This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete Package Insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete Package Insert in accordance with FDA labeling regulation (21 CFR 809.10).

Quidel Corporation provides CLSI procedures for your use. The procedures are required to include the same information as listed in the Package Insert. Any modifications to this document are the sole responsibility of the Laboratory.

Solana Trichomonas

CLIA Complexity: Moderate

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.

SUMMARY AND EXPLANATION

Trichomonas vaginalis infection (Trichomoniasis) is the most common curable, non-viral sexually transmitted disease (STD). In the United States, an estimated 3.7 million people have the infection, but only about 30% develop any symptoms of Trichomoniasis.[1] Trichomoniasis may lead to preterm birth, low birth weight, and pelvic inflammatory disease when left untreated.[2] Effective diagnosis and treatment of *T. vaginalis* infections in women are important to prevent disease acquisition, transmission, and associated complications. Conventional identification methods for *T. vaginalis* infection from vaginal swabs include wet mount microscopy and culture. Wet mount microscopy is the most common method of *T. vaginalis* detection. Although this technique is rapid and inexpensive, it is only about 36 to 75% sensitive compared to culture even in the hands of trained operators.[3] The culture method is technically challenging and time consuming, requiring up to 7 days for getting the final result. The Solana Trichomonas Assay is a nucleic acid amplification test based on Helicase-Dependent Amplification (HDA) technology. The assay is performed in the Solana instrument, where *T. vaginalis* DNA is amplified by a HDA reaction which amplifies a *T. vaginalis* specific sequence in the presence of a process control sequence. The amplicons are simultaneously detected by fluorescence probes.

PRINCIPLE OF THE TEST

The Solana Trichomonas Assay amplifies and detects *T. vaginalis* DNA present in vaginal swab or female urine specimens obtained from symptomatic and asymptomatic patients.

The assay consists of two major steps: (1) specimen preparation, and (2) amplification and detection of target sequence specific to *T. vaginalis* using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probe.

Patient specimen is transferred to a Lysis Tube and subjected to heat-treatment at 95°C for 5 minutes. The heat-treated sample is added to a Dilution Tube, and then transferred to a Reaction Tube. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the diluted sample, the Reaction Tube is placed in Solana for amplification and detection of *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 will then report the test results to the user on its display screen, and the results can be printed via an attached printer.

MATERIALS PROVIDED

Cat. #M304.S for swab testing or Cat. #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°C to 8°C
Dilution Tubes	48 tubes/kit, 1.5 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C
Solana Trichomonas Assay Kit – M304.U		
Component	**Quantity**	**Storage**
Lysis Buffer Tubes	48 tubes/kit, 0.2 mL	2°C to 8°C
Dilution Tubes	48 tubes/kit, 1.5 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C

MATERIALS REQUIRED BUT NOT PROVIDED

- External controls for *T. vaginalis* (e.g. Quidel Molecular Trichomonas Control Set (M119), which contains positive and negative controls, serves as an external processing and extraction control)
- Sterile DNAse-free filter-blocked or positive displacement micropipettor tips
- Micropipettor
- BD BBL™ CultureSwab™ collection and transport device
- Stopwatch or timer
- Scissors or a blade
- Workflow Tray and Transfer Rack
- Heat block capable of 95° ±2°C temperature
- Thermometer
- Solana instrument

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Refer to the Solana Operator's Manual for further information regarding instrument installation and operation.
- Treat all specimens/samples as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- All Tubes should be capped tightly prior to vortexing.
- Proper sample collection, storage and transport are essential for correct results.
- Store assay reagents as indicated on their individual labels.
- Reagents are not interchangeable between lots.
- Never pool reagents from different tubes even if they are from the same lot.
- Do not use the reagents after their expiration date.

