510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K161182

B. Purpose for Submission:

To obtain clearance for the Solana® Trichomonas Assay on the Solana® Instrument

C. Measurand:

Trichomonas vaginalis repeated DNA fragment

D. Type of Test:

Nucleic acid amplification test using helicase dependent amplification (HDA)

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Solana® Trichomonas Assay

G. Regulatory Information:

1. Regulation section:

21 CFR 866.3860

2. Classification:

Class II

3. Product code:

OUY- *Trichomonas vaginalis* nucleic acid amplification test system

4. Panel:

83 - Microbiology

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

I. Device Description:

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

The vaginal swab is eluted in a swab lysis tube or a urine specimen is added to a urine lysis tube, and the cells are lysed by 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, which are rehydrated upon addition of the diluted sample. The reaction tube is placed in the Solana instrument for amplification and detection of the *T. vaginalis*-specific target sequence. In the Solana instrument, the target sequence is amplified by *T. vaginalis* specific primers and detected by a *T. vaginalis* specific fluorescent probe. 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 fluorescent probe.

The target and PRC probes are dual-labeled with a quencher and fluorophore on either end. Upon annealing to *T. vaginalis* or PRC amplicons, the fluorescent probes are cleaved and the fluorescent signal increases due to physical separation of the fluorophore from the quencher. The

Solana instrument measures and interprets the fluorescent signal using on-board method-specific algorithms. Solana instrument then reports the test results to the user on its display screen and can print the results via a printer.

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	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 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.	The AmpliVue® Trichomonas Assay is an in vitro diagnostic test, uses isothermal amplification technology (helicase-dependent amplification, HDA) for the qualitative detection of *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	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

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 Solana® Trichomonas assay on the Solana® instrument uses helicase-dependent amplification (HDA) to detect a conserved repeated fragment in the *T. vaginalis* genome. For vaginal swab specimens, the swab is eluted in the lysis buffer tube. For urine specimens, an 800 µl aliquot of urine is added to the lysis buffer tube. In addition to containing the reagents needed for lysis, the lysis buffer tube also contains an internal process control. The samples in the lysis buffer are then heated to lyse the cells, and an aliquot of the lysed sample is added to the dilution buffer tube. The diluted sample is then added to the reaction tube, which contains the lyophilized reagents necessary for the HDA reaction, including the primers, fluorescently labeled probe, dNTPs and PCR reagents. The reaction tube is placed in the Solana® instrument, where amplification of the targeted sequence occurs and is detected via fluorescence intensity. The fluorescent signal is then converted to a qualitative result, which is displayed for the end user.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

Within Laboratory Precision

Within laboratory precision of the Solana® Trichomonas Assay on the Solana® instrument was tested using a four member panel consisting of three different concentrations of the G3 strain of *T. vaginalis* diluted in negative vaginal swab or urine clinical matrix. A negative sample consisting of clinical matrix alone was also tested. The panel included a moderate positive (3X

LoD), low positive (1X LoD) and a high negative (1/54X LoD for samples in vaginal swab matrix and 1/27X LoD for samples in urine matrix). Each panel member, along with positive and negative controls, was tested in triplicate by two operators per day over twelve non-consecutive days. For each sample type, a total of 72 replicates per each panel member were tested. The overall percent agreement between all 72 replicates for the high negative samples in the vaginal swab and urine matrices was 72% and 67%, respectively. All other panel members in both clinical matrices had an overall agreement of 100%. Tables 1 and 2 list the precision study data for the vaginal swab and urine specimen types, respectively

Table 1: Within Laboratory Precision for Vaginal Swab

Category [redacted] **Workflow**	**Operator**						**Overall Percent Agreement**		**95% Confidence Interval**
	Operator #1			**Operator #2**					
	#expected results/# tested	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*			
High Negative (1.89 trophozoites /mL)	28/36	78%	61.9% to 88.3%	24/36	67%	50.3% to 79.8%	52/ 72	72%	61.0% to 81.2%
Low Positive (102 trophozoites /mL)	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%
Moderate Positive (306 trophozoites /mL)	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%
Negative	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%
Positive Control	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%
Negative Control	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%

