510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K200533

B Applicant

binx health Inc

C Proprietary and Established Names

binx io CT/NG Assay and binx io CT/NG System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QEP	Class II	21 CFR 866.3393 - Nucleic Acid Detection System for Non-Viral Microorganism(S) Causing Sexually Transmitted Infections	MI - Microbiology
LSL	Class II	21 CFR 866.3390 - Neisseria spp. direct serological test reagents	MI - Microbiology
MKZ	Class I, reserved	21 CFR 866.3120 - Chlamydia serological reagents	MI - Microbiology
NSU	Class II	21 CFR 862.2570 - Instrumentation for clinical multiplex test systems	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

The binx *io* System and CT/NG Assay were previously cleared on August 8, 2019 under K191352 for use with female vaginal swab specimens. The purpose of this submission is to provide data to support addition of male urine specimens as an acceptable sample type for testing with the binx *io* CT/NG system. The presented data and all references herein pertain to male urine specimens only.

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 detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA by polymerase chain reaction. The binx health *io* CT/NG Assay is intended for use with female vaginal swab specimens, collected either by a clinician or self-collected by a patient in a clinical setting, or male urine specimens, as an aid in the diagnosis of symptomatic or asymptomatic *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* infection. For a symptomatic male patient with a chlamydia negative test result, further testing with a laboratory-based molecular test is recommended.

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 device description was provided in detail and may be found under K191352. Briefly, the binx health *io* CT/NG Assay is a qualitative *in vitro* diagnostic system consisting of a table-top instrument and test cartridges containing all the necessary reagents to perform the test. Each cartridge is packaged with a single-use, fixed-volume transfer pipet for transferring the sample to the Cartridge. Specimen collection kits are provided separately:

1. Female Vaginal Swab Specimen Collection Kit consisting of a sterile flocked swab and a sample collection tube containing preservation medium;

2. Male Urine Specimen Collection Kit consisting of a sample collection tube containing preservation medium and a single 2 mL transfer pipet.

To perform the test, 0.5 mL of sample (swab eluate or urine in the preservation medium) is added to the port of the Cartridge using the included sample transfer pipet and the Cartridge is inserted into the Instrument to begin the testing. Each Cartridge label contains a barcode that includes the test type, batch information, and expiration date, which is automatically scanned by the Instrument. The test results are displayed on the instrument touchscreen.

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 and male urine. The binx *io* Cartridge is assay-specific and is intended for a single-use on a single patient. 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.

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 and, as a result, the electrochemical label is not released, and no current is generated.

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* Male Urine Specimen Collection Kit. The specimen 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):

binx health io CT/NG Assay

B Predicate 510(k) Number(s):

K191352

C Comparison with Predicate(s):

Device & Predicate Device(s):	K200533	K191352
Device Trade Name	**binx *io* CT/NG Assay**	**binx *io* CT/NG Assay**
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 detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA by polymerase chain reaction. The binx health *io* CT/NG Assay is intended for use with female vaginal swab specimens, collected either by a clinician or self-collected by a patient in a clinical setting, or male urine specimens, as an aid in the diagnosis of symptomatic or asymptomatic *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* infection. For a symptomatic male patient with a chlamydia negative test result, further testing with a laboratory-based molecular test is recommended.	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 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 patients with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.
Regulation	Same	866.3393
Technology	Same	Automated multiplex polymerase chain reaction with electrochemical detection
Instrument	Same	binx *io* analyzer
Assay Targets	Same	Genomic DNA from *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*
Target Purification	Same	Nucleic Acid Extraction and purification
Assay Results	Same	Qualitative
Quality Control	Same	Internal Process Control
General Device Characteristic Differences		
Specimen Type	Female vaginal swabs Male urine	Female vaginal swabs
Specimen Collection Kits	Vaginal Swab Specimen Collection Kit	Vaginal Swab Specimen Collection Kit

	Male Urine Specimen Collection Kit	

VI Standards/Guidance Documents Referenced:

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*
IEC	61010-1:2012	*Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements*

VII Performance Characteristics:

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility of the binx *io* CT/NG Assay System, testing female vaginal swab samples was conducted, and the results were presented, under K191352.

Reproducibility of the binx *io* CT/NG Assay System, testing male urine samples, was evaluated across three POC testing sites, i.e., clinics where the testing was performed outside of central CLIA certified laboratory, by six users (two per site) representing healthcare professionals that may be encountered at such sites. The study was conducted over five testing days, with two *io* Instruments at each site, using one lot of Cartridges. Each sample was tested three times a day, for a total of 90 measurements (3x per day, 2 operators, 5 days, 3 sites).

The test samples were prepared in pooled negative male urine and included combinations of three concentration levels for each organism, CT and NG; one negative sample for both organisms, i.e., un-spiked negative male urine was also included in the panel.

Eleven panel members were constructed in order to evaluate both the reproducibility of each organism at a low positive level, medium positive level, and at high positive level alone and together. Of those, four panel members were prepared to evaluate competitive inhibition and the reproducibility of one organism at a low and medium positive concentration (1x and 3x LoD, respectively) in the presence of the other organism at a high concentration.

The organisms were obtained from ATCC with titers of organisms expressed in IFU/mL for CT and CFU/mL for NG. The organisms were then quantified by qPCR in copies/uL, allowing for converting the original stock concentrations into copies/uL units. For the purpose of harmonizing the concentration units across all analytical studies the IFU and CFU concentrations were converted into Genome Equivalents (GE).