- Do not interchange caps among reagents as contamination may occur and compromise test results.
- Only open the tubes when adding aliquots into tubes or removing aliquots from tubes. Keep the tubes closed at any other time to avoid contamination.
- To avoid contamination of the environment with *T. vaginalis* amplicons, do not open the reaction tubes post-amplification.
- Avoid microbial and deoxyribonuclease (DNAse) contamination of reagents when removing aliquots from tubes. The use of sterile DNAse-free disposable filter-blocked or positive displacement pipettor tips is recommended.
- Use a new pipettor tip for each specimen or reagent.
- Performing the assay outside of the recommended time ranges can produce invalid results. Assays not completed within specified time ranges should be repeated.
- To avoid exposure to excessive heat, care should be taken when inserting and removing tubes from the heat blocks, and when handling the heated tubes.
- Additional controls may be tested according to guidelines or requirements of local, state, provincial and/or federal regulations or accrediting organizations.
- Do not pipette by mouth.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- For accurate results, pipette carefully using only calibrated equipment.
- Maintenance and decontamination of workspace and equipment should follow and be performed according to established laboratory protocols and schedules.
- Use micropipettes with an aerosol barrier or positive displacement tips for all procedures.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

STORAGE AND HANDLING OF KIT REAGENTS

Store the Assay Kit at 2°C to 8°C until the expiration date listed on the outer kit box.

SPECIMEN COLLECTION, STORAGE AND HANDLING

Vaginal Specimen Collection and Storage

Collect vaginal specimens using an appropriate collection and transport system.

Note: The collection and transport system used in the clinical evaluation was the BD BBL™ CultureSwab™

1. Using the sterile swab, carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus.
2. Gently rotate the swab for 10 to 30 seconds against the vaginal wall ensuring the entire circumference of the swab has touched the vaginal wall.
3. Swab the lateral vaginal wall while removing the swab.
4. After collection, transport and store the swab at 2°C to 8°C for up to 7 days or room temperature (up to 30°C) for up to 48 hours prior to testing.

Urine Specimen Collection and Storage

Collect urine specimens using an appropriate collection and transport container.

1. The patient should not have urinated for at least 1 hour prior to specimen collection.
2. Patients should not cleanse the labial area prior to providing the specimen.
3. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives.
   Note: Collection of larger volumes of urine may result in target dilution that may reduce test sensitivity.

4. After collection, transport and store the urine at 2°C to 8°C for 7 days or room temperature (up to 30°C) for up to 24 hours prior to testing.

