510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K230267

B Applicant

NeuMoDx Molecular, Inc.

C Proprietary and Established Names

NeuMoDx CT/NG Assay 2.0

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QEP	Class II	21 CFR 866.3393 - Device To Detect Nucleic Acids From Non-Viral Microorganism(S) Causing Sexually Transmitted Infections And Associated Resistance Marker(S)	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

NeuMoDx Molecular, Inc submitted a Traditional 510(k) to obtain market clearance for the distribution and/or use of a new device called NeuMoDx CT/NG Assay 2.0, on the NeuMoDx 96 Molecular System and NeuMoDx 288 Molecular System.

Measurand:

Chlamydia trachomatis and/or *Neisseria gonorrhoeae* DNA.

B Type of Test:

Nucleic acid amplification assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The NeuMoDx CT/NG Assay 2.0, as implemented on the NeuMoDx 96 Molecular System and NeuMoDx 288 Molecular System, is an automated, qualitative test for the direct detection and differentiation of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA as an aid in the diagnosis of chlamydial and gonococcal urogenital disease in symptomatic and asymptomatic individuals. The Assay utilizes real-time Polymerase Chain Reaction (PCR) and may be used to test male and female urine, and self-collected vaginal swab specimens (collected in a clinical setting).

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
For in vitro diagnostic use.

IV Device/System Characteristics:

A Device Description:

The NeuMoDx CT/NG Assay 2.0 is an automated *in vitro* diagnostic test which aims at providing direct detection of CT and/ or NG DNA from asymptomatic and symptomatic patient specimens.

- The assay utilizes real-time polymerase chain reaction (PCR) for the amplification of CT and/or NG DNA and fluorogenic target- specific TaqMan probes for the detection of the amplified DNA.
- Results are interpreted with pre-established decision criteria.
- The assay is implemented on NeuMoDx 96 Molecular System (N96) and NeuMoDx 288 (N288) Molecular System PCR instruments which deliver complete automation from initial steps of specimen lysis to final steps of amplicon detection and aims to provide complete sets of results in 8 hours.
- Each of the instruments, N96 and N288, consists of XPCR modules, liquid/cartridge/plate workstation, extraction plate module, liquid reagent module, barcode scanner, PC with touch screen interface, power system and enclosure. These systems also utilize sample racks, rack trays and other accessories.

The NeuMoDx System consists of assay-specific test strip, consumables, reagents, accessories, analyzers, and software. The following components, consumables and reagents are required with NeuMoDx CT/NG Assay 2.0

- NeuMoDx CT/NG Test Strip 2.0 (included with assay) - contains ambient-temperature stable PCR reagents which are required for the amplification of CT/NG and SPC1 nucleic acids.

- NeuMoDx Extraction Plate required for cell lysis, protein degradation, nucleic acid binding, and process monitoring.

- NeuMoDx Cartridge incorporates a proprietary microfluidic design and facilitates nucleic acid extraction and purification, as well as PCR amplification and detection.

- NeuMoDx Lysis buffer 2 helps lyse bacterial targets in human urogenital specimens.

- NeuMoDx Wash Reagent.

- NeuMoDx Release Reagent.

B Principle of Operation:

The NeuMoDx CT/NG Assay 2.0 is a nucleic acid-based test using real-time polymerase chain reaction (PCR) technology to determine the presence of CT and/ or NG. A proprietary paramagnetic bead technology is employed for efficient nucleic acid capture from lysed urine and swab specimens. Following extraction, DNA is subjected to real-time PCR to determine the presence of CT and NG. detection, and reporting of results.

C Instrument Description Information:

1. Instrument Name:

   - NeuMoDx 288 Molecular System
   - NeuMoDx 96 Molecular System

2. Specimen Identification:

   By hand-held barcode reader or automated barcode reader and positional checks.

3. Specimen Sampling and Handling:

   Fully automated

4. Calibration:

   Not Applicable

5. Quality Control:

   - Internal Sample Processing Control: This monitors the efficacy of the entire test process including nucleic acid extraction and real-time PCR amplification.

