Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K191352

B Applicant

binx health, Inc.

C Proprietary and Established Names

binx health io CT/NG Assay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QEP, LSL, MKZ, NSU	Class II	21 CFR 866.3393 -	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

Notification of intent to market a new device.

B Measurand:

1. *Chlamydia trachomatis* genomic DNA
2. *Neisseria gonorrhoeae* genomic DNA

C Type of Test:

Nucleic acid amplification assay, qualitative.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The binx health io CT/NG Assay, when tested using the binx health io Instrument, is a fully automated, rapid, qualitative test intended for use in point-of-care or clinical laboratory settings for the rapid detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in female vaginal swab specimens collected either by a clinician or self-collected by a patient in a clinical setting, to aid in the diagnosis of symptomatic or asymptomatic infection in female patients with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

binx health *io* Instrument

IV Device/System Characteristics:

A Device Description:

The binx health *io* CT/NG Assay is a qualitative *in vitro* diagnostic system consisting of the following:

1. The binx health *io* Instrument for running the test Cartridge,
2. The binx health *io* CT/NG Cartridge; each Cartridge contains all the necessary reagents to test one patient sample,
3. A single-use, fixed-volume transfer pipet for transferring the sample to the Cartridge,

A female Vaginal Swab Specimen Collection Kit consisting of a sterile flocked swab and a sample collection tube containing preservation medium, is provided separately.
The Cartridges are packaged in cartons of 10 single use units.

The assay results are displayed on the instrument screen.

Assay Result	Interpretation of Assay Results
CT Not Detected	*Chlamydia trachomatis* target DNA **was not detected** in the patient specimen. The IPC passed specification. This is a valid result
CT Detected	*Chlamydia trachomatis* target DNA **was detected** in the patient specimen. This is a valid result.
NG Not Detected	At least one of the DNA targets for *Neisseria gonorrhoeae* **was not detected** in the patient specimen. The IPC passed specification. This is a valid result.
NG Detected	Both DNA targets for *Neisseria gonorrhoeae* **were detected** in the patient specimen. This is a valid result.
Test Invalid	The presence or absence of the DNA targets for Chlamydia trachomatis and/or Neisseria gonorrhoeae could not be ascertained in the patient specimen. If a CT or NG Not Detected result is obtained, and the IPC was outside the acceptable range, Test Invalid indicates a failure in the Assay process. The Assay should be repeated using the same patient specimen.
User Aborted	A user cancelled the Assay. No result is given.
Error	An internal fault occurred that terminated the Assay before it finished. No result is given.

B Principle of Operation:

The binx health *io* CT/NG Assay detects and amplifies DNA from CT and NG organisms that may be present in female vaginal swabs. The binx *io* Cartridge is assay-specific and is intended for a single-use on a single patient. All reagents are contained in the Cartridge as a combination of liquid reagents in blister packs and dried reagents. The Cartridge contains reagents for three main assay steps: (i) sample preparation to isolate and purify target DNA, (ii) target DNA amplification by PCR, and (iii) a proprietary electrochemical detection to identify the presence of amplified DNA.

The assay uses a vaginal swab collected in a preservation medium (eNAT). After the sample (0.5 mL of the swab eluate) is added to the port of the Cartridge using the included sample transfer pipet, the Cartridge is inserted into the Instrument and the assay begins. Each Cartridge label contains a barcode that includes the test type, batch information, and expiration date, which is automatically scanned by the Instrument. At the start of the assay, the instrument initiates the

release of reagents and, after extraction and purification, the sample is divided between two PCR chambers allowing for CT and NG DNA amplification by thermal cycling to be run separately. While only one genomic DNA target is used for the detection of CT, two genomic DNA targets are amplified for the NG and both must be present to generate a positive result for NG. In the next step, complementary electrochemically-labeled DNA probes hybridize to the amplified DNA followed by enzymatic digestion of the double stranded DNA-probe complexes releasing the electrochemical label. After application of voltage to a carbon electrode and oxidation of the released label, a current is generated which is measured to indicate the presence of CT and/or NG DNA. In negative specimens, the probes remain as single-stranded DNA and cannot be digested by the enzyme; no release of the electrochemical label occurs and no current is generated.

C Instrument Description Information:

1. Instrument Name:

   binx health *io* Instrument

2. Specimen Identification:

   Manual entry of the specimen ID on the touchscreen, or
   Handheld barcode scanner, or
   Automatic assignment of unique ID.

3. Specimen Sampling and Handling:

   Requires binx health *io* Vaginal Swab Specimen Collection Kit. The specimen (swab eluate) is loaded onto the *io* test Cartridge which is inserted into the *io* Instrument. The sample is processed automatically by the Instrument.

4. Calibration:

   No calibration is required.

5. Quality Control:

   The assay incorporates a positive Internal Process Control (IPC) which is processed along with each patient sample, from the sample DNA extraction and purification through the detection. If the IPC measurement is outside of the specified range, the instrument will return an “Assay Invalid” message. A negative result for CT and/or NG will only be returned if the IPC measurement is within the acceptable range. Where CT and/or NG DNA is detected, the IPC will be disregarded as the detection of the CT and/or NG DNA target will verify that the assay functions as expected.

   External controls are not provided with the assay. The package insert recommends a commercial source of external controls.

V Substantial Equivalence Information:

A Predicate Device Name(s):
BD ProbeTec Chlamydia trachomatis (CT) Qx CT Amplified DNA Assay
BD ProbeTec Neisseria gonorrhoeae (GC) Qx Amplified DNA Assay

B Predicate 510(k) Number(s):
K091724
K091730

C Comparison with Predicate(s):

Device & Predicate Device(s):	K191352	K091724	K091730
Device Trade Name	**binx health *io* CT/NG Assay**	**BD ProbeTec Q^{x} CT**	**BD ProbeTec Q^{x} GC**
General Device Characteristic Similarities			
Intended Use/Indications for Use	The binx health *io* CT/NG Assay, when tested using the binx health *io* Instrument, is a fully automated, rapid, qualitative test intended for use in point-of-care or clinical laboratory settings for the rapid detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in female vaginal swab specimens collected either by a clinician or self-collected by a patient in a clinical setting, to aid in the diagnosis of symptomatic or asymptomatic infection in female patients with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.	The BD ProbeTec *Chlamydia trachomatis* Q*x* Amplified DNA Assay, when tested with either the BD Viper™ System in Extracted Mode or the BD Viper LT System, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Chlamydia trachomatis* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™	The BD ProbeTec™ *Neisseria gonorrhoeae* Q*x* Amplified DNA Assay, when tested with either the BD Viper™ System in Extracted Mode or the BD Viper LT System, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™

		Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease.	Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.
Technology	Automated multiplex PCR amplification with electrochemical detection	Automated multiplex strand displacement amplification with fluorescent detection.	Automated multiplex strand displacement amplification with fluorescent detection.
Instrument	binx health *io* Instrument	BD Viper	BD Viper
Assay Results	Qualitative	Qualitative	Qualitative
Analyte/Assay Targets	CT Genomic DNA NG Genomic DNA	CT Cryptic Plasmid DNA	NG Genomic DNA
Nucleic Acid extraction	Yes	Yes	Yes
Specimen	Vaginal Swab (clinician collected and self-collected in clinical setting)	• Vaginal Swab (clinician collected and self-collected in clinical setting) • Endocervical Swab • Male urethral swab Male urine • Female urine (both UPT and neat). • LBC specimens collected in BD SurePath™ Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test.	• Vaginal Swab (clinician collected and self-collected in clinical setting) • Endocervical Swab • Male urethral swab Male urine • Female urine (both UPT and neat). • LBC specimens collected in BD SurePath™ Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test.
Collection Kit	binx health *io* Vaginal Swab Specimen	• Vaginal Specimen	• Vaginal Specimen

	Collection Kit	Transport • BD ProbeTec Q^x Collection Kit for Endocervical or Lesion Specimens. • Male Urethral Specimen Collection Kit • Q^x UPT urine collection kit	Transport • BD ProbeTec Q^x Collection Kit for Endocervical or Lesion Specimens. • Male Urethral Specimen Collection Kit • Q^x UPT urine collection kit
Quality Control	Internal Process Control	Internal Extraction Control	Internal Extraction Control

VI Standards/Guidance Documents Referenced:

The following voluntary standards were utilized in part in the studies carried out for the preparation of this 510(k).

Standards organization	Standard No.	*Standard Title,*
CLSI	MM03-A2	*Molecular Diagnostic Methods for Infectious Diseases.*
CLSI	EP07-A2	*Interference Testing in Clinical Chemistry.*
CLSI	EP17-A2-17A	*Protocols for Determination of Limits of Detection and Limits of Quantitation.*
CLSI	EP12-A2	*User Protocol for Evaluation of Qualitative Assay Performance*
ISTA	3A	*General Simulation Performance Tests*
ISO	14155	*Clinical investigation of medical devices for human participants — Good clinical practice*
IEC	60601-1-2	*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

VII Performance Characteristics:

A Analytical Performance:

1. Precision/Reproducibility:

The reproducibility study was conducted at three POC testing sites, i.e., clinics where the testing was performed outside of a central CLIA certified laboratory, by non-laboratorians representing healthcare professionals that may be encountered at such sites. None of the users were trained in general laboratory procedures but were trained in the use of the binx *io* System. The study was conducted over 7 days, by 6 operators (2 at each site), with two *io* Readers at each site, using one lot of Cartridges.

The reproducibility test panel consisted of 11 panel members prepared in pooled negative vaginal matrix collected in eNAT. Each test panel was run twice a day by each operator to generate 28 test results for each panel member at each of the three sites, for a total of 84 test results for each panel member across the three testing sites (924 Cartridges tested in total).

The test samples were prepared to include three concentration levels for each organism, in combination and one sample negative for both organisms, i.e., unspiked negative swab matrix.

Reproducibility Test Panel

Sample	Organism Concentration	CT	NG
LOW POS	Expected to test positive approximately 95% of the time	1x LoD	1x LoD
MOD	Expected to test positive approximately 100% of the time	3x LoD	3x LoD
HIGH	Expected to test positive 100% of the time (at a high end of medically relevant concentration)	2.26×10^5 GE/mL	1.18×10^6 GE/mL
NEG	Expected to test negative approximately 95% of the time	No target	No target

The composition of the reproducibility test panel along with results of the testing (% agreement with expected results) at each testing site and overall is shown below.

Reproducibility of the binx health *io* CT/NG Test System

Sample	Concentration CT/NG	Analyte	Site 1		Site 2		Site 3		Overall Agreement		
			No. of Correct/ Total No. Tested	% Agreement	No. of Correct/Total No. Tested	% Agreement	No. of Correct/Total No. Tested	% Agreement	No. of Correct/ Total No. Tested	% Agreement	95% CI
1	**CT: NEG**	CT	26/28	92.9	28/28	100.0	26/28	92.9	80/84	95.2	88.4 to 98.1
	NG: HIGH	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
2	**CT: NEG**	CT	25/28	89.3	27/28	96.4	26/28	92.9	78/84	92.9	85.3 to 96.7
	NG: MOD	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
3	**CT: NEG**	CT	28/28	100.0	28/28	100.0	26/28	92.9	82/84	97.6	91.7 to 99.3
	NG: LOD	NG	28/28	100.0	28/28	100.0	27/28	96.4	83/84	98.8	93.6 to 99.8
4	**CT: HIGH**	CT	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
	NG: NEG	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
5	**CT: MOD**	CT	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100

	NG: NEG	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
6	**CT: LOD**	CT	27/28	96.4	26/28	92.9	28/28	100.0	81/84	96.4	90.0 to 98.8
	NG: NEG	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
7	**CT: HIGH**	CT	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
	NG: HIGH	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
8	**CT: HIGH**	CT	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
	NG: LOD	NG	28/28	100.0	27/28	96.4	28/28	100.0	83/84	98.8	93.6 to 99.8
9	**CT: LOD**	CT	28/28	100.0	27/28	96.4	27/28	96.4	82/84	97.6	91.7 to 99.3
	NG: HIGH	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
10	**CT: LOD**	CT	28/28	100.0	26/28	92.9	28/28	100.0	82/84	97.6	91.7 to 99.3
	NG: LOD	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100
11	**CT: NEG**	CT	26/28	92.9	28/28	100.0	26/28	92.9	80/84	95.2	88.4 to 98.1
	NG: NEG	NG	28/28	100.0	28/28	100.0	28/28	100.0	84/84	100.0	95.6 to 100

*For the Negative panel member, the number of "Detected" samples indicates the number of correct (negative) results.