TEST PROCEDURE

Swab specimens

1. Turn on Solana by pressing the power button and wait until it completes self-testing.
   Note: Do not open the lid during the self-testing.
2. 25 minutes prior to the heat lysis step, warm a heating block to 95°C.
3. Place the required number of Swab Lysis Tubes into the Workflow tray. Mark the Swab Lysis Tubes on the cap and/or side of the tube.
   Note: One (1) Swab Lysis Tube is required for each specimen or control to be tested.
   Note: A maximum of 12 tests can be performed in a single Solana instrument.
4. Place a swab in a patient-identified Swab Lysis Tube and vigorously twirl the swab for 10 seconds to elute specimen material. Remove the swab and discard as appropriate for your laboratory.
   Note: The specimens in Lysis Tubes may be stored at 2°C to 8°C for up to 72 hours.
5. Heat the Swab Lysis Tubes at 95°C ±2°C for 5 minutes and then vortex the Swab Lysis Tubes for 5 seconds.
   Note: Begin 5-minute lysis procedure when the heat block measures 95° ± 2°C. The timer must be stopped if the temperature falls out of range at any time during the 5 minute period and cannot be restarted until the heat block returns to 95° ± 2°C.
   Note: The lysed specimens may be stored at 2°C to 8°C for up to 72 hours.
6. Place the required number of Dilution Tubes into the Workflow tray. Mark the Dilution Tubes on the cap and/or side of the tube.
   Note: One (1) Dilution Tube is required for each specimen or control to be tested.
7. Transfer 50 µL of lysis buffer for each specimen to an identified Dilution Tube. Close the cap and mix the solution well by vortexing the tubes for 5 seconds.
   Note: Use a new pipette tip for each specimen.
   Note: The diluted specimen or control can be stored at room temperature or at 2°C to 8°C for up to 24 hours.
8. Remove the required number of Reaction Tubes from the protective pouch and place into the Workflow tray, remove the excess air and reseal the bag. Mark the Reaction Tubes on the cap.
9. Transfer 50 µL of the diluted specimen to the labeled Reaction Tube, mix the solution by vigorously pipetting up and down a minimum of 5 times and close the cap. The solution should be clear, free of solid material.
   Note: Use a new pipette tip for each diluted sample.
   Note: Proceed immediately to the next step. Do not allow reconstituted reaction mix to sit for longer than 15 minutes.
10. Open the lid and place the Reaction Tubes in Solana.
    Note: Be sure that all tubes are in tight contact with heat block.
11. Enter User ID and Password and press ↵ (ENTER).
12. Select “NEW TEST”. If Solana displays a different screen, go to the home screen. Select the tube positions to use.
13. Scan the assay barcode or select “Trichomonas Assay” from the Select Test drop-down menu and manually enter Lot ID/Exp Date, and press “▶.”
14. Select sample type (patient or QC) from the drop-down menu and enter Sample IDs (optional; see 2nd Note in next step).
15. Close the lid and press “Start” to initiate the Solana Trichomonas Assay. Solana will display the progress and the count-down to assay completion. The test results on the screen in approximately 25 minutes.
    Note: To avoid laboratory contamination, once the tube has been closed and the amplification reaction started, **DO NOT** open the Reaction Tube.
    Note: While the test is running, sample ID can be entered or edited by pressing the pencil icon.

16. After the run is completed the results can be printed by selecting the print button.
    Note: Do not navigate away from this screen before printing results. Once the screen is gone it cannot be revisited. If this occurs the results can be viewed individually by going Home then selecting Review Results.

Urine specimens

1. Turn on Solana by pressing the power button and wait until it completes self-testing.
   Note: Do not open the lid during the self-testing.
2. 25 minutes prior to the heat lysis step, warm a heating block to 95°C.
3. Place the required number of Urine Lysis Tubes into the Workflow tray. Mark the Urine Lysis Tubes on the cap and/or side of the tube.
   Note: One (1) Urine Lysis Tube is required for each specimen or control to be tested.
   Note: A maximum of 12 tests can be performed in a single Solana instrument.
4. Vortex the urine transport device for 5 seconds. Transfer 0.8 mL of urine specimen in a patient-identified Urine Lysis Tube.
   Note: The specimens in Lysis Tubes may be stored at 2°C to 8°C for up to 72 hours.
5. Heat the Urine Lysis Tubes at 95°C± 2°C for 5 minutes and then vortex the Urine Lysis Tubes for 5 seconds.
   Note: Begin 5-minute lysis procedure when the heat block measures 95 ± 2°C. The timer must be stopped if the temperature falls out of range at any time during the 5 minute period and cannot be restarted until the heat block returns to 95 ± 2°C.
   Note: The lysed specimens may be stored at 2°C to 8°C for up to 72 hours.
6. Place the required number of Dilution Tubes into the Workflow tray. Mark the Dilution Tubes on the cap and/or side of the tube.
   Note: One (1) Dilution Tube is required for each specimen or control to be tested.
7. Transfer 50 µL of each heat lysed specimen to an identified Dilution Tube. Close the cap and mix the solution well by vortexing the tubes for 5 seconds.
   Note: Use a new pipette tip for each specimen.
   Note: The diluted specimen or control can be stored at room temperature or at 2°C to 8°C for up to 24 hours.
8. Remove the required number of Reaction Tubes from the protective pouch and place in the Workflow tray, remove the excess air and reseal the bag. Mark the Reaction Tubes on the cap.
9. Transfer 50 µL of the diluted specimen to the labeled Reaction Tube, mix the solution by vigorously pipetting up and down a minimum of 5 times and close the cap. The solution should be clear, free of solid material.
   Note: Use a new pipette tip for each diluted sample.
   Note: Proceed immediately to the next step. Do not allow reconstituted reaction mix to sit for longer than 15 minutes.
10. Open the lid and place the Reaction Tubes in Solana.
    Note: Be sure that all tubes are in tight contact with heat block.
11. Enter User ID and Password and press ↵ (ENTER).
12. Select “NEW TEST”. If Solana displays a different screen, go to the home screen.
13. Select the tube positions to use.
14. Scan the assay barcode or select “Trichomonas Assay” from the Select Test drop-down menu and manually enter Lot ID/Exp Date, and press “▶.”
15. Select sample type (patient or QC) from the drop-down menu and enter Sample IDs (optional; see 2nd Note in next step).
16. Close the lid and press “Start” to initiate the Solana Trichomonas Assay. Solana will display the progress and the count-down to assay completion. The test results will be displayed on the screen in approximately 25 minutes.