- External Controls: 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):

Aptima Combo 2 Assay (Panther System)

B Predicate 510(k) Number(s):

K190515

C Comparison with Predicate(s):

Device & Predicate Device(s):	k230267	k190515
Device Trade Name	NeuMoDx CT/NG Assay 2.0	Aptima Combo 2 Assay (Panther System)
General Device Characteristic Similarities and Differences		
Intended Use/Indications for Use	The NeuMoDx CT/NG Assay 2.0, as implemented on the NeuMoDx 96 Molecular System and NeuMoDx 288 Molecular System, is an automated, qualitative test for the direct detection and differentiation of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA as an aid in the diagnosis of chlamydial and gonococcal urogenital disease in symptomatic and asymptomatic individuals. The Assay utilizes real-time Polymerase Chain Reaction (PCR) and may be used to test male and female urine, and self-collected vaginal	The Aptima Combo 2 Assay is a target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of ribosomal RNA (rRNA) from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) to aid in the diagnosis of chlamydial and/or gonococcal disease using the Panther System as specified. On the Panther System, the assay may be used to test the following specimens from symptomatic and asymptomatic individuals: clinician- collected endocervical, vaginal, throat, rectal and male urethral swab specimens,

	swab specimens (collected in a clinical setting).	clinician-collected gynecological specimens collected in the PreservCyt Solution, patient- collected vaginal swab specimens[1], and female and male urine specimens. [1]Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Aptima Multitest Swab Specimen Collection Kit has not been evaluated for home use.
Assay principle	Real-time PCR	Target Capture (TC), Transcription- Mediated Amplification (TMA), Hybridization Protection Assay (HPA)
Instrumentation	NeuMoDx 288 Molecular System and NeuMoDx 96 Molecular System	Panther System
Analyte targets	CT cryptic plasmid DNA CT *OMP*-putative porin gene NG *OPC*- opacity gene	*Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) rRNA
Amplification technology	Real-time PCR	Target Capture (TC), Transcription- Mediated Amplification (TMA), Hybridization Protection Assay (HPA)
Test interpretation	Automated test interpretation	Same
Controls	External positive and negative controls Internal sample process control	External positive and negative controls
Organism detected	*Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*	Same
Specimen type	**Female specimens:** • Vaginal self-	**Female specimens:** • Vaginal swab

	collected swab (collected in a clinical setting) • Urine **Male Specimens:** • Urine	• Endocervical swab • Gynecological specimens in PreservCyt solution • Urine • Throat swab • Rectal swab **Male Specimens:** • Urethral swab • Urine • Throat swab • Rectal swab

VI Standards/Guidance Documents Referenced:

- 21 CFR 866.3393: Device to detect nucleic acids from non-viral microorganism(s) causing sexually transmitted infections and associated resistance marker(s)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-Laboratory Precision

The within-laboratory precision of the NeuMoDx CT/NG 2.0 Assay was evaluated at NeuMoDx internal facility using N96 and N288 systems. Panel members were created by spiking CT and NG into pooled negative, urine specimen and UVT-transport medium for swab samples. Six panel members for each organism were prepared in negative matrix. Testing was performed using three of each instrument over 12 days with 2 runs per day and 3 replicates of each CT/NG panel member per run. The results were evaluated for overall % agreement with expected results. Additionally, the standard deviation and % coefficient of variation (CV) was calculated for each component of variability (repeatability, between-run, between days, within systems, between systems, within laboratories and overall/total) for each panel member are shown in tables 1 and 2.