2. Linearity:

Not applicable; this is a qualitative assay;

3. Detection Limit:

The limit of detection (LoD) of the binx health *io* CT/NG Assay was evaluated using genomic DNA extracted from whole CT and NG cells. Two CT serovars (E and F) and two strains of NG were included in the study. The extracted CT and NG DNA was quantified using qPCR against a reference standard in genome equivalents (GE)/mL.

The quantified stocks were diluted in pooled vaginal matrix using a range of concentrations (100 to 756 GE/mL for CT and 60 to 246 GE/mL for NG). The study was conducted using two distinct lots of Cartridges, testing each dilution with the binx health *io* CT/NG Assay in at least 20 replicates. At least five different concentrations (for each of the four organisms and for each of the two lots of Cartridges), covering the range around the putative LoD (0.01-99% detection rates) were tested. The LoDs for CT and for NG were determined by probit regression analysis to identify the concentration level that demonstrated a detection rate of 95%. The determined LoD was then confirmed by testing two additional preparations of each CT serovar and each NG strain using two lots of Cartridges (for a total of 40 Cartridges per serovar/strain per Cartridge lot). The results from the LoD study are summarized in the table below.

Summary of the LoD Study Results

Organism	Cartridge Lot	Pre-determined LoD (GE/mL)	Verification Study Results	
			POS/No. Tested	% Detection
CT serovar E (ATCC-VR-348B)	Lot 1	407.4	40/40	100%
	Lot 2	309.6	39/40	97.5%
CT serovar F (ATCC-VR-346)	Lot 1	**755.5***	40/40	100%
	Lot 2	734.0	40/40	100%
	Lot 1	**245.6****	40/40	100%

NG strain (ATCC 49226)	Lot 2	193.2	40/40	100%
NG strain (ATCC 700825)	Lot 1	206.1	39/40	97.5%
	Lot 2	163.7	39/40	97.5%

*CT claimed LoD (the highest value obtained)
**NG claimed LoD (the highest value obtained)

The final claimed LoD concentrations are shown below in GE/mL; the concentrations are also shown in IFU/ml or CFU/mL, as applicable, based on the concentrations stated on the Certificates of Analysis for the stocks used in the study.

LoD for the binx health *io* CT/NG Assay in Vaginal Swab Samples

Organism	Serovar/Strain	GE/mL	IFU/mL	CFU/mL
C. trachomatis	Serovar E (ATCC-VR-348B)	407.4	5.6	N/A
	Serovar F (ATCC-VR-346)	755.6	0.3	N/A
N. gonorrhoeae	Strain 1 (ATCC 49226)	245.6	N/A	2.1
	Strain 2 (ATCC 700825)	206.1	N/A	2.5

4. Analytical Reactivity (Inclusivity)

The Assay's ability to detect additional 14 CT serovars, including the nvCT (Swedish variant) was evaluated by spiking each of the serovars (quantified in GE/mL) into vaginal matrix at 1x LoD and 0.5x LoD concentrations. Each dilution was tested with the binx health *io* CT/NG Assay in 20 replicates, using two lots of Cartridges. While four CT serovars (A, I, L1, and L3) were detected at the claimed LoD (755.5 GE/mL), the remaining 10 serovars were detected at 0.5x LoD (377.8 GE/mL). The summary of the inclusivity testing for CT is presented below.

CT Serovars-Limit of Detection

CT Serovar	**No. Positive/No. Tested at 1x LoD (755.5 GE/mL)**	**No. Positive/No. Tested at 0.5x LoD (377.8 GE/mL)**	**Claimed LoD (GE/mL)**
A	20/20	18/20	755.5
B	20/20	19/20	377.8
Ba	20/20	20/20	377.8
C	20/20	20/20	377.8
D	20/20	20/20	377.8
G	20/20	20/20	377.8
H	20/20	19/20	377.8
I	20/20	18/20	755.5
J	20/20	19/20	377.8
K	20/20	20/20	377.8
L1	20/20	17/20	755.5
L2	20/20	20/20	377.8
L3	19/20	18/20	755.5
NvCT	19/20	20/20	377.8

The assay's ability to detect multiple NG strains was evaluated by testing 30 unique NG strains, including two fluoroquinolone resistant isolates (quantified in genome copies by qPCR and spiked into vaginal matrix). At least 3 replicates of each strain were tested at 1x LoD concentration (245.6 GE/mL). If any of the 3 replicates yielded negative results, additional testing was performed until a concentration was reached that generated ≥19/20 positive results. Of the 30 NG strains tested, 16 strains tested positive at 1x LoD in the first three replicates; the remaining 14 strains were tested at 5x LoD (1228 GE/mL) generating at least 19/20 positive results. For the strains detected in 3/3 replicates tested, the concentration is expressed as Reported Detectable Level (RDL); for the strains that were detected in at least 19/20 replicates, the concentration is expressed as LoD (Limit of Detection). The summary of the inclusivity testing for NG is presented below.

Reactivity with NG Strains

NG Strain	No. Detected at 1x LOD (245.6 GE/mL)	No. Detected at 5x LOD (1228.0 GE/mL)	Detectable Concentration	
			RDL*/LoD	GE/mL
Alabama 201301 #06	7/9	20/20	LoD	1228.0
Alabama 201310 #01	6/9	20/20	LoD	1228.0
California 201302 #03	3/3	N/A	RDL	245.6
California 201302 #06	3/3	N/A	RDL	245.6
California 201304 #01	5/9	20/20	LoD	1228.0
California 201307 #02	7/9	20/20	LoD	1228.0
California 201301 #10	3/3	N/A	RDL	245.6
California 201301 #12	7/9	20/20	LoD	1228.0
California 201302 #10	6/9	20/20	LoD	1228.0
California 201303 #14	1/3	20/20	LoD	1228.0
California 201310 #04	3/3	N/A	RDL	245.6
Maryland 201301 #01	3/3	N/A	RDL	245.6
Maryland 201301 #02	17/20	20/20	LoD	1228.0
Alabama 201310 #05	1/3	20/20	LoD	1228.0
Maryland 201309 #21	1/3	19/20	LoD	1228.0
Maryland 201311 #16	6/9	20/20	LoD	1228.0
North Carolina 201302 #10	3/3	N/A	RDL	245.6
Pennsylvania 201301 #10	3/3	N/A	RDL	245.6
Pennsylvania 201301 #25	3/3	N/A	RDL	245.6
Pennsylvania 201312 #28	3/3	N/A	RDL	245.6
Virginia 201304 #01	7/9	20/20	LoD	1228.0
Virginia 201305 #01	3/3	N/A	RDL	245.6
ATCC 19424	17/20	20/20	LoD	1228.0
ATCC 31426	3/3	N/A	RDL	245.6
ATCC 43070	3/3	N/A	RDL	245.6
ATCC 49498	3/3	N/A	RDL	245.6
UK 8454 R1*	3/3	N/A	RDL	245.6
UK 9155 R2*	3/3	N/A	RDL	245.6
UK 9156 S1**	1/3	20/20	LoD	1228.0