Reproducibility Samples Target Concentrations

Target Concentration	Expected Positivity Rate	CT GE/mL	NG GE/mL
LOW Positive (1x LoD)	~ 95%	769.3	212.3
MOD Positive (3x LoD)	100%	2307.9	636.9
HIGH Positive	100%	4.15×10^6	8.4×10^5

The results from the reproducibility study, expressed as percent agreement with expected results per site and overall, are shown below.

Reproducibility of binx *io* CT/NG Test System with Male Urine

Panel No.	Sample	Analyte	Site 1		Site 2		Site 3		Overall Agreement	
			No. Detected	% Agreement	No. Detected	% Agreement	No. Detected	% Agreement	No. Detected	% Agreement
1	CT: NEG NG: HIGH	CT	30	100.0	30	100.0	29	96.7	89	**98.9**
		NG	30	100.0	30	100.0	30	100.0	90	**100.0**
2	CT: NEG NG: MOD	CT	30	100.0	30	100.0	30	100.0	90	**100.0**
		NG	30	100.0	30	100.0	30	100.0	90	**100.0**
3	CT: NEG NG: LOD	CT	29	96.7	30	100.0	30	100.0	89	**98.9**
		NG	28	93.3	29	96.7	28	93.3	85	**94.4**
4	CT: HIGH NG: NEG	CT	30	100.0	30	100.0	30	100.0	90	**100.0**
		NG	30	100.0	30	100.0	30	100.0	90	**100.0**
5	CT: MOD NG: NEG	CT	29	96.7	30	100.0	30	100.0	89	**98.9**
		NG	30	100.0	30	100.0	30	100.0	90	**100.0**
6	CT: LOD NG: NEG	CT	28	93.3	25	83.3	29	96.7	82	**91.1**
		NG	30	100.0	30	100.0	30	100.0	90	**100.0**
7	CT: HIGH NG: HIGH	CT	30	100.0	30	100.0	30	100.0	90	**100.0**
		NG	30	100.0	30	100.0	30	100.0	90	**100.0**
8	CT: HIGH NG: LOD	CT	30	100.0	30	100.0	30	100.0	90	**100.0**
		NG	29	96.7	28	93.3	29	96.7	86	**95.6**
		CT	30	100.0	30	100.0	28	93.3	88	**97.8**

9	**CT: LOD NG: HIGH**	NG	30	100.0	30	100.0	30	100.0	90	**100.0**
10	**CT: LOD NG: LOD**	CT	26	86.7	30	100.0	28	93.3	84	**93.3**
		NG	27	90.0	30	100.0	28	93.3	85	**94.4**
11	**CT: NEG NG: NEG**	CT	28	93.3	30	100.0	30	100.0	88	**97.8**
		NG	30	100.0	30	100.0	30	100.0	90	**100.0**

The results were also analyzed separately for each organism.

There were four panel members that were negative for CT (360 total measurements), three panel members that were Low Positive (at LoD) for CT (270 total measurements), one panel member that was moderate positive (3x LoD) for CT (90 total measurements), and two panel members that were high positive ($1x10^4$ IFU/mL) for CT (180 total measurements).

Reproducibility of binx *io* CT/NG for *C. trachomatis* with Male Urine Samples

Sample	Site 1		Site 2		Site 3		Overall Agreement	
	No. Detected	Agreement	No. Detected	Agreement	No. Detected	Agreement	No. Detected	Agreement
CT NEG	117/120	97.5%	120/120	100%	119/120	99.2%	354/360	98.3%
CT LOW Positive	84/90	93.3%	85/90	94.4%	85/90	94.4%	254/270	94.1%
CT MOD Positive	29/30	96.7%	30/30	100%	30/30	100%	89/90	98.9%
CT High Positive	60/60	100%	60/60	100%	60/60	100%	180/180	100%

The number of individual results for each of the concentration levels for NG were the same as outlined above for CT.

Reproducibility of binx *io* CT/NG for *N. gonorrhoeae* with Male Urine Samples

Sample	Site 1		Site 2		Site 3		Overall Agreement	
	No. Detected	Agreement	No. Detected	Agreement	No. Detected	Agreement	No. Detected	Agreement
NG NEG	120/120	100%	120/120	100%	120/120	100%	360/360	100%
NG LOW Positive	84/90	93.3	87/90	96.7	85/90	94.4	256/270	94.8
NG MOD Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%
NG High Positive	60/60	100%	60/60	100%	60/60	100%	180/180	100%

The study demonstrated adequate reproducibility of the binx *io* CT/NG Test when testing male urine samples.

2. Linearity:

Not Applicable.

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 copies/equivalents (GE)/mL.

The LoD of the assay for vaginal swab samples was established under K191352.

The determination of LoD with male urine samples was conducted in a similar manner as that for female vaginal swab samples. The quantified stocks, as described above, were diluted in pooled male urine to target a range of concentrations (50 to 356 copies per test for CT for CT and 15-77 copies per test 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 claimed LoD for each CT serovar and NG strain was set as the highest value generated from the two reagent batches and of the two tested serovars/strains. The results from the LoD study are summarized in the table below.