Note: To avoid laboratory contamination, once the tube has been closed and the amplification reaction started, **DO NOT** open the Reaction Tube.

Note: While the test is running, sample ID can be entered or edited by pressing the pencil icon.

17. After the run is completed the results can be printed by selecting the print button.
    Note: Do not navigate away from this screen before printing results. Once the screen is gone it cannot be revisited. If this occurs the results can be viewed individually by going Home then selecting Review Results.

INTERPRETATION OF RESULTS

Samples	Assay Result	Interpretation
Patient specimen	Trichomonas POSITIVE	*T. vaginalis* DNA detected
	Trichomonas NEGATIVE	No *T. vaginalis* DNA detected and PRC detected
	INVALID	No *T. vaginalis* DNA and No PRC detected; for invalid test results, retest the same Swab Lysis Tube first. If the test is invalid upon retesting obtain a new sample or urine sample and re-test.

QUALITY CONTROL

The Solana Trichomonas Assay incorporates several controls to monitor assay performance.

- The internal control is used to control for 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.
- External assay positive control (e.g. Quidel Molecular Trichomonas Control Set, Cat. #M119) serves as the assay positive control. Transfer 25 µL of positive control into a labeled lysis buffer tube and proceed with processing as described above in Step 5 of TEST PROCEDURE for either the swab or the urine specimens. The external assay positive control is intended to monitor substantial reagent and instrument failure.
- External assay negative control (e.g. Quidel Molecular Trichomonas Control Set, Cat. #M119) serves as the assay negative control. Transfer 25 µL of negative control into a labeled lysis buffer tube and proceed with processing as described above in Step 5 of TEST PROCEDURE for either the swab or the urine specimens. The external assay negative control is intended to detect reagent or environment contamination or carry-over by either *T. vaginalis* DNA or amplicons.

LIMITATIONS

- Although there is no need for reagent preparation, the main laboratory technique required is pipetting; good laboratory technique is essential for the proper performance of this assay. Due to the high analytical sensitivity of this test, extreme care should be taken to preserve the purity of all reagents, especially in cases where multiple aliquots are taken from a tube.
- Performance of Solana Trichomonas Assay has not been evaluated in pregnant women or in patients less than 16 years of age.
- Mutations or polymorphisms in primer or probe binding regions may affect detection of new or unknown *T. vaginalis* variants and may result in a false negative result with the Solana Trichomonas Assay.
- Assay performance has not been evaluated in the presence of *Dientamoeba fragilis*.
- A positive test result does not necessarily indicate the presence of viable organisms.
- Negative test results may occur from improper specimen collection, handling or storage, presence of inhibitors, technical error, sample mix-up or because the number or organisms in the specimen is below the analytical sensitivity of the test. Careful compliance with the instructions given in this insert is necessary to avoid erroneous results. Use of this assay should be limited to personnel trained on the procedure.
- This assay has been tested using only the specimen types indicated. Performance with other specimen types has not been evaluated.
- This test does not replace cervical exams and endocervical specimens for diagnosis of female urogenital

infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- As with other diagnostic tests, results from Solana Trichomonas Assay should be interpreted in conjunction with other clinical data available to the clinician.
- Therapeutic failure or success cannot be determined with the assay since nucleic acid may persist following appropriate antimicrobial therapy.