ATCC 19999	3/3	N/A	RDL	245.6

RDL: Reported detectable level tested, 3/3 replicates tested positive
LoD: Limit of Detection level, ≥19/20 replicates tested positive
*Fluoroquinolone resistant mutant strain
**Fluoroquinolone sensitive mutant strain

5. Analytical Specificity/Interference:

Cross-reactivity with other Microorganisms

The analytical specificity of the binx health *io* CT/NG Assay was evaluated by spiking pooled vaginal swabs in eNAT buffer with relevant bacteria, fungi, protozoa, or viral organisms that may be present at the sampling site, such as commensal bacteria that may come into contact with the sampling device or genetically closely related species to *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.

The potential for cross-reactivity was evaluated with a panel of microorganisms, using cultured organisms at a concentration of 1x 10^6 CFU/mL for bacteria, or 1x 10^5 PFU/mL for viruses, or genome equivalents at 2 ng/mL of genomic DNA (≥1x 10^5GE/mL). The panel also included *H. sapiens* DNA at 5.7 x 10^2 GE/mL. Each organism was tested in three replicates. All tests generated expected results, i.e., negative for CT and NG in all 3 replicates, except for one organism, *N. sicca*, which tested positive for CT in one of the three replicates. Additional 17 replicates of the organism were tested, with no additional positive results (1/20). This organism is listed in the package insert as a possible cross-reactant for CT.

To demonstrate that the two target organisms do not cross-react with each other, one NG strain and one CT strain (serovar F) were included in the study, generating expected results, i.e., samples containing *C. trachomatis* generated negative results for NG and positive results for CT, and samples containing *N. gonorrhoeae* generated negative results for CT and positive results for NG, in all three replicates.

Two species, *Megasphaera*-type 1 and BVAB-2, were evaluated using *in silico* analysis of the genetic targets used in the binx health *io* CT/NG Assay against the published genome sequences for these organisms. *In silico* analysis demonstrated that neither of these organisms would be detected by the binx health *io* CT/NG Assay.

The table below lists all the organisms evaluated for cross-reactivity with the binx health *io* CT/NG Assay.

Microorganisms Evaluated for Cross-reactivity in the binx health *io* CT/NG Assay

Organism	Input/mL	Organism	Input/mL
*Atopobium vaginae**	1.3x10^6 GE/mL	*Mobiluncus mulieris**	7.6 x 10^5 GE/mL
*Bacteriodes fragilis**	3.5x10^5 GE/mL	*Moraxella lacunata*	1 x 10^6 CFU/mL
*Bacteriodes ureolyticus**	1.1x10^6 GE/mL	*Mycoplasma genitalium**	3.2 x 10^6 GE/mL

*Bifidobacterium longum**	$8.2x10^5$ GE/mL	*Mycoplasma hominis**	2.8×10^6 GE/mL
BVAB-2	*in silico*	*Neisseria meningitidis* Serogroup A*	8.2×10^5 GE/mL
Candida albicans	1×10^6 CFU/mL	*Neisseria meningitidis* Serogroup B*	8.2×10^5 GE/mL
Candida glabrata	$1 x10^6$ CFU/mL	*Neisseria meningitidis* Serogroup C*	8.2×10^5 GE/mL
Candida parapsilosis	$1 x10^6$ CFU/mL	*Neisseria meningitidis* Serogroup D*	$8.2x10^5$ GE/mL
*Chlamydia pneumoniae**	$1.5 x10^6$ GE/mL	*Neisseria meningitidis* Serogroup W135*	$8.2x10^5$ GE/mL
*Chlamydia psittaci**	$1.6 x10^6$ GE/mL	*Neisseria meningitidis* Serogroup Y*	$8.2x10^5$ GE/mL
*Chlamydia trachomatis**	$2.3 x10^7$ GE/mL	*Neisseria cinerea*	1×10^6 CFU/mL
*Clostridium perfringens**	$5.7x10^5$ GE/mL	*Neisseria denitrificans*	1×10^6 CFU/mL
Corynebacterium genitalium	1×10^6 CFU/mL	*Neisseria elongata* (4)	1×10^6 CFU/mL
Corynebacterium xerosis	1×10^6 CFU/mL	*Neisseria gonorrhoeae**	$1.2x10^8$ GE/mL
Enterococcus faecalis	1×10^6 CFU/mL	*Neisseria flava*	1×10^6 CFU/mL
Escherichia coli	1×10^6 CFU/mL	*Neisseria flavescens* (3)	1×10^6 CFU/mL
*Gardnerella vaginalis**	$1.1x10^6$ GE/mL	*Neisseria lactamica* (3)	1×10^6 CFU/mL
*Haemophilus ducreyi**	$1.1x10^6$ GE/mL	*Neisseria mucosa* (4)	1×10^6 CFU/mL
Herpes simplex virus 1*	1.2×10^7 GE/mL	*Neisseria perflava* (2)	1×10^6 CFU/mL
Herpes simplex virus 2	1.2×10^7 GE/mL	*Neisseria polysaccharea*	1×10^6 CFU/mL
*Homo sapiens**	$5.7x10^2$ GE/mL	*Neisseria sicca* (4)*	$6.7x10^5$ GE/mL
Human papilloma virus 16*	1.8×10^6 GE/mL	*Neisseria subflava* (2)	1×10^6 CFU/mL
Kingella dentrificans	1×10^6 CFU/mL	*Peptostreptococcus anaerobius**	8.8×10^5 GE/mL
Kingella kingae	1×10^6 CFU/mL	*Proteus mirabilis*	1×10^6 CFU/mL
Klebsiella pneumoniae	1×10^6 CFU/mL	*Pseudomonas aeruginosa*	1×10^6 CFU/mL
Lactobacillus acidophilus	1×10^6 CFU/mL	*Staphylococcus aureus*	1×10^6 CFU/mL