Summary of LoD Study Results for binx *io* CT/NG Assay in Male Urine Samples

Organism	Cartridge Lot	Claimed LoD (GE/mL)	Verification Study Result	
			POS/No. tested	% Detection
CT serovar E (ATCC-VR-348B)	Lot 1	467.08	38/40	95%
	Lot 2	485.32	38/40	95%
CT serovar F (ATCC-VR-346)	Lot 1	**769.28***	39/40	97.5%
	Lot 2	600.44	38/40	95%
NG strain (ATCC 49226)	Lot 1	104.92	39/40	97.5%
	Lot 2	125.60	39/40	97.5%
NG strain (ATCC 700825)	Lot 1	145.02	38/40	95%
	Lot 2	**212.30****	40/40	100%

*Claimed LoD for CT

**Claimed LoD for NG

The final claimed LoD concentrations are shown below in GE/mL; the concentrations are also shown in IFU/ml (Inclusion Forming Units/mL) for CT and CFU/mL (Colony Forming Units/mL) for NG, based on the concentrations stated on the Certificates of Analysis for the stocks used in the study.

Claimed LoD for binx health *io* CT/NG Assay in Male Urine Samples

Organism	Serovar/Strain	GE/mL	IFU/mL	CFU/mL
C. trachomatis	Serovar E (ATCC-VR-348B)	485.3	6.6	N/A
	Serovar F (ATCC-VR-346)	769.3	0.3	N/A
N. gonorrhoeae	Strain 1 (ATCC 49226)	125.6	N/A	1.1

	Strain 2 (ATCC 700825)	212.3	N/A	2.5

4. Analytical Reactivity (inclusivity)

Analytical reactivity and inclusivity of the binx *io* CT/NG assay when used with male urine samples was evaluated using panels of multiple CT serovars and NG strains diluted in pooled male urine.

Fourteen CT serovars, including the nvCT (Swedish variant), were extracted and quantified in DNA copies using qPCR. The quantified organisms were then spiked into male urine at the concentration established as LoD, which is 769.3 for CT. Each serovar dilution was tested with the binx CT/NG assay in 20 replicates. Those serovars that tested positive in 19 or 20 replicates were further diluted to 0.5x LoD and tested in further 20 replicates. All the serovars tested were detected by the binx CT/NG assay at the claimed LoD of 769.33 GE/mL, or below at 384.6 GE/mL. The results of the study are shown below.

***C. trachomatis* Serovars - Limit of Detection in Male Urine**

CT Serovar	% Detected 1x LoD (769.3 GE/mL)	% Detected 0.5x LoD (384.6 GE/mL)	Claimed LoD GE/mL
A	100	100	384.6
B	100	100	384.6
Ba	100	100	384.6
C	100	100	384.6
D	100	100	384.6
G	100	85	769.3
H	95	90	769.3
I	100	95	384.6
J	100	100	384.6
K	100	90	769.3
L1	100	75	769.3
L2	100	100	384.6
L3	100	90	769.3
nvCT	100	95	384.6

Reactivity of the binx *io* CT/NG assay for NG was evaluated with 30 unique NG strains (including two fluoroquinolone resistant isolates) which were extracted and quantified in DNA copies using qPCR. Each strain was spiked into pooled male urine at 1x the LoD and tested in 3 replicates with the binx *io* CT/NG assay. Of the 30 NG strains tested, 16 strains were detected at 212.3 GE/mL (14 strains were positive in 3/3 replicates and 2 strains were positive in ≥19/20). Thirteen strains were tested at 5x LoD and were detected at 1,061.0 GE/mL in ≥19/20 replicates. One strain (NG California 201304 #1) was subjected to a Probit LoD study which yielded a detection level of 553.38 GE/mL, confirmed by a verification study (40/40 replicates detected using two lots of cartridges). The results of the inclusivity study are shown below.

Reactivity of binx *io* CT/NG Assay with Various NG Strains in Male Urine

NG Strain	No. detected at 1X LoD	No. detected at 5X LoD	Reported Detectable Level (GE/mL)
Alabama 201301 #06	3/3	N/A	212.3
Alabama 201310 #01	6/10	20/20	1,061
California 201302 #03	3/3	N/A	212.3
California 201302 #06	3/3	N/A	212.3
California 201304 #01	2/10	17/20	553.4[1]
California 201307 #02	3/3	N/A	212.3
California 201301 #10	19/20	N/A	212.3
California 201301 #12	3/3	N/A	212.3
California 201302 #10	3/3	N/A	212.3
California 201303 #14	17/20	19/20	1,061
California 201310 #04	8/10	20/20	1,061
Maryland 201301 #01	3/3	N/A	212.3
Maryland 201301 #02	7/10	20/20	1,061
Alabama 201310 #05	8/10	20/20	1,061
Maryland 201309 #21	5/10	20/20	1,061
Maryland 201311 #16	1/3	20/20	1,061
North Carolina 201302 #10	3/3	N/A	212.3
Pennsylvania 201301 #10	3/3	N/A	212.3
Pennsylvania 201301 #25	3/3	N/A	212.3
Pennsylvania 201312 #28	17/20	20/20	1,061
Virginia 201304 #01	3/3	N/A	212.3
Virginia 201305 #01	8/10	20/20	1,061
ATCC 19424	7/10	20/20	1,061
ATCC 31426	3/3	N/A	212.3
ATCC 43070	19/20	N/A	212.3
ATCC 49498	3/3	N/A	212.3
NG (UK 8454 R1)[2]	7/10	20/20	1,061
NG (UK 9155 R2)[2]	3/3	N/A	212.3
NG (UK 9156 S1)[3]	8/10	20/20	1,061
ATCC 19999	1/3	20/20	1,061

[1]As determined by Probit analysis
[2]Fluoroquinolone resistant mutant strain
[3]Fluoroquinolone sensitive mutant strain

Additionally, a bioinformatic review was carried out following the identification of a new serovar 'Finnish serovar E' which confirmed that the binx *io* CT primers hybridize to an area of the genome distinct from the mutation. Due to the sporadic nature of the mutation and the lack of clinical samples available to culture this serovar, it is still not publicly available for experimental testing.