Table 2: Within Laboratory Precision for Urine

Category Urine Workflow	**Operator**						**Overall Percent Agreement**		**95% Confidence Interval**
	Operator #1			**Operator #2**					
	#expected results/# tested	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*			
High Negative (0.2 trophozoites /mL)	24/36	67%	50.3% to 79.8%	24/36	67%	50.3% to 79.8%	48/ 72	67%	55.2% to 76.5%
Low Positive (4 trophozoites /mL)	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%
Moderate Positive (12	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%

Category [redacted] Workflow	[redacted]								
	Operator #1			Operator #2					[redacted] Confidence Interval
	#expected results/# tested	*% Agreement*	*95% Confidence Interval*	*#expected results/# tested*	*% Agreement*	*95% Confidence Interval*			
trophozoites /mL)									
Negative	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%
Positive Control	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%
Negative Control	36/36	100%	90.4% to 100%	36/36	100%	90.4% to 100%	72/ 72	100%	94.9% to 100%

Reproducibility

The reproducibility of the Solana® Trichomonas assay was assessed using a panel consisting of three concentrations of *Trichomonas vaginalis* diluted in negative clinical matrix as well as a negative sample for both the vaginal swab and urine specimen types. The concentrations of the panel members consisted of a moderate positive (3X LoD), low positive (1X LoD) and a high negative (1/54 LoD for vaginal swab studies and 1/27 LoD for urine studies). Each panel member, along with positive and negative controls, was tested in triplicate by two operators per day for five non-consecutive days at three testing sites. A total of 90 replicates per panel member were tested. In both, the urine and vaginal swab low positive, moderate positive, and negative panel members, 100% agreement was found between all 90 replicates for each respective panel member. The negative and positive controls that were run with each panel also exhibited a 100% overall agreement between all replicates. An overall agreement of 69% and 68% was found for the vaginal swab and urine high negative panel members, respectively. These percent agreements for the high negative samples fall within the recommended 20-80% range. Results are presented in Table 3 and Table 4 for the vaginal swab and urine samples, respectively.

Table 3: Reproducibility for vaginal swab workflow

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%
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	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 [redacted] Workflow	[redacted]									[redacted]		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*			
/mL)												
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%

Table 4: Reproducibility for urine workflow

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%

b. Linearity/assay reportable range:

Not Applicable

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

Traceability

Not applicable

Specimen Stability

Vaginal Swabs: The stability of TV in two types of vaginal swab transport media, Liquid Amies and Liquid Stuart, was tested. A 2X LoD concentration of TV organisms was inoculated into the transport media with negative vaginal matrix. The samples were stored at either 2-8°C for 0, 1, 2, 3, 5, 7 and 8 days, or room temperature (30°C) for 0, 2.5, 6.5, 24, 25, 27, 48 and 49 hours. The samples were tested in triplicate per time point along with positive and negative controls. The data indicated that specimens may be stored in both transport media between 2 and 8°C for up to 7 days, and at 30°C for up to 48 hours prior to testing.

Urine: Negative urine matrix was spiked with a 2X LoD concentration of TV and stored according to the same protocol as the vaginal swab samples. The data indicated that urine specimens can be stored between 2 and 8°C for up to 7 days, and at 30°C for up to 24 hours prior to testing.

Sample Stability in Lysis Buffer:

The sample stability after the addition of lysis buffer was assessed before and after the sample was heated as per instructions in the package insert. For the samples stored before the heat step, TV was inoculated at the 2X LoD concentration into negative clinical matrix (either vaginal swab or urine), mixed with the lysis buffer and then stored at 2-8°C for 0, 24, 48, 72 and 73 hours. For the samples stored after the heat step, the inoculated negative matrix was mixed with lysis buffer, heated at 95°C for 5 minutes, and then stored at 2-8°C for 0, 24, 48, 72 and 73 hours. The samples were tested in triplicate per time point along with positive and negative controls. The data indicate that urine and vaginal swab samples that are mixed with lysis buffer are stable for up to 72 hours at 2-8°C both before and after heat treatment.