Lactobacillus brevis	1 x 10^6 CFU/mL	*Staphylococcus epidermidis*	1 x 10^6 CFU/mL
Lactobacillus jensenii	1 x 10^6 CFU/mL	*Streptococcus agalactiae*	1 x 10^6 CFU/mL
Lactobacillus lactis	1 x 10^6 CFU/mL	*Trichomonas vaginalis*	1 x 10^6 CFU/mL
Megasphaera type 1	*in silico*	*Ureaplasma urealyticum**	2.0x10^6 GE/mL
*Mobiluncus curtisii**	8.6 x 10^5 GE/mL	*Ureaplasma parvum**	2.5x10^6 GE/mL

(n) number of strains tested
*Organisms tested with genomic DNA (GE = 2ng/mL)

Interference with Substances Potentially Present at the Anatomic Collection Site

The analytical performance of the binx health *io* CT/NG Assay was evaluated in the presence of a panel of potentially interfering substances that may be found in a vaginal swab sample. Each potential interferent was spiked into pooled vaginal matrix and subsequently spiked with a low concentration (2x LoD) of CT (serovar F) and NG (strain ATCC 49226). Additionally, each potential interferent was spiked into pooled vaginal matrix with no CT or NG present at the highest concentration expected to be found in a vaginal sample (i.e., clinically relevant). All tests generated expected results, demonstrating that the substances listed at the concentrations shown in the table below, do not interfere with the binx health *io* CT/NG Assay.

Evaluation of Interference

Interfering Substance	Concentration
Human blood	10% (v/v)
Contraceptive Jelly	0.25% (v/v) (Non-oxynol 9 – Gygel)
Mucus	0.8% (v/v) (Pooled vaginal fluid)
Seminal fluid	5.0% (v/v)
Moisturizer	0.25% (v/v)
Anti-fungal cream	0.25% (v/v) (Clotrimazole -Canesten)
	0.25% (v/v) (Miconazole nitrate - Daktarin)
Vaginal lubricant	0.25% (v/v) (KY Jelly)
Feminine anti-itch cream	0.25% (v/v) (2% lidocaine cream)
Leukocytes	1x 10^6 cells/mL
Progesterone	7 mg/mL
β-Estradiol	0.25% (v/v) (Estrace cream)
Anti-viral cream	0.25% (v/v) (Acyclovir)
Haemorrhoidal cream	0.25% (v/v)

Microbial Interference

The analytical performance of the binx health *io* CT/NG Assay was also evaluated for interference from microorganisms that may be encountered at the anatomical site of the swab

collection. The study was designed as above, where 10 microorganisms were added at 1 x 10^5 CFU/mL into pooled vaginal matrix, however, for this study, low levels (2x LoD) of CT and NG organisms were subsequently added to the test samples. The samples were tested with the binx health *io* CT/NG Assay to check for interference. All tests generated expected results (CT Detected and NG Detected), demonstrating that the organisms listed in the table below, tested at the concentrations shown, do not interfere with the binx health *io* CT/NG Assay.

Microbial Interference

Interfering Microorganism	Concentration Tested
Corynebacterium xerosis	1x 10^5 CFU/mL
Lactobacillus acidophilus	1x 10^5 CFU/mL
Lactobacillus jensenii	1x 10^5 CFU/mL
Staphylococcus epidermidis	1x 10^5 CFU/mL
Candida albicans	1x 10^5 CFU/mL
Escherichia coli	1x 10^5 CFU/mL
Lactobacillus brevis	1x 10^5 CFU/mL
Lactobacillus lactis	1x 10^5 CFU/mL
Streptococcus agalactiae	1x 10^5 CFU/mL
Candida glabrata	1x 10^5 CFU/mL

6. Assay Cut-Off:

Thresholds for each of the assay targets were calculated from testing negative clinical specimens and low positive-spiked negative clinical specimens. The negative status of clinical samples was derived from testing with three FDA cleared CT/NG assays, using the two-out-of-three algorithm (any two negatives constituted a negative status). The goal was to balance sensitivity and specificity for CT, NG1 and NG2 targets to maximize the detection of infected subjects while minimizing false positive results. The calculations were based on the distribution of peak heights (in nA), such that the selected threshold provided a clear and distinct separation between positive and negative samples. The selection of the threshold was made with additional consideration of previously generated clinical data which included a large negative dataset. The following peak thresholds were selected:

CT – 115nA
NG1 – 50nA
NG2 – 45nA

The data set was also used to set appropriate IC (Internal Control) peak thresholds to allow for detection of significant reagent degradation.

7. Carry-Over:

The risk of carryover from a high positive sample to a sample that sequentially follows testing was evaluated by testing 50 samples, alternating between high positive samples and negative samples. The test samples were prepared in female vaginal swab matrix in eNAT buffer. The positive samples were double spiked to a concentration of 1 x 10^5 IFU/mL of CT (serovar F) and 1 x 10^5 CFU/mL of one NG strain. The negative samples consisted of vaginal swab matrix in

eNAT buffer. The testing was performed using four binx *io* CT/NG instruments, with 50 tests (25 negative and 25 positives, run alternately), generating a total of 200 results. All 100 positive samples were correctly reported as CT Detected and NG Detected, and all 100 negative samples were correctly reported as CT Not Detected and NG Not Detected; no false positive results were observed.

8. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Sample Stability

The stability of vaginal swab samples in the Vaginal Swab Collection Kit was evaluated in an analytical study which used samples of pooled vaginal swab matrix spiked with CT organisms (serovar F) and NG organisms at 3x LoD concentration. Twenty replicates were tested at t=0; additional 20 aliquots were placed in controlled storage at 25°C and another 20 aliquots were placed at 2-8°C. Six replicates of the pooled vaginal matrix were tested as experimental negative controls at each timepoint. A positive and negative daily control was run on each instrument on each testing day. The samples were tested with the binx health *io* CT/NG Assay at the following storage timepoints:

- After 25 hours when stored at 25°C
- After 8 days when stored at 2-8°C

All positive samples generated expected results, i.e., CT Detected/NG Detected. One of the six negative samples returned a positive result for CT after storage at 2-8°C and additional six replicates of negative swab matrix (stored at 2-8°C for 8 days) were tested, generating expected results for all replicates, for a total of one false positive CT in 12 tests. This suggested a low-level contamination of the test sample rather than contamination of the entire pooled matrix.