5. Analytical Specificity/Interference:

Cross-reactivity with other Microorganisms

The cross-reactivity of the binx *io* CT/NG Assay was evaluated by spiking pooled male urine in eNAT buffer with relevant bacteria, fungi, protozoa or viral organisms that may be present at the sampling site, e.g., commensal bacteria or genetically related species to *Chlamydia trachomatis* or *Neisseria gonorrhoeae.* The organisms were spiked at a concentration of 10^6 CFU/mL for bacteria and 10^5 PFU/mL for viruses, or 2 ng/mL of genomic DNA or DNA generated by reverse transcription. The test panel included *H. sapiens* DNA and multiple strains of Neisseria species. Each organism was tested in three replicates. All but two organisms generated expected results, i.e., negative for CT and NG in all 3 replicates; Herpes Simplex Virus 2 generated one false positive CT and *Corynebacterium xerosis* generated one false positive NG result. No additional false positive results were obtained upon additional testing of these organisms in 17 replicates (for a total of one false positive in 20 replicates). This may indicate potential cross-reactivity and is disclosed in the product labeling. The test panel also included *C. trachomatis and N. gonorrhoeae* which gave the expected positive result for CT and NG, respectively.

Additionally, potential cross-reactivity of two organisms was assessed using *in silico* analysis: (a) a Blast search of the CT, NG1, NG2 and IC targets was performed against the published genome sequence of *Megasphaera* type 1 and (b) taxonomic analysis was carried out for BVAB-2 (there is no published genome for this organism). The *in silico* analysis demonstrated that neither of these organisms would be detected by the binx health *io* CT/NG Assay.

The organisms assessed in the cross-reactivity study are shown below.

Organisms Assessed for Cross-Reactivity with the binx *io* CT/NG Assay

*Bacteroides fragilis**	*N. meningitidis Serogroup D**
*Bacteroides ureolyticus**	*N. meningitidis Serogroup W135**
*Clostridium perfringens**	*N. meningitidis Serogroup Y**
Corynebacterium genitalium	*Neisseria cinerea*
Corynebacterium xerosis[2]	*Neisseria denitrificans*
Escherichia coli	*Neisseria elongata (4)*
*Gardnerella vaginalis**	*Neisseria gonorrhoeae**
*Haemophilus ducreyi**	*Neisseria flava*
Herpes simplex virus 1*	*Neisseria flavescens (3)*
*Homo sapiens**	*Neisseria lactamica (3)*
Human papilloma virus 16*	*Neisseria mucosa (4)*
Kingella denitrificans	*Neisseria perflava (2)*
Kingella kingae	*Neisseria polysaccharea*
Lactobacillus acidophilus	*Neisseria sicca (4) **
Lactobacillus brevis	*Neisseria subflava (2)*
Lactobacillus jensenii	*Trichomonas vaginalis*
Lactobacillus lactis	*Ureaplasma urealyticum**
Moraxella lacunata	*Ureaplasma parvum**

Staphylococcus epidermidis	*Atopobium vaginae**
Streptococcus agalactiae	*Bifidobacterium longum**
Candida albicans	*BVAB-2*†
Candida glabrata	*Enterococcus faecalis*
Candida parapsilosis	Herpes Simplex Virus 2*[1]
*Chlamydia pneumoniae**	*Klebsiella pneumoniae*
*Chlamydia psittaci**	*Megasphaera* type 1†
*Mycoplasma genitalium**	*Mobiluncus curtisii**
*Mycoplasma hominis**	*Mobiluncus mulieris**
*N. meningitidis Serogroup A**	*Peptostreptococcus anaerobius**
*N. meningitidis Serogroup B**	*Proteus mirabilis*
*N. meningitidis Serogroup C**	*Pseudomonas aeruginosa*
-	*Staphylococcus aureus*
-	*Chlamydia trachomatis**

(n) Number of strains tested * Organisms tested with genomic DNA (2 ng/mL) † *In silico* analysis

[1]Herpes Simplex Virus 2 may interfere with the CT assay (1 replicate (out of 20 tested) was positive for CT)
[2]*Corynebacterium xerosis* may interfere with the NG assay (1 replicate (out of 20 tested) was positive for NG)

Microbial Interference

The binx *io* CT/NG Assay was evaluated for interference from microorganisms that may be found in a urine sample. The study included 10 microorganisms which were added into pooled urine targeting a concentration of 10^5 CFU/mL. Subsequently, the urine samples were spiked with a low concentration (2x LoD) of CT Serovar F and one NG strain (ATCC 49226). A control set of urine samples spiked only with the potential interferent was also prepared to include in the testing with the binx *io* CT/NG Assay. Each sample was tested in three replicates. All samples containing CT, NG and the interferent were expected to generate positive results. All samples containing only the interferent organism were expected to yield negative results. All tests generated expected results, 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 in Male Urine Samples