Specimen Stability in Dilution Buffer

The stability of the lysed TV sample mixed with dilution buffer was assessed in triplicate in both urine and vaginal swab samples at 2-8°C and 25°C for 0, 6.5, 24 and 25 hours. Negative clinical matrix for each specimen type was inoculated with TV at a concentration of 2X LoD. The data indicate that lysed samples diluted in dilution buffer are stable for up to 24 hours at 2-8°C and 25°C.

Controls:

The Solana® Trichomonas Assay contains an internal processing control that is included in the lysis buffer tube. Quidel Molecular Trichomonas Control Set #M119 contains external positive and negative controls. These controls are described as follows:

1. 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 and monitors the entire extraction, amplification and detection process.

2. An external assay positive control is included in the Quidel Molecular Trichomonas Control Set (M119). The external assay positive control contains intact, non-viable trophozoites and is intended to monitor substantial reagent and instrument failure.

3. An external assay negative control is included in the Quidel Molecular Trichomonas Control Set (M119). The external assay negative control is the same matrix as the positive control but is trophozoite-free. This control is intended to detect reagent or environment contamination or carry-over by either *T. vaginalis* DNA or amplicons.

d. Detection limit:

Two *T. vaginalis* strains, G3, which is metronidazole susceptible, and CDC888, which is metronidazole resistant, were used to determine the analytical sensitivity of the Solana® Trichomonas Assay. The strains were freshly grown and quantified using a hemocytomoter. Serial dilutions of these two strains were made in negative clinical matrix for both the urine and vaginal swab specimen types. Each dilution was tested in 20 replicates along with positive and negative controls using 1 reagent lot. The LoD was determined to be the dilution at which greater than 95% of the replicates tested positive. The LoD was then confirmed by testing 20 additional replicates at the determined LoD dilution using 2 additional reagent lots.

In the vaginal swab matrix, the LoDs for the G3 and CDC888 strains were 102 trophozoite/mL and 306 trophozoite/mL, respectively. In the urine matrix, the LoD for the G3 and CDC888 strains were 4 trophozoite/mL and 108 trophozoite/mL, respectively. This 27-fold difference in LoD between the two strains in the urine matrix may be due to differences in the number of repeated fragments that the assay targets in the genomes of these two strains.

e. Analytical specificity:

Inclusivity:

An inclusivity study was performed to test reactivity of the Solana® Trichomonas Assay with 20 TV reference strains and clinical isolates at a starting concentration of 2-3X LoD in each negative clinical matrix (8 TV/mL for urine matrix, 306 TV/mL for vaginal swab matrix). Each strain was tested in triplicate. Table 5 lists the TV strains and clinical isolates tested.

Table 5: Strains used for inclusivity study

Organisms	ATCC number	Geographic Origin	Year	Metronidazole Susceptibility
CDC899	NA	Marrero, LA	NK*	Highly Resistant
CDC1031	NA	New Lenox, IL	NK	Highly Resistant
CDC938	NA	Bakersfield, CA	NK	Highly Resistant
CDC963	NA	Scottsdale, AZ	NK	Highly Resistant

CDC911	NA	Chicago, IL	NK	Resistant
CDC1256	NA	Eastern USA	NK	Susceptible
MOR31	NA	Bronx, NY	NK	Susceptible
BUSH20	50167	Brooklyn, NY	1986	Susceptible
CDC1095	NA	Everett, WA	NK	Susceptible
CDC1080	NA	NYC, NY	NK	Highly Resistant
PMGH25	NA	Port Moresby, PNG	2004	Unknown
F1623	NA	Brisbane, Australia	2009	Susceptible
B7708/1839	NA	Brisbane, Australia	2003	Susceptible
SD1	NA	San Diego, CA	1998	Susceptible
SA-A53	NA	South Africa	2003	Susceptible
CDC948	NA	Chicago	NK	Highly Resistant
CDC1230	NA	Atlanta	NK	Susceptible
SA-A19	NA	South Africa	2003	Susceptible
SD10	NA	San Diego, CA	1998	Susceptible
SA-384	NA	South Africa	2003	Susceptible

*NK: Not known

In the vaginal swab matrix, all isolates were detected at a concentration of 306 trophozoite/mL. In the urine matrix, B7708/1839 was detected at a concentration of 36 trophozoite/mL, CDC911, CDC1256, MOR31, CDC1095, CDC948 and SA-384 were all detected at a concentration of 16 trophozoite/mL, and the rest of the strains/isolates were detected at 8 trophozoite/mL.

