (76.4 to 93.8)	99.8 (98.7 to 100)
	Symptomatic	543	65	10	463	5	12.9	92.9 (84.3 to 96.9)	97.9 (96.2 to 98.8)	86.7 (77.2 to 92.6)	98.9 (97.5 to 99.5)
	All	1044	114	17	907	6	11.5	95.0 (89.5 to 97.7)	98.2 (97.1 to 98.8)	87.0 (80.2 to 91.7)	99.3 (98.6 to 99.7)
Site 1	Asymptomatic	77	6	0	70	1	9.1	85.7 (48.7 to 97.4)	100 (94.8 to 100)	100 (61.0 to 100)	98.6 (92.4 to 99.8)
	Symptomatic	27	2	3	22	0	7.4	100 (34.2 to 100)	88.0 (70.0 t0 95.8)	40.0 (11.8 t 76.9)	100 (85.1 to 100)
	All	104	8	3	92	1	8.7	88.9 (56.5 to 98.0)	96.6 (91.1 to 98.9)	72.7 (43.4 to 90.3)	98.9 (94.2 to99.8)
Site 2	Asymptomatic	108	13	0	95	0	12.0	100 (77.2 to 100)	100 (96.1 to 100)	100 (77.2 to 100)	100 (96.1 to 100)
	Symptomatic	214	35	4	173	2	17.3	94.6 (82.3 to 98.5)	97.7 (94.3 to 99.1)	89.7 (76.4 to 95.9)	98.9 (95.9 to 99.7)
	All	322	48	4	268	2	15.5	96.0 (86.5 to 98.9)	98.5 (96.3 to 99.4)	92.3 (81.8 to 97.0)	99.3 (97.3 to 99.8)
Site 3	Asymptomatic	146	19	1	126	0	13.0	100 (83.2 to 100)	99.2 (95.7 to 99.9)	95.0 (76.4 to 99.1)	100 (97.0 to 100)
	Symptomatic	67	9	0	58	0	13.4	100 (70.1 to 100)	100 (93.8 to 100)	100 (70.1 to 100)	100 (93.8 to 100)
	All	213	28	1	184	0	13.1	100 (87.9 to 100)	99.5 (97.0 to 99.9)	96.6 (82.8 to 99.4)	100 (97.9 to 100)
Site 4	Asymptomatic	170	11	6	153	0	6.5	100 (74.1 to 100)	96.2 (92.0 to 98.3)	64.7 (41.3 to 82.7)	100 (97.6 to 100)
	Symptomatic	235	19	3	210	3	9.4	86.4 (66.7 to 95.3)	98.6 (95.9 to 99.5)	86.4 (66.7 to 95.3)	99.5 (97.4 to 99.9)
	All	405	30	9	363	3	8.1	90.9 (76.4 to 96.9)	97.6 (95.5 to 98.7)	76.9 (61.7 to 87.4)	99.2 (97.6 to 99.7)

b. Clinical specificity:

See Section 3a.

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values:

510(k) Summary

The prevalence of *T. vaginalis* (by asymptomatic, symptomatic clinician designations and combined) detected by the Solana® Trichomonas Assay in the multi-center study was calculated and is provided in the table below.

Study Prevalence					
Swab specimens					
Symptom Status	**Combined**	**Site 1**	**Site 2**	**Site 3**	**Site 4**
Asymptomatic	10.0%	9.1%	12.0%	13.0%	6.5%
Symptomatic	12.9%	7.4%	17.4%	13.4%	9.4%
Combined	11.5%	8.7%	15.6%	13.1%	8.1%
Urine specimens					
Symptom Status	**Combined**	**Site 1**	**Site 2**	**Site 3**	**Site 4**
Asymptomatic	10.0%	9.1%	12.0%	13.0%	6.5%
Symptomatic	12.9%	7.4%	17.3%	13.4%	9.4%
Combined	11.5%	8.7%	15.5%	13.1%	8.1%

Positive and Negative Predictive Values

The estimated positive predictive value (PPV) and negative predictive value (NPV) of the Solana Trichomonas Assay across different hypothetical prevalence rates are shown in the table below. These calculations are based on the overall estimated sensitivity and specificity for clinician-collected vaginal swab specimens in the Solana Trichomonas Assay clinical study.

Hypothetical PPV and NPV of the Solana Trichomonas Assay with clinician-collected vaginal swab specimens		
Prevalence %	PPV (%)	NPV (%)
1	43.5	100
2	60.9	100
5	80.1	100
10	89.5	99.9
15	93.1	99.9
20	95.0	99.8
25	96.2	99.7

The estimated positive predictive value (PPV) and negative predictive value (NPV) of the Solana Trichomonas Assay across different hypothetical prevalence rates are shown in the table below. These calculations are based on the overall estimated sensitivity and specificity for urine specimens in the Solana Trichomonas Assay clinical study.

510(k) Summary

Hypothetical PPV and NPV of the Solana Trichomonas Assay with Urine specimens		
Prevalence %	PPV (%)	NPV (%)
1	38.0	100
2	55.1	100
5	76.6	99.9
10	86.6	99.8
15	91.7	99.6
20	94.0	99.5
25	95.4	99.3

N. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Instrument: Solana® Instrument

O. System Descriptions:

1. Modes of Operation:

The Solana instrument heats each reaction tube to 64°C. If present, the target sequence is amplified by *T. vaginalis* specific primers and detected by a *T. vaginalis* specific fluorescence probe included in the Reaction Tube. The target probes are labeled with a quencher on one end and a fluorophore on the other end. In addition, the target probes carry a ribonucleic acid. Upon annealing to *T. vaginalis* amplicons, the fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. The Solana instrument measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana instrument will then report the test results to the user on its display screen, and the results can be printed via a printer.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ____X____ No _____

P. Proposed Labeling:

510(k) Summary

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10, 21 CFR 801.109, and the special controls.