		Interferent *plus* CT and NG		**Interferent *only***	
Interferent	**Concentration**	**CT Result**	**NG Result**	**CT Result**	**NG Result**
Corynebacterium xerosis	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected
Escherichia coli	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected
Lactobacillus acidophilus	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected
Lactobacillus brevis	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected
Lactobacillus jensenii	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected

Lactobacillus lactis	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected
Staphylococcus epidermidis	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected
Streptococcus agalactiae	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected
Candida albicans	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected
Candida glabrata	1 x 10^5 CFU/mL	Detected	Detected	Not Detected	Not Detected

Interference from Endogenous and Exogenous Substances

The binx *io* CT/NG Assay was evaluated for interference from substances that may be found in a urine sample. The study was designed in a similar manner as above where each potential interferent was added to a urine sample in the presence and absence of CT and NG at low positive concentrations, followed by testing with the binx *io* CT/NG Assay in 3 replicates. All tests generated expected results, except for Leukocytes which generated 1/3 false negative for NG on initial testing. Additional testing of 17 replicates yielded expected results for NG and for CT (19/20 detected for NG). Leukocytes will be listed in the IFU as a potential interferent.

Interfering Substances in Male Urine Samples

		Interferent *plus* CT and NG		**Interferent *only***	
Interferent	**Concentration**	**CT Result**	**NG Result**	**CT Result**	**NG Result**
Human blood	1% (v/v)	Detected	Detected	Not Detected	Not Detected
Seminal fluid	5% (v/v)	Detected	Detected	Not Detected	Not Detected
Mucin	0.5% (w/v)	Detected	Detected	Not Detected	Not Detected
Albumin (BSA)	10 mg/mL	Detected	Detected	Not Detected	Not Detected
Glucose	10 mg/mL	Detected	Detected	Not Detected	Not Detected
Bilirubin	0.2 mg/mL	Detected	Detected	Not Detected	Not Detected
Leukocytes*	1x10^6 cells/mL	Detected	Detected	Not Detected	Not Detected
Progesterone	7 mg/mL	Detected	Detected	Not Detected	Not Detected

β-Estradiol	0.25% (v/v) (Estrace cream)	Detected	Detected	Not Detected	Not Detected
Paracetamol	3.2 mg/mL	Detected	Detected	Not Detected	Not Detected
Aspirin	40 mg/mL	Detected	Detected	Not Detected	Not Detected

*Leukocytes generated 1/3 false negative for NG on initial testing. Additional testing of 17 replicates yielded expected results for NG and for CT (19/20 detected for NG).

6. Assay Cut-Off:

The details of the assay threshold determination have been previously described and may be found under K191352.

Briefly, the threshold values for each of the assay targets were determined by testing clinical swab and urine samples determined to be negative by three commercially available molecular tests and low positive-spiked negative clinical specimens. 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.

7. Carry-Over:

A study to evaluate the risk of cross-contamination from a high positive sample to a sample that sequentially follows testing was previously conducted in support of K191352. Briefly, 25 high positive samples (10^5 IFU/mL of CT serovar F and 10^5 CFU/mL of one NG strain in clinical matrix) and 25 negative samples were tested in alternating pattern in two sets (50 samples per set) on four separate *io* Instruments resulting in 200 total tests. 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. Assay Reportable Range:

Not applicable. The binx *io* CT/NG Assay is a qualitative assay.

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

Sample Stability

Stability of Male Urine after transfer to the Collection Tube

The stability of processed urine samples, i.e., urine transferred to the preservative buffer within the collection kits within 15 minutes of collection, was evaluated when stored at 25°C for 25 hours and at 2°-8°C for 8 days. The sponsor evaluated three batches of kits:

1. Current kits that have been received from Copan and stored at RT (control)

2. Kits previously stored at 4°C for 12 month and 32 days after the day of manufacture
3. Kits previously stored at 30°C for 12 month and 32 days after the day of manufacture

Each "batch" consisted of three manufacturing lots of the collection tubes. Positive samples were contrived by adding pooled male urine containing CT (serovar F) and NG (ATCC 49226) at a concentration of 4x LoD to each tube. There were 18 positive samples from Batch 2 and Batch 3 placed in storage for each of the designated conditions, for a total of 36 positive samples placed at 2°-8°C for 8 days and 36 positive samples placed at 25°C for 25 hrs. Batch 1, representing a "control", was evaluated with nine positive samples at each of the storage conditions. Two negative samples were included in each batch at each storage condition. All samples were tested immediately at t=0, then placed in the designated temperature chambers for the specified time period. The following table illustrates the study design and the number of replicates tested at each condition, for each batch of the collection kits.

Sample Stability in Collection Medium

	Batch 1		Batch 2		Batch 3	
	Current, stored at RT (Control)		Previously stored at 4°C		Previously stored at 30°C	
Storage Conditions	POS	NEG	POS	NEG	POS	NEG
	Number of Replicates Tested					
2°- 8°C for 8 days	9	2	18	2	18	2
25°C for 25 hours	9	2	18	2	18	2

All samples tested at the end of the designated storage interval yielded expected results. The study supports male urine sample stability in the collection medium, as claimed in the labeling:

- 24 hours if stored at room temperature (2°- 25°C)
- Seven days if stored refrigerated (2°- 8°C)

10. Invalid Results in Analytical Studies

There were 8,642 cartridges run in the analytical validation of the binx CT/NG assay when used with male urine, of which 2,097 were used for daily Quality Controls. There were 98 invalid results in total obtained across all the analytical studies, with an invalid rate of 1.12% (95% CI: 0.92%-1.36%).