Cross Reactivity

A cross reactivity study was performed to determine the potential reactivity of the Solana® Trichomonas Assay with a panel of 47 microorganisms (37 bacteria, 4 yeast, 4 viruses, 2 parasites) that included common flora of the female genitourinary tract, opportunistic organisms and closely related organisms. Each microorganism was diluted in either vaginal swab or urine negative clinical matrix to the desired concentration (10^6 or higher CFU/mL for bacteria and yeast, 10^6 or higher copies/mL for DNA/RNA and 10^5 or higher $TCID_{50}$/mL for viruses) and tested in triplicate. Table 6 lists the microorganisms tested in the cross reactivity panel.

Table 6: Cross Reactivity Study

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
Haemophilus ducreyi	1.0×10^6 copies/mL	*Enterobacter cloacae*	1.0×10^6 CFU/mL

Microorganism	Concentration	Microorganism	Stock Concentration
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	$1.23\ x10^8$ copies/mL
Synthetic *Mycoplasma genitalium* DNA	1.0×10^6 copies/mL		

No cross reactivity was seen on the Solana® Trichomonas Assay with any of the 47 microorganisms tested.

Microbial Interference

The *T. vaginalis* strains G3 and CDC888 were inoculated in both vaginal swab and urine negative clinical matrix at their respective 2X LoD concentrations in the presence of the 47 microorganisms tested in the cross reactivity study to determine if the presence of the microorganisms interfered with the ability of the Solana® Trichomonas Assay to detect *T. vaginalis*. Each microorganism was diluted in negative clinical matrix at a concentration of 10^6 or higher CFU/mL for bacteria and yeast, 10^6 or higher copies/mL for DNA/RNA and 10^5 or higher $TCID_{50}$/mL for viruses and tested in triplicate in the presence of the two *T. vaginalis* strains. No microbial interference was observed with the detection of each of the two *T. vaginalis* strains in either the vaginal or urine matrices.

Interfering substances

Vaginal swab matrix: A study was conducted to determine whether a panel of 14 substances potentially present in vaginal swab specimens would inhibit the detection of *T. vaginalis.* Each of the potentially interfering substances was tested in triplicate in the presence or absence of two *T. vaginalis* strains, G3 and CDC888, at their respective 2X LoD concentrations in negative vaginal matrix. The potentially interfering substances and the concentrations that were tested are listed in Table 7.

Table 7: Interfering substance study in vaginal swab matrix

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)

Class		
	Vagisil Creme Maximum Strength	1% (w/v)
	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 ability of the Solana® Trichomonas Assay to detect *T. vaginalis* at the 2X LoD concentration.

Urine matrix: A study was conducted to determine whether a panel of 17 substances potentially present in urine specimens would inhibit the detection of *T. vaginalis.* Each of the potentially interfering substances was tested in triplicate in the presence or absence of two *T. vaginalis* strains, G3 and CDC888, at their respective 2X LoD concentrations in negative urine matrix. The potentially interfering substances and the concentrations that were tested are listed in Table 8.

Table 8: Interfering substance study in urine matrix

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)
Analgesics & Antibiotics	AZO Standard Urinary Relief Tablets (Phenazopyridine Hydrochloride)	1.0 mg/mL
	Acetylsalicylic Acid	8 mg/mL
	Acetaminophen	3.2 mg/mL

Class		
	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 ability of the Solana® Trichomonas Assay to detect *T. vaginalis* at the 2X LoD concentration.