Table 1. NeuMoDx CT/NG Assay 2.0 Within-Laboratory Precision for CT

		Vaginal Swabs									
		Overall				**SD (% CV)**					
Panel Member (Conc)		No. of Correct/Total No. of Tested	Avg Ct	% Agreement **	95% CI	Repeatability	Between Run	Between Day	Within System	Between System	Within Lab
Moderate CT	N96	216/216	29.7	100	98.2-100.0	0.614 (2.1)	0.191 (0.6)	0.0 (0.0)	0.643 (2.2)	0.104 (0.3)	0.651 (2.2)
	N288	216/216	29.6	100	98.2-100.0	0.733 (2.5)	0.0 (0.0)	0.303 (1.0)	0.793 (2.7)	0.099 (0.3)	0.799 (2.7)
Low CT*	N96	432/432	31.7	100	99.1-100.0	0.771 (2.4)	0.196 (0.6)	0.0 (0.0)	0.795 (2.5)	0.115 (0.4)	0.803 (2.5)
	N288	431/431	31.7	100	99.1-100.0	0.771 (2.4)	0.08 (0.3)	0.193 (0.6)	0.799 (2.5)	0.133 (0.4)	0.810 (2.6)
High Negative CT	N96	36/218	N/A	16.5	12.7-22.3	N/A					
	N288	31/216	N/A	14.4	10.3-19.6	N/A					
True Negative CT	N96	215/216	N/A	99.5	97.4-99.9	N/A					
	N288	217/217	N/A	100	98.3-100.0	N/A					
		Urine									
		Overall				**SD (% CV)**					
Panel Member		No. of Correct/Total No. of Tested	Avg Ct	% Agreement **	95% CI	Repeatability	Between Run	Between Day	Within System	Between System	Within Lab
Moderate CT	N96	216/216	30.1	100	98.2-100.0	0.545 (1.8)	0.300 (1.0)	0.101 (0.3)	0.630 (2.1)	0.094 (0.3)	0.637 (2.1)
	N288	215/215	29.9	100	98.2-100.0	0.702 (2.3)	0.079 (0.3)	0.117 (0.4)	0.716 (2.4)	0.158 (0.5)	0.734 (2.5)
Low CT*	N96	432/432	32.0	100	99.1-100.0	0.648 (2.0)	0.294 (0.9)	0.108 (0.3)	0.720 (2.2)	0.056 (0.2)	0.722 (2.3)
	N288	216/216	31.9	100	98.2-100.0	0.641 (2.0)	0.096 (0.3)	0.128 (0.4)	0.666 (2.1)	0.0 (0.0)	0.666 (2.1)
High Negative CT	N96	31/215	N/A	14.4	10.2-20.0	N/A					
	N288	35/216	N/A	16.2	11.7-22.0	N/A					
True Negative CT	N96	214/215	N/A	99.5	97.4-99.9	N/A					
	N288	215/215	N/A	100	98.2-100.0	N/A					

Note: Repeatability = Between Replicates, Avg= Average, SD= Standard Deviation, CV= Coefficient of Variation, CI= Confidence Interval, * Low level data pooled from two panel members, ** Agreement with expected results.

Table 2. NeuMoDx CT/NG Assay 2.0 Within-Laboratory Precision for NG

		Vaginal Swabs									
		Overall				**SD (% CV)**					
Panel Member		No. of Correct/Total No. of Tested	Avg Ct	% Agreement **	95% CI	Repeatability	Between Run	Between Day	Within System	Between System	Within Laboratory
Moderate NG	N96	216/216	27.3	100	98.2-100	0.528 (1.9)	0.166 (0.6)	0.0 (0.0)	0.553 (2.0)	0.014 (0.1)	0.554 (2.0)
	N288	216/216	27.2	100	98.2-100	0.643 (2.2)	0.128 (0.4)	0.108 (0.4)	0.664 (2.3)	0.049 (0.2)	0.666 (2.3)
Low NG*	N96	432/432	29.1	100	99.1-100	0.538 (1.8)	0.155 (0.5)	0.101 (0.3)	0.569 (2.0)	0.116 (0.4)	0.581 (2.0)
	N288	432/432	29.1	100	99.1-100	0.643 (2.2)	0.128 (0.4)	0.108 (0.4)	0.664 (2.3)	0.049 (0.2)	0.666 (2.3)
High Negative NG	N96	124/215	N/A	57.7	51.0-64.1	N/A					
	N288	121/216	N/A	56.0	49.3-62.5	N/A					
True Negative NG	N96	216/216	N/A	100	98.2-100	N/A					
	N288	216/216	N/A	100	98.2-100	N/A					
		Urine									
		Overall				**SD (% CV)**					
Panel Member		No. of Correct/Total No. of Tested	Avg Ct	% Agreement	95% CI	Repeatability	Between Run	Between Day	Within System	Between System	Within Laboratory
Moderate NG	N96	216/216	28.4	100	98.2-100.0	0.503 (1.8)	0.337 (1.2)	0.0 (0.0)	0.605 (2.1)	0.095 (0.3)	0.612 (2.1)
	N288	216/216	28.3	100	98.2-100.0	0.491 (1.7)	0.191 (0.7)	0.0 (0.0)	0.527 (1.9)	0.026 (0.1)	0.528 (1.9)
Low NG*	N96	432/432	30.0	100	99.1-100.0	0.648 (2.0)	0.294 (0.9)	0.0 (0.0)	0.614 (2.0)	0.073 (0.2)	0.618 (2.1)
	N288	431/432	30.0	99.8	98.2-100.0	0.680 (2.3)	0.0 (0.0)	0.210 (0.7)	0.712 (2.4)	0.134 (0.4)	0.724 (2.4)
High Negative NG	N96	69/215	N/A	32.1	26.0-38.8	N/A					
	N288	70/216	N/A	32.4	26.5-39.0	N/A					
True Negative NG	N96	216/216	N/A	100	98.2-100.0	N/A					
	N288	215/215	N/A	100	97.8-100.0	N/A					