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 when used with male urine samples was evaluated in a prospective study, with male patients enrolled at 10 individual clinical locations; testing with the binx *io* CT/NG assay was performed at nine of those sites. The participating testing sites, at various geographic 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. Comparator 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 1,157 of male participants between the ages of 17 and 76 (with the median age of 29 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, eight subjects were excluded due to ineligibility or withdrawal, leaving 1,149 subjects available for testing. Specimens from 136 participants were excluded from one clinical site due to deviations to the shipping protocol, and additional 91 subjects were excluded due to improper specimen handling issues (e.g., urine not aliquoted into the preservation medium within allowable time after collection, prolonged time in transit (shipped over a holiday), shipping temperature dropping below 2°C subjecting samples to freezing, etc.), leaving 922 subjects fully evaluable. There were 15 initial invalid results reported from testing male patients with the binx health *io* CT/NG Assay (15/937) for an overall invalid rate of 1.60% (95% CI: 0.97%-2.62%).

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

Excluded Samples

Exclusion Category from line list	Number excluded
Participant Ineligible	6
Participant Withdrew	2
Improper Specimen Collection (expired collection tubes)	4
Improper Testing with comparators (e.g., outside of sample stability window)	16
Shipping temperature outside specifications	56
Improper shipping (not following protocol)	136*
Specimen Handling	
Urine not transferred into collection tube within 15 minutes (per protocol)	10
Miscellaneous	4
Samples lost in transit	1
Total	235

*A deviation to the shipping protocol (incorrect packaging procedure) at one of the collection sites resulted in the exclusion of 136 samples. Because temperature monitoring was not used, as required by the procedure, it could not be determined whether the samples in question may have been subjected to freezing (the transport temperature must be > 2°C). The enrollment of patients was halted and re-training of the sites on the shipping procedure was conducted before the recruitment was re-started. As a result, all samples shipped from the one site, up to the date when the deviation was noted, were excluded from data analysis.

All male participants provided first catch urine samples for use in the study. Aliquots from a single first catch urine sample were transferred to the binx male collection kit tube and to each of the comparator buffer tubes.

The testing with the binx health *io* CT/NG Assay was performed by 27 operators (test users), of which 23 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.

Quality Control

External Quality Control samples (positive and negative) were run on each testing day. A total of 1175 control samples were run throughout the study; there was a total of 18 invalid results obtained from testing external QC samples.

Clinical Sensitivity and Specificity

The clinical performance of the binx health *io* CT/NG Assay when testing male subjects, 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 male urine. 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."

The clinical sensitivity and specificity of the binx *io* CT/NG Assay, when used with male urine samples, was calculated in comparison with the CIS comparator algorithm and is shown by symptom status for *C. trachomatis* and *N. gonorrhoeae* separately.

***C. trachomatis* Clinical Performance of binx health *io* CT/NG Assay with Male Urine**

Symptom Status	N	TP	FN	TN	FP	Sensitivity (95% CI)	Specificity (95% CI)
Asx	614	56	4	549	5	93.3% (84.1; 97.4)	99.1% (97.9; 99.6)
Sx	308	55	5	247	1	91.7% (81.9; 96.4)	99.6% (97.8; 99.9)
Total	922	111	9	796	6	92.5% (86.4; 96.0)	99.3% (98.4; 99.7)

Asx = Asymptomatic Sx Symptomatic
TP = True Positive; FN = False Negative; TN = True Negative; FP = False Positive
95% Confidence Intervals (CI) by Wilson's Score Method

N. gonorrhoeae Clinical Performance of binx health *io* CT/NG Assay with Male Urine

Symptom Status	N	TP	FN	TN	FP	Sensitivity (95% CI)[1]	Specificity (95% CI)[1]
Asx	614	11	1	602	0	91.7% (64.6; 98.5)	100% (99.4; 100)
Sx	308	61	1	246	0	98.4% (91.4; 99.7)	100% (98.5; 100)
Total	**922**	**72**	**2**	**848**	**0**	**97.3% (90.7; 99.3)**	**100% (99.5; 100)**

Asx = Asymptomatic; Sx Symptomatic
TP = True Positive FN = False Negative; TN = True Negative; FP = False Positive
95% Confidence Intervals (CI) by Wilson's Score Method

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

Chlamydia trachomatis Frequency of Test Outcomes, by Symptom Status in Male Urine