The study supported a claim that *C. trachomatis* and *N. gonorrhoeae* organisms in vaginal swab samples collected in eNAT buffer are stable when stored for 24 hours at 25°C or for a week, when stored at 2-8°C. The summary of the data is shown below.

Specimen Stability Test Results

Timepoint	Temp.		*C. trachomatis*		*N. gonorrhoeae*	
			POS	NEG	POS	NEG
T=0	Ambient	No. Valid Results	19[1]	6	20/20	6
T=25 Hrs	25°C	No. Correct Results	19/19	6/6	20/20	6/6
		% Correct	100	100	100	100
		95% CI	83.2-100	61.0-100	83.9-100	61.0-100
T=8 Days	2-8°C	No. Correct Results	20/20	11/12[2]	20/20	6/6
		% Correct	100	91.7	100	100
		95% CI	83.9-100	64.6-98.5	83.9-100	61.0-100

[1]One test was invalid

[2]One false positive CT result

Shipping Stability

A study was carried out to verify the performance of the binx health *io* CT/NG Assay after the cartridges were subjected to simulated shipping conditions conducted using temperature-controlled chambers. Two lots of cartridges were stored for 5 days at 25°C. Subsequently, the cartridges were subjected to two cycles of the following conditions:

9 hours at 10°C
6 hours at 25°C
2 hours at 35°C
7 hours at 25°C

Temperature cycling was carried out in monitored and controlled incubators. Twenty positive samples (at 4x LoD) and 20 negative (eNAT buffer only) samples were tested with the binx health *io* CT/NG assay using cartridges that were exposed to the above conditions. The positive samples were spiked with CT serovar F and NG strain ATCC 49226 at with 4x LoD; the negative samples consisted of eNAT buffer. Each sample type was tested in 20 replicates. All samples tested generated expected results, i.e., all positive samples generated CT Detected; NG Detected results; all negative samples generated CT Not Detected; NG Not Detected results. The results demonstrated that the binx *io* CT/NG Cartridges are stable following temporary shipping cycles as shown above and therefore will be suitable for shipping as airfreight.

ISTA 3A Testing

ISTA (International Safe Transit Association) 3A testing was carried out to determine whether the packaging is suitable for storage and distribution by surface or air to prevent damage during transit when shipped from the manufacturer to the customer.

One shipping container of five cartons of 10 binx *io* CT/NG Cartridges (50 Cartridges) from a single lot was sent for ISTA 3A testing. The cartons were packed by the manufacturer, shipped, and returned to the manufacturer. Upon receipt, the Cartridges were assessed and scored for damages from 1 to 5:

1. No visible damage
2. Minor damage to the outer packaging and/or slight misshapen appearance that still allows any flaps to open/close without significant re-shaping of the package by hand. No punctures.
3. Moderate damage, medium tears/breaches to the outer packaging and/or squashing of the packaging to the extent that the package can be re-shaped by hand to allow any flaps to open/close.
4. Significant damage/tearing/breach to the outer packaging but the integrity of the package is maintained such that it is still capable of retaining the contents in the ‘this way up’ orientation.
5. The integrity of the outer packaging is damaged to the extent that the packaging no longer holds the contents in any orientation.

When the shipping container and each carton were inspected following shipping simulation, the following observations were documented:

Integrity During Shipping

Packaging	Score	Pass/Fail
Shipping container (outer box)	2	Pass
Carton 1 (inner box)	2	Pass
Carton 2	1	Pass
Carton 3	2	Pass
Carton 4	2	Pass
Carton 5	2	Pass

All 50 Cartridges were assessed individually and none showed any visible damage during shipping. The Cartridges were used in testing of positive and negative samples and all yielded expected result. The results showed that the packaging is adequate for transporting the Cartridges and that the performance of the binx health *io* CT/NG Assay was unaffected by shipping simulation.

Shelf Life Stability

A real-time stability study is being conducted to determine the shelf-life of the binx health *io* CT/NG Cartridge and its consumables. The study is performed with reagents that have been stored at the upper limit of the tests' claimed room temperature range (28-30°C) and at 2-8°C. The study is conducted with a panel of three samples at the following concentrations of the organism: a low positive sample, a moderate positive sample, and a negative sample, using two distinct lots of Cartridges. The testing will be conducted monthly for the first three months, then every two months, with the remaining test points at 12 months, 14 months, 18 months, and 20 months. The sponsor included the evaluation criteria and the acceptance criteria (lowest peak heights above threshold for each analyte target) in the 510(k) submission. At this time, the results of the testing support a shelf life claim for the binx health *io* CT/NG Cartridge of three months at less than 30°C (i.e., 25°C), and four months at 2-8°C.

Daily Quality Controls

One positive and one negative control were run daily on each instrument that was used to run female patient samples on each day of testing. A total of 1,096 daily controls were run throughout the study with 17 invalid results (8 invalids for Positive Control and 9 invalids for Negative Control), with an overall invalid rate of 1.55%. There were also five false negative results obtained for NG, which subsequently generated correct results upon repeat.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See Clinical Studies section below.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

The clinical performance of the binx health *io* CT/NG Test System used with female vaginal swabs was evaluated in a prospective study conducted at nine clinical sites, of which seven performed testing with the binx health *io* CT/NG Assay and two sites served as patient enrollment and specimen collection sites only. The participating testing sites, at geographically different locations across the U.S., were representative of point-of-care (POC) environments and included STD clinics, family planning/OB-GYN clinics, and HIV clinics. Reference testing was conducted at one CLIA certified clinical laboratory. The study was conducted between September 2018 and March 2019 and consisted of prospective enrollment of 1634 female participants between the ages of 16 and 74 (median age of 27 years) with signs and symptoms of genitourinary infection or who were at risk of such an infection.

All subjects enrolled in the study provided a signed informed consent form; however, 21 subjects were excluded due to ineligibility or withdrawal, leaving 1613 subjects available for testing. Specimens from 89 participants were excluded due to deviations from the study protocol, leaving 1524 subjects for testing with the binx health *io* CT/NG Assay. Approximately half of the vaginal samples tested with the binx assay were self-collected (736) and half were clinician-collected (788). There were 17 initial invalid results reported from testing patients with the binx health *io* CT/NG Assay (17/1524) for an overall invalid rate of 1.11%. However, one specimen (clinician-collected vaginal swab) was indeterminate after generating two successive invalid results on the binx health *io* CT/NG Assay, leaving a total of 1,523 evaluable vaginal swab specimens for inclusion in the final data analysis.