EXPECTED VALUES

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%

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.

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

CLINICAL PERFORMANCE

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 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 retested according to the instructions provided in the Package Insert. Nine (9) of these specimens generated valid results upon retesting (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 Numbe	Symptom Statu	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.	100 (99.1 to 100
	Symptomatic	542	69	7	465	1	12.9	98.6 (92.3 to 99.	98.5 (97.0 to 99.3	90.8 (82.2 to 95.	99.8 (98.8 to 100
	All	1043	119	12*	911	1*	11.5	99.2	98.7	90.8	99.7

Performance Characteristics of the Solana Trichomonas Assay with Vaginal Swabs by Symptom Status compared to the Composite Reference Method											
Site Numbe	Symptom Status	N	TP	FP	TN	FN	Prev%	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV % (95% CI)	NPV % (95% CI)
								(95.4 to 99.	(97.7 to 99.3	(84.7 to 94.	(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.	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.	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.	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.	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.	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.	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.	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.	100 (97.6 to 100
	Symptomatic	235	21	3	210	1	9.4	95.5 (78.2 to 99.	98.6 (95.9 to 99.5	87.5 (69.0 to 95.	99.5 (97.4 to 99.
	All	405	32	7	365	1	8.1	97.0 (84.7 to 99.	98.1 (96.2 to 99.1	82.1 (67.3 to 91.	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, it 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 retested according to the instructions provided in the Package Insert. All five (5) of these specimens generated valid results upon retesting (four (4) negative and one (1) positive results). 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.

Performance Characteristics of the Solana Trichomonas Assay with Urine Specimens by Symptom Status compared to the Composite Reference Method											
Site Numbe	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.	98.4 (96.8 to 99.2	87.5 (76.4 to 93.	99.8 (98.7 to 100

Performance Characteristics of the Solana Trichomonas Assay with Urine Specimens by Symptom Status compared to the Composite Reference Method											
Site Numbe	Symptom Statu	N	TP	FP	TN	FN	Prev%	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV % (95% CI)	NPV % (95% CI)
	Symptomatic	543	65	10	463	5	12.9	92.9 (84.3 to 96.	97.9 (96.2 to 98.8	86.7 (77.2 to 92.	98.9 (97.5 to 99.5
	All	1044	114	17	907	6	11.5	95.0 (89.5 to 97.	98.2 (97.1 to 98.8	87.0 (80.2 to 91.	99.3 (98.6 to 99.7
Site 1	Asymptomatic	77	6	0	70	1	9.1	85.7 (48.7 to 97.	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.	96.6 (91.1 to 98.9	72.7 (43.4 to 90.	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.	97.7 (94.3 to 99.1	89.7 (76.4 to 95.	98.9 (95.9 to 99.7
	All	322	48	4	268	2	15.5	96.0 (86.5 to 98.	98.5 (96.3 to 99.4	92.3 (81.8 to 97.	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.	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.	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.	100 (97.6 to 100
	Symptomatic	235	19	3	210	3	9.4	86.4 (66.7 to 95.	98.6 (95.9 to 99.5	86.4 (66.7 to 95.	99.5 (97.4 to 99.9
	All	405	30	9	363	3	8.1	90.9 (76.4 to 96.	97.6 (95.5 to 98.7	76.9 (61.7 to 87.	99.2 (97.6 to 99.7

ANALYTICAL PERFORMANCE

Limit of Detection

The analytical sensitivity (limit of detection or LOD) of the Solana Trichomonas Assay was determined using quantified (trophozoite/mL) stocks of two (2) *T. vaginalis* strains, one metronidazole-susceptible G3 and one metronidazole-resistant CDC888 serially diluted in negative clinical matrix.