CIS	Comparator Test Results			binx *io* Result	Symptom Status		Total
	NAAT1	NAAT2	NAAT3		Sx	Asx	
NI	-	-	-	-	243	542	785
NI	-	-	+	-	0	3	3
NI	-	+	-	-	0	0	0
NI	+	-	-	-	0	1	1
NI	-	-	IND	-	2	1	3
NI	-	IND	-	-	1	0	1
NI	IND	-	-	-	1	2	3
NI	-	-	-	+	1	5	6
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
NI	-	-	-	IND	0	0	0
NI	-	-	+	IND	0	0	0
NI	-	+	-	IND	0	0	0
NI	+	-	-	IND	0	0	0
NI	-	-	IND	IND	0	0	0
NI	-	IND	-	IND	0	0	0
NI	IND	-	-	IND	0	0	0
		Total Not Infected			**248**	**554**	**802**
I	+	+	+	+	54	56	110
I	+	+	-	+	0	0	0
I	+	-	+	+	0	0	0
I	-	+	+	+	0	0	0
I	+	+	IND	+	0	0	0
I	+	IND	+	+	0	0	0
I	IND	+	+	+	1	0	1
I	+	+	+	-	3	3	6
I	+	+	-	-	1	0	1
I	+	-	+	-	1	0	1
I	-	+	+	-	0	1	1
I	+	+	IND	-	0	0	0
I	+	IND	+	-	0	0	0
I	IND	+	+	-	0	0	0
I	+	+	+	IND	0	0	0

I	+	+	-	IND	0	0	0
I	+	-	+	IND	0	0	0
I	-	+	+	IND	0	0	0
I	+	+	IND	IND	0	0	0
I	+	IND	+	IND	0	0	0
I	IND	+	+	IND	0	0	0
		Total Infected			**60**	**60**	**120**

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

Neisseria gonorrhoeae Frequency of Test Outcomes, by Symptom Status in Male Urine

CIS	Comparator Test Results			binx *io* Result	Symptom Status		Total
	NAAT1	NAAT2	NAAT3		Sx	Asx	
NI	-	-	-	-	241	594	835
NI	-	-	+	-	1	4	5
NI	-	+	-	-	0	0	0
NI	+	-	-	-	1	2	3
NI	-	-	IND	-	2	1	3
NI	-	IND	-	-	1	0	1
NI	IND	-	-	-	0	1	1
NI	-	-	-	+	0	0	0
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
NI	-	-	-	IND	0	0	0
NI	-	-	+	IND	0	0	0
NI	-	+	-	IND	0	0	0
NI	+	-	-	IND	0	0	0
NI	-	-	IND	IND	0	0	0
NI	-	IND	-	IND	0	0	0
NI	IND	-	-	IND	0	0	0
		Total Not Infected			**246**	**602**	**848**
I	+	+	+	+	59	10	69
I	+	+	-	+	0	0	0
I	+	-	+	+	0	0	0
I	-	+	+	+	0	0	0
I	+	+	IND	+	0	0	0
I	+	IND	+	+	0	0	0
I	IND	+	+	+	2	1	3
I	+	+	+	-	0	1	1
I	+	+	-	-	0	0	0
I	+	-	+	-	1	0	1
I	-	+	+	-	0	0	0
I	+	+	IND	-	0	0	0
I	+	IND	+	-	0	0	0
I	IND	+	+	-	0	0	0
I	+	+	+	IND	0	0	0
I	+	+	-	IND	0	0	0
I	+	-	+	IND	0	0	0

I	-	+	+	IND	0	0	0
I	+	+	IND	IND	0	0	0
I	+	IND	+	IND	0	0	0
I	IND	+	+	IND	0	0	0
		Total Infected			**62**	**12**	**74**

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

Prevalence at the Clinical Collection Sites (based on the Comparator Results)

Site	Clinic Type	US State	N	Chlamydia trachomatis	Pos/N	Neisseria gonorrhoeae	Pos/N
1	STD	IN	89	27%	(24/89)	18%	(16/89)
2	STD	MD	125	8.8%	(11/125)	10.4%	(13/125)
3	STD	LA	258	15.5%	(40/258)	7%	(18/258)
4	HIV	MS	12	16.7%	(2/12)	0%	(0/12)
5	Planned Parenthood	TX	127	14.2%	(18/127)	4.7%	(6/127)
6	Planned Parenthood	PA	33	12.1%	(4/33)	3.0%	(1/33)
7	STD	AL	59	16.9%	(10/59)	13.6%	(8/59)
8	HIV	CA	181	5.5%	(10/181)	5%	(9/181)
9	STD	NC	9	0%	(0/9)	22.2%	(2/9)
10	STD	MS	29	3.4%	(1/29)	3.4%	(1/29)
		Total	**922**	**13.0%**	**(120/922)**	**8.0%**	**(74/922)**

The hypothetical predictive values, based on the performance estimates observed in the study, are shown below.

Hypothetical Positive and Negative Predictive Values for binx *io* CT/NG for Male Urine

	Chlamydia trachomatis			***Neisseria gonorrhoeae***		
Hypothetical Prevalence	***Binx CT/NG* Sens./Spec**	**% PPV 95% CI**	**% NPV 95% CI**	***Binx CT/NG* Sens./Spec**	**% PPV 95% CI**	**% NPV 95% CI**
1%	92.5%/99.3%	57.2% 33.3%-78.1%	99.9% 99.4%-100%	97.3%/100%	100% 70.0-100%	100% 99.5%-100%
2%	92.5%/99.3%	72.9% 52.7%-86.7%	99.8% 99.3%-100%	97.3%/100%	100% 82.4%-100%	99.5% 99.5%-100%