The table below shows the excluded samples for each exclusion category.

Excluded Samples

Exclusion Category from line list	Number excluded
Improper Specimen Collection	12
Improper Testing	6
Miscellaneous	4
Participant Ineligible	17
Participant Withdrew	4
Specimen Handling	
No temperature log during transit	7
Sample leaked in transit	4
Samples lost in transit	3
Shipping temperature outside specifications	53

The testing with the binx health *io* CT/NG Assay was performed by 30 operators (test users), of which 26 were representative of an intended test user in POC environments, i.e., a member of the healthcare providing team without laboratory training. The users who participated in the binx study were trained to use the binx *io* CT/NG Assay.

External Quality Control samples (positive and negative) were run on each testing day. A total of 1,142 daily controls were run throughout the study, using 29 *io* instruments across the testing sites. There was a total of 16 invalid results obtained from testing external QC samples.

Clinical Sensitivity and Specificity

The clinical performance of the binx health *io* CT/NG Assay was assessed by comparing the test results obtained with the binx health *io* CT/NG Assay to a Composite Infected Status (CIS) for each subject, derived by an algorithm of test results obtained with three FDA-cleared assays (each with different DNA targets for CT and NG than the binx assay), testing vaginal samples. Participants were classified as "infected" if at least two of the three comparator assays provided positive results; all other participants were classified as "not infected."

All female subjects provided four vaginal swab samples for use in the study. Three vaginal swabs from each participant were collected by a clinician, according to a pre-determined randomization scheme regarding the order of collection, for testing with three FDA cleared molecular assays (NAATs) detecting CT and NG. The fourth swab, either self-collected or clinician collected, was used for testing with the binx health *io* CT/NG Assay. For self-collected specimens, the binx vaginal swab sample was collected first and for clinician-collected specimens, the binx vaginal swab sample was collected last.

The clinical sensitivity and specificity of the binx health *io* CT/NG Assay, when used with vaginal specimens, was calculated in comparison with the CIS comparator algorithm and is shown by symptom status, along with prevalence rates observed during the clinical study in the two tables below.

Clinical Performance of the binx health *io* CT/NG Assay for *C. trachomatis* with Vaginal Swab Specimens

Symptom Status	N	TP	FN	TN	FP	Sensitivity (95% CI)[1]	Specificity (95% CI)[1]	Prevalence	PPV (95% CI)[2]	NPV (95% CI)[2]
Asx	706	65	2	634	5	97.0% (89.8; 99.2)	99.2% (98.2; 99.7)	9.5%	92.7% (84.1; 97.6)	99.7% (98.9; 100.0)
Sx	817	59	3	747	8	95.2% (86.7; 98.3)	98.9% (97.9; 99.5)	7.6%	88.1% (77.8; 94.7)	99.6% (98.8; 99.9)
Total	**1523**	**124**	**5**	**1381**	**13**	**96.1% (91.3; 98.3)**	**99.1% (98.4; 99.5)**	**8.5%**	**90.5% (84.3; 94.9)**	**99.6% (99.2; 99.9)**

Asx = Asymptomatic; Sx Symptomatic
TP = True Positive FN = False Negative; TN = True Negative; FP = False Positive
PPV = Positive Predictive Value; NPV = Negative Predictive Value
[1]95% Confidence Intervals (CI) by Wilson's Score Method
[2]95% Confidence Intervals (CI) by Exact Method

Clinical Performance of the binx health *io* CT/NG Assay for *N. gonorrhoeae* with Vaginal Swab Specimens

Symptom Status	N	TP	FN	TN	FP	Sensitivity (95% CI)[1]	Specificity (95% CI)[1]	Prevalence	PPV (95% CI)[2]	NPV (95% CI)[2]
Asx	706	16	0	689	1	100.0% (80.6; 100.0)	99.9% (99.2; 100.0)	2.3%	94.1% (71.3; 99.9)	100.0% (99.5; 100.0)
Sx	817	29	0	787	1	100.0% (88.3; 100.0)	99.9% (99.3; 100.0)	3.5%	96.7% (82.8; 99.9)	100.0% (99.5; 100.0)
Total	**1523**	**45**	**0**	**1476**	**2**	**100.0% (92.4; 100.0)**	**99.9% (99.51; 100.0)**	**3.0%**	**95.7%** (85.5; 99.5)	**100.0%** (99.8; 100.0)

Asx = Asymptomatic; Sx Symptomatic
TP = True Positive FN = False Negative; TN = True Negative; FP = False Positive
PPV = Positive Predictive Value; NPV = Negative Predictive Value
[1]95% Confidence Intervals (CI) by Wilson's Score Method
[2]95% Confidence Intervals (CI) by Exact Method

The frequency of test outcomes from the reference NAATs and the binx health *io* CT/NG Assay is summarized for each target (organism) in the two tables below.

Frequency of Test Outcomes for *Chlamydia trachomatis* by Symptom Status

CIS	Comparator Test Results			binx *io* Result	Symptom Status		Total
	NAAT1	NAAT2	NAAT3		Sx	Asx	
NI	-	-	-	-	731	620	1351
NI	-	-	+	-	2	3	5
NI	-	+	-	-	5	7	12
NI	+	-	-	-	0	0	0
NI	-	-	IND	-	2	1	3
NI	-	IND	-	-	1	2	3
NI	IND	-	-	-	6	1	7
NI	-	-	-	+	8	5	13
NI	-	-	+	+	0	0	0
NI	-	+	-	+	0	0	0
NI	+	-	-	+	0	0	0
NI	-	-	IND	+	0	0	0
NI	-	IND	-	+	0	0	0
NI	IND	-	-	+	0	0	0
Total not Infected					755	639	1394
I	+	+	+	+	56	63	119
I	+	+	-	+	0	1	1
I	+	-	+	+	0	1	1
I	-	+	+	+	1	0	1
I	+	+	IND	+	0	0	0
I	+	IND	+	+	1	0	1
I	IND	+	+	+	1	0	1
I	+	+	+	-	1	2	3
I	+	+	-	-	2	0	2