Note: Repeatability = Between Replicates, Ave= Average, SD= Standard Deviation, CV= Coefficient of Variation, CI= Confidence Interval, * Low level data pooled from two panel members, ** Agreement with expected results.

Using urine as a representative matrix, the precision of the NeuMoDx CT/NG 2.0 Assay was evaluated at 1X and 2X of the confirmed LoD. Low positive CT and NG samples were processed on each of five days, along with a negative control sample, one on each N96 and N288 system, using three lots of the NeuMoDx CT/NG Test Strip 2.0. Each panel consisted of two replicates of CT at 1x LoD, two replicates of NG at 1x LoD, two replicates of 2x LoD of CT and NG together, and two negative control samples, resulting in 60 data points per target level per system across five days, for a total of 120 replicates per level across both systems. Summary of results are shown below in Tables 3 and 4.

Table 3. Precision of NeuMoDx CT/NG Assay 2.0 with Low-Positive CT and NG in Urine Samples

URINE											
System Level	Reagent Lot	CT (Serovar D)					NG (B5025)				
		n	Avg Ct	% Agreement (95% CI)**	SD	% CV	n	Avg Ct	% Agreement (95% CI)**	SD	% CV
N96	1x LoD CT	59 *	33.37	96.6% (88.5 -99.1%)	1.01	3.04	N/A				
	1x LoD NG	N/A					60	32.68	100% (94.0-100.0%)	0.66	2.01
	2x LoD CT/ NG	60	33.05	100% (94.0- 100.0%)	0.84	2.55	60	31.89	100% (94.0-100.0%)	0.54	1.71
N288	1x LoD CT	60	33.70	100% (94.0-100.0%)	0.62	1.85	N/A				
	1x LoD NG	N/A					59 *	32.66	100% (93.9-100.0%)	0.48	1.46
	2x LoD CT/NG	60	33.05	100% (94.0-100.0%)	0.66	2.00	60	32.01	100% (94.0-100.0%)	0.50	1.57

Note: Avg= Average, SD= Standard Deviation, CV= Coefficient of Variation

*1 replicate was invalid, ** Agreement with expected results

Table 4. Precision of NeuMoDx CT/NG Assay 2.0 with Low-Positive CT and NG in Urine Samples by Reagent Lot

URINE												
System	Level	Reagent Lot	CT (Serovar D)					NG (B5025)				
			n	Avg Ct	% Agreement (95% CI)**	SD	% CV	n	Avg Ct	% Agreement (95% CI)**	SD	% CV
N96	1x LoD	1	20	33.36	90.0% (69.9-97.2%)	1.28	3.83	20	32.86	100% (83.9-100.0%)	0.48	1.45
		2	20	33.21	100% (83.9-100.0%)	1.03	3.11	20	32.53	100% (83.9-100.0%)	0.60	1.84
		3	19 *	33.54	100% (83.2- 100.0%)	0.68	2.04	20	32.75	100% (83.9-100.0%)	0.79	2.40
	2x LoD	1	20	33.17	100% (83.9-100.0%)	0.86	2.59	20	31.87	100% (83.9-100.0%)	0.52	1.62
		2	20	32.68	100% (83.9-100.0%)	0.73	2.22	20	31.69	100%	0.58	1.83