	Chlamydia trachomatis			*Neisseria gonorrhoeae*		
Hypothetical Prevalence	***Binx CT/NG* Sens./Spec**	**% PPV 95% CI**	**% NPV 95% CI**	***Binx CT/NG* Sens./Spec**	**% PPV 95% CI**	**% NPV 95% CI**
5%	92.5%/99.3%	87.4% 75.3%-94.1%	99.6% 98.9%-99.9%	97.3%/100%	100% 92.1%-100%	99.9% 99.3%-100%
10%	92.5%/99.3%	93.6% 86.6%-97.1%	99.2% 98.3%-99.6%	97.3%/100%	100% 95.9%-100%	99.7% 99.0%-99.9%
15%	92.5%/99.3%	95.9% 91.0%-98.2%	98.7% 97.6%-99.3%	97.3%/00%	100% 97.2%-100%	99.5% 98.7%-99.8%
20%	92.5%/99.3%	97.1% 93.4%-98.7%	98.1% 96.9%-98.9%	97.3%/00%	100% 97.9%-100%	99.3% 98.4%-99.7%
25%	92.5%/99.3%	97.8% 94.8%-99.1%	97.5% 96.1%-98.5%	97.3%/00%	100% 98.3%-100%	99.1% 98.1%-99.6%

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 males during the clinical study, testing male urine samples, are shown below.

Binx *io* CT/NG Assay Positivity Rates in Males (observed during 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		IN	89	22	24.7%	16	18.0%
2	STD		MD	125	11	8.8%	12	9.6%
3	STD		LA	258	38	14.7%	18	7.0%
4	HIV		MS	12	2	16.7%	0	0%
5	Planned Parenthood		TX	127	19	15.0%	6	4.7%
6	Planned Parenthood		PA	33	4	12.1%	1	3.0%
7	STD		AL	59	9	15.3%	7	11.9%
8	HIV		CA	181	11	6.1%	9	5.0%
9	STD		NC	9	0	0%	2	22.2%
10	STD		MS	29	1	3.4%	1	3.4%
			Total	**922**	**117**	**12.7%**	**72**	**7.8%**

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 variable operational scenarios when used outside of the laboratory environment with 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

A study was conducted to evaluate the effect of varied environmental conditions on the performance of the assay. 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 *io* Instrument manual specifies the range of operational conditions as 10°C-35°C and 0%-80% RH. A typical ambient working environment is expected to be 20°C-25°C and 20%-60% RH.

The study was executed by placing the *io* Instruments in monitored environmental chambers held at a range of temperatures and humidity levels that were outside the typical expected Instrument operating range. Positive test samples were prepared in eNAT buffer with CT and NG concentrations at 4x LoD. Negative samples consisted of eNAT buffer. The instruments were equilibrated to its environment for a minimum of 15 minutes, after which the samples were transferred into the cartridges and processed by the instruments within the chambers; each sample was tested in three replicates at each of the conditions. The results demonstrated that the System performs reliably at or near the specified ranges of temperature and humidity. The results are summarized below.

Operational Environment

Temperature	Relative Humidity	Expected Results	% Correct Results	Expected Results	% Correct Results
		Positive Samples		Negative Samples	
9°C	40%	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
37°C	40%	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
22°C	83%	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
30°C	83%	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
20°C	15%	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%

Open Pack Stability

This study evaluated the effect of environmental conditions on the assay performance when the sample is added to the cartridge, but the testing is delayed.

Positive and negative samples, prepared as in the study above, were added to the cartridges which were then placed in controlled incubators set at 30°C for a specified time interval. Each sample was tested in three replicates at each of the conditions. In addition, a set of cartridges loaded with samples was incubated at 30°C for 6 hours under controlled humidity, both low (≤ 20% RH) and high (≥ 60% RH).

The table below shows the conditions tested and the results which demonstrate that a delay in testing, after sample addition to the cartridge, is not affected by exposure to 30°C in both high and low humidity conditions following up to six hours of storage.

Sample Stability within Cartridge

Length of Exposure to 30°C	Humidity	Expected Results	% Correct Results	Expected Results	% Correct Results
		Positive Samples		Negative Samples	
1 hour	Ambient	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
2 hours	Ambient	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
3 hours	Ambient	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
4 hours	Ambient	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
5 hours	Ambient	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
6 hours	Ambient	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
6 hours	≥ 60% RH	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%
6 hours	≤ 20%	CT Detected/ NG Detected	100%	CT Not Detected/ NG Not Detected	100%

Performance with "Cold" Cartridges

A study was conducted to demonstrate that binx *io* CT/NG Cartridges and/or samples can be run immediately following storage in a refrigerator. For this study, all cartridges, and urine samples had been stored at 2-8°C for a minimum of 12 hours prior to testing. The test samples using pooled male urine samples that had either been stored at room temperature for 12 hours or stored refrigerated at 2-8°C for a minimum of 12 hours. Each sample was tested in 3 replicates. All tests gave expected results. The study results support the statement in the package insert that the cartridges do not need to equilibrate to RT prior to testing.

Shipping Stability

A shipping stability study for cartridges was conducted in-house by simulating conditions that may occur during transport, in particular temperature cycling. Test samples were prepared in eNAT buffer spiked with CT and NG organisms at 4x LoD.

The cartridges were stored for 5 days at 25°C, then subjected to two cycles of the following conditions:

- 9 hours at 10°C
- 6 hours at 25°C Two cycles
- 2 hours at 35°C
- 7 hours at 25°C

Following the two cycles, 40 cartridges were used to test 20 positive and 20 negative samples.ll tests expected results. The data indicates that the cartridges remain unaffected by repeated changes (cycles) in temperature, within the temperature range tested.

Additionally, 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. The details of the study and the results can be found under K191352.

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.