I	+	-	+	-	0	0	0
I	-	+	+	-	0	0	0
I	+	+	IND	-	0	0	0
I	+	IND	+	-	0	0	0
I	IND	+	+	-	0	0	0
Total Infected					62	67	129

CIS = Comparator Infected Status
NI = Not Infected; I = Infected
IND = Indeterminate
Sx = Symptomatic; Asx = Asymptomatic

Frequency of Test Outcomes for *Neisseria gonorrhoeae* by Symptom Status

CIS	Comparator Test Results			binx *io* Result	Symptom Status		Total
	NAAT1	NAAT2	NAAT3		Sx	Asx	
NI	-	-	-	-	776	681	1457
NI	-	-	+	-	3	4	7
NI	-	+	-	-	0	0	0
NI	+	-	-	-	0	0	0
NI	-	-	IND	-	2	1	3
NI	-	IND	-	-	0	2	2
NI	IND	-	-	-	6	1	7
NI	-	-	-	+	0	0	0
NI	-	-	+	+	0	0	0
NI	-	+	-	+	0	0	0
NI	+	-	-	+	1	0	1
NI	-	-	IND	+	0	0	0
NI	-	IND	-	+	0	1	1
NI	IND	-	-	+	0	0	0
Total not Infected					788	690	1478
I	+	+	+	+	24	15	39
I	+	+	-	+	1	0	1
I	+	-	+	+	2	1	3
I	-	+	+	+	1	0	1
I	+	+	IND	+	0	0	0
I	+	IND	+	+	0	0	0
I	IND	+	+	+	1	0	1
I	+	+	+	-	0	0	0
I	+	+	-	-	0	0	0
I	+	-	+	-	0	0	0
I	-	+	+	-	0	0	0
I	+	+	IND	-	0	0	0
I	+	IND	+	-	0	0	0
I	IND	+	+	-	0	0	0
Total Infected					29	16	45

CIS = Comparator Infected Status
NI = Not Infected; I = Infected
IND = Indeterminate
Sx = Symptomatic; Asx = Asymptomatic

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The prevalence of infection with CT and/or NG in patient populations depends on risk factors such as age, gender, type of clinic, and the sensitivity of the test used to detect infections. The observed positivity rates of the binx health *io* CT/NG Assay in females during the clinical study, testing vaginal swab samples, are shown below.

Positivity Rates by binx health *io* CT/NG Assay in the Clinical Study

				CT		NG	
Site No.	**Type of Clinic**	**US State**	**Total No. Samples**	**No. Positive by binx**	**% Positivity Rate**	**No. Positive by binx**	**% Positivity Rate**
1	STD Clinic	IN	74	5	6.8%	8	10.8%
2	STD Clinic	MD	39	2	5.1%	1	2.6%
3	STD Clinic	LA	85	16	18.8%	0	0.0%
4	Family Planning	TX	1053	99	9.4%	26	2.5%
5	Family Planning	PA	73	3	4.1%	1	1.4%
6	STD Clinic	AL	154	11	7.1%	9	5.8%
7	STD Clinic	NC	14	0	0.0%	2	14.3%
8	OBGYN	MD	9	1	11.1%	0	0.0%
9	STD Clinic	MS	22	0	0.0%	0	0.0%
	Total		1523	137	9.0%	47	3.0%

F Other Supportive Instrument Performance Characteristics Data:

The sponsor performed usability studies as well as analytical studies to evaluate the robustness of the test system under sub-optimal operational scenarios in a point-of-care environment, when used by non-laboratory-trained personnel.

Usability Studies

The binx *io* System was designed for use in near-patient settings, such as a clinic or a medical practice, with laboratories conducting moderate complexity diagnostic testing under CLIA oversight. The sponsor developed the system with built-in risk-mitigation features specifically to meet the requirements of the intended users in those settings, including:

- The design of the Cartridge includes a self-metering pipet for sample transfer and an invertible sample chamber.
- All reagents are enclosed in the test Cartridge.

- The instrument is simple to set up and requires no calibration.
- The screen display is interactive and informative.
- The software provides prompts for correct sequence of operations, including specimen identification.
- Two levels of user credentials are employed to include basic users and administrators.
- No access to the operating system is possible, to avoid malicious access.

The usability of the system was evaluated prior to production by a group of users that represented the intended users in POC settings and was found acceptable.

Operational Environment

The sponsor evaluated the *io* CT/NG Test System operation to assess whether the assay can run reliably within the specified temperature and humidity limits and whether it aborts due to marginal conditions (rather than giving incorrect results).

The sponsor considered the following:

Instrument operating range (specifications): 10°C-35°C / 0%-80% RH
Typical ambient working environment: 20°C-25°C / 20%-60% RH

The testing was performed at the outermost limits of the potential environmental conditions:

- 9°C/40% RH
- 37°C/40% RH
- 20°C/83% RH
- 30°C/83% RH
- 20°C/15% RH

The instrument and cartridges were equilibrated to the set conditions, followed by testing 3 consecutive positive samples (spiked with CT and NG organisms at 4x LoD). All tests returned valid positive results. No instrument failures were observed. The summary of the study conditions and results is shown below.

Condition	Temperature	Relative Humidity	CT/NG Positive Sample	CT/NG Negative Sample	Pass/Fail
1	9°C	40%	3/3	3/3	Pass
2	37°C	40%	3/3	3/3	Pass
3	20°C	83%	3/3	3/3	Pass
4	30°C	83%	3/3	3/3	Pass
5	20°C	15%	3/3	3/3	Pass

External controls were included with each test condition under evaluation. One positive control generated a false negative result; a positive result was obtained upon a retest.

Performing Testing with Cold (out of refrigerator) Reagents.

To demonstrate that binx health *io* CT/NG Cartridges and/or samples can be run immediately following refrigerator storage, a study was carried out to evaluate the performance of binx *io* CT/NG Cartridges when tested immediately after removing from storage (for a minimum of 12

hours) at 2-8°C, using samples that were either at room temperature or stored refrigerated at 2-8°C for a minimum of 12 hours. Vaginal swab matrix was spiked to 4x LoD concentration with one CT strains (serovar F) and one NG strain (ATCC 49226). Three positive samples and three negative samples (unspiked negative matrix) were tested for each condition. All tests generated expected results.

Cartridge Storage	Sample Storage	No. Correct Results	
		CT/NG Positive	CT/NG Negative
2-8°C	Ambient	3/3	3/3
2-8°C	2-8°C	3/3	3/3

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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