Carry-over/Cross Contamination

A carry-over/cross contamination study was performed to determine if the testing of high positive samples had the potential to cross-contaminate negative samples being processed at the same time during the Solana® Trichomonas Assay reaction. High positive samples containing approximately 10^6 trophozoites/mL in negative clinical matrix were alternated with negative samples (clinical matrix alone) and tested using the Solana® Trichomonas Assay. Two operators tested a total of 50 positive and 50 negative samples in multiple runs. Each run tested 5 positive and 5 negative samples in alternating order and included positive and negative controls. Upon testing, 100% of the negative samples yielded negative results, indicating that no carry-over or cross contamination occurred.

f. Assay cut-off:

The cutoff value for the Solana® Trichomonas Assay was determined based on specific parameters of the amplification curve calculated from negative samples and contrived samples at concentrations near the LoD. These parameters included the slope of the amplification curve for samples near the LoD ("slope threshold") and the time required to reach the slope threshold. The cutoff was set based on the longest amount of time to obtain a positive amplification result.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity and Specificity:

A multi-center clinical study was performed to evaluate the Solana® Trichomonas Assay using 1044 clinician-collected vaginal swab and urine specimens obtained from 501 asymptomatic and 543 symptomatic patients. The study was performed November 2015 through March 2016 at 4 locations in the United States.

Vaginal Swab Specimens:

For each subject, three vaginal swab specimens were collected using the BD BBL™ CultureSwab collection kit with liquid Stuart's transport media, and one vaginal swab specimen was collected using a collection kit from an FDA-cleared molecular device. The four clinician collected vaginal swabs were used for reference and Solana testing. The first two swabs were randomized and used for the reference method testing, which consisted of wet mount and InPouch TV Culture. The third swab was used for testing the Solana® Trichomonas Assay**.** The FDA-cleared molecular device collection swab was used for discordant testing. The specimen was considered positive if either of the two reference methods returned a positive result.

Ten vaginal swab specimens generated invalid results upon initial testing with the Solana® Trichomonas Assay (0.96%). Nine of these specimens generated valid results upon re-testing (6 negative and 3 positive), and one specimen generated a second invalid result (0.1%). Table 9 below shows the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the Solana® Trichomonas Assay and the prevalence of *T. vaginalis* (by asymptomatic, symptomatic clinician designations and combined) for the remaining 1043 subjects.

Table 9: Clinical performance of the Solana® Trichomonas Assay with clinician-collected vaginal swabs

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)

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)
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)

Urine Specimens:

For the urine specimens, 5 specimens generated invalid results upon initial testing (0.5%). All 5 of these specimens generated valid results upon re-testing (4 negative and 1 positive result). Table 10 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 1044 subjects.

Table 10: Clinical performance of the Solana® Trichomonas Assay with urine

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)

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

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

The prevalence of *T. vaginalis* (by asymptomatic, symptomatic status and combined) detected by the Solana® Trichomonas Assay in the multi-center clinical study was calculated for the vaginal swab and urine specimen types and is provided in Table 11 below:

Table 11: Prevalence of TV by study site

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%

The estimated positive and negative predictive values of the Solana® Trichomonas Assay across different hypothetical prevalence rates for the vaginal swab and urine specimen types are listed below in Tables 12 and 13, respectively. These values are based on the sensitivity and specificity estimates for each specimen type from the clinical study.

Table 12: Positive and Negative Predictive Values of the Solana® Trichomonas Assay Vaginal Swab Specimens

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

Table 13: Positive and Negative Predictive Values of the Solana® Trichomonas Assay Urine Specimens

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. Instrument Name:

Solana® Instrument

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ____X____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ____X____

2. Software:

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

   Yes ____X____ or No _____

3. Specimen Identification:

   Specimens are identified by scanning a barcode or by manual entry.

4. Specimen Sampling and Handling:

   A vaginal swab is expressed into a swab lysis tube or a urine specimen is added to a urine lysis tube. After heat lysis, 50 µl of lysed specimen is transferred to dilution tube, 50 µl of which is then transferred to a reaction tube for automated amplification and detection. See section I above for more information.

5. Calibration:

   The end user is not required to calibrate the instrument. Automated calibration happens by comparing between the measured magnitude of the optical signal of and an integrated calibration standard and the expected magnitude of the optical signal.

6. Quality Control:

   See section M.1.*c* for information on internal and external controls.
   See section M.3.*a* for information on external control performance during clinical trials.

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

Not applicable

Q. Proposed Labeling:

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

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.