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

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 assay LOD levels of the assay in both the swab and urine workflows.

Bacterial Strain	Swab specimens Strain Detected (Yes/No)	Urine Specimens Strain Detected (Yes/No)
CDC899	Yes	Yes
CDC938	Yes	Yes
CDC963	Yes	Yes
CDC1031	Yes	Yes
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 the concentrations near the LOD levels of the assay were detected in both the swab and urine workflows of the Solana Trichomonas assay.

Precision – Repeatability

The Precision/Within Laboratory Repeatability was determined via a study consisting of the following four-member panel: 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 panels were tested by two (2) operators, twice a day (2X) for 12 days. The testing was performed using appropriate swab or urine workflows.

The Solana Trichomonas Assay produces results that are highly reproducible in the swab workflow. This observation is based on the following findings:

- All negative samples generated negative results for *Trichomonas vaginalis*.
- The percentage of positive results in high negative samples is 27.7%, this is within the target range of 20% to 80%.
- The percentage of positive results in low positive samples was 100%.
- The percentage of positive results in moderate positive samples was 100%.

The Solana Trichomonas Assay produces results that are highly reproducible in the urine workflow. This observation is based on the following findings:

- All negative samples generated negative results for Trichomonas vaginalis.
- The percentage of positive results in high negative samples is 33.3%, this is within the target range of 20% to 80%.
- The percentage of positive results in low positive samples was 100%.
- The percentage of positive results in moderate positive samples was 100%.

Precision – 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 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%
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%

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*			
Low Positive (4trophozoites /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 Solana Trichomonas Assay generated reproducible results in this study with both the swab and urine workflows.

Analytical Specificity – Microbial Interference

A study was performed to evaluate the performance of Solana Trichomonas Assay in the presence of forty-seven (47) microorganisms (37 bacteria, 4 yeast, 4 viruses, 2 parasites) 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), and tested in triplicate in the presence of each of the two (2) *T. vaginalis* (G3 and CDC888) strains at their respective 2x LOD levels using either the swab or urine workflows. The organisms and their concentrations included in the interference 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

Microorganism	Stock Concentration	Microorganism	Stock Concentration
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
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		

No interference was observed with the detection of each of the two (2) *T. vaginalis* strains in the Solana Trichomonas Assay.

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

Microorganism	Stock Concentration	Microorganism	Stock Concentration
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
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		

No cross-reactivity was seen with the Solana Trichomonas Assay with any of the microorganisms tested.

Analytical Specificity – Interfering Substances

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)
	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%)

Class	Substances	Concentration Tested
	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)
Analgesics & Antibiotics	AZO Standard Urinary Relief Tablets (Phenazopyridine Hydrochloride)	1.0 mg/mL
	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 Deoderant Powder	1% (w/v)
	Summer's Eve Feminine Deoderant 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.

Carryover – Cross Contamination

A glycerol stock of *T. vaginalis* G3 was thawed and diluted in either swab negative matrix or negative urine matrix to a final concentration of 10^6 trichomonads per mL. These dilutions served as high positive controls for their respective workflows.

For each workflow run, five (5) replicates of *T. vaginalis* high positive sample alternating with five (5) replicates of negative matrix were tested in the Solana Trichomonas Assay along with an external positive control and an external negative control. A total of five (5) runs of twelve (12) assays were performed by two (2) operators.

Consecutive testing of alternating *T. vaginalis* high positive samples and *T. vaginalis* negative samples resulted in no carry over or cross contamination in either workflow as 50/50 *T. vaginalis* -positive samples tested *T. vaginalis* -positive and 50/50 *T. vaginalis* -negative samples tested *T. vaginalis* -negative.

CUSTOMER AND TECHNICAL SUPPORT

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