										(83.9-100.0%)		
		3	20	33.32	100% (83.9-100.0%)	0.84	2.51	20	32.09	100% (83.9-100.0%)	0.48	1.51
N288	1x LoD	1	20	33.79	100% (83.9-100.0%)	0.7	2.07	20	32.79	100% (83.9-100.0%)	0.37	1.13
		2	20	33.51	100% (83.9-100.0%)	0.47	1.41	19*	32.42	100% (83.2-100.0%)	0.48	1.49
		3	20	33.81	100% (83.9-100.0%)	0.66	1.56	20	32.75	100% (83.9-100.0%)	0.50	1.53
	2x LoD	1	20	32.97	100% (83.9-100.0%)	0.66	1.99	20	31.84	100% (83.9-100.0%)	0.54	1.68
		2	20	33.00	100% (83.9-100.0%)	0.45	1.36	20	32.00	100% (83.9-100.0%)	0.36	1.13
		3	20	33.86	100% (83.9- 100.0%)	0.75	2.20	20	32.18	100% (83.9- 100.0%)	0.55	1.71

Note: Avg= Average, SD= Standard Deviation, CV= Coefficient of Variation,
*1 replicate was invalid, ** Agreement with expected results.

Reproducibility

The between-laboratory reproducibility of the NeuMoDx CT/NG Assay 2.0 was conducted at two external sites and one internal site, by two operators on one N96 system and one N288 system, at each of the three sites. The study was conducted over 5 days, with 2 runs per day by 2 operators using individual lots of NeuMoDx strips. Six reproducibility panel members were prepared in pooled negative, urine specimen and UVT-transport medium for swab samples (Table 5). Panels were prepared to include varying LoD for each organism, in combination and one sample negative for both organisms, i.e., unspiked negative urine matrix or UTV for swab matrix. The variability between days, between runs, and within runs was calculated separately for each low and moderate positive panel member and is shown in Tables 5 and 6.

Table 5. NeuMoDx CT/NG Assay 2.0 Multi-site Reproducibility for CT

Vaginal Swabs										
			Overall			**SD (% CV)**				
Panel Member		No. of Correct/ Total No. of Tested	Avg Ct	% Agreement **	95% CI	Within Run	Between Run	Between Day	Between Site	Overall
Moderate CT	N96	90/90	29.4	100	95.9-100.0	0.63 (2.1)	0.15 (0.5)	0.22 (0.7)	0.23 (0.8)	0.69 (2.4)
	N288	90/90	29.4	100	95.9-100.0	0.56 (1.9)	0.0 (0.0)	0.0 (0.0)	0.38 (1.3)	0.64 (2.2)
Low CT*	N96	180/180	31.2	100	97.9-100.0	1.06 (3.4)	0.0 (0.0)	0.0 (0.0)	0.16 (0.5)	1.07 (3.4)
	N288	180/180	31.4	100	97.9-100.0	0. 60 (1.9)	0.0 (0.0)	0.11 (0.4)	0.35 (1.1)	0.67 (2.1)
High Negative	N96	77/90	N/A	85.6	76.9-91.4	N/A				
	N288	70/90	N/A	77.8	68.2-85.1	N/A				
True Negative	N96	90/90	N/A	100	95.9-100.0	N/A				
	N288	90/90	N/A	100	95.9-100.0	N/A				
Urine										
			Overall			**SD (% CV)**				
Panel Member		No. of Correct/ Total No. of Tested	Avg Ct	% Agreement **	95% CI	Within Run	Between Run	Between Day	Between Site	Overall
Moderate CT	N96	90/90	29.5	100	95.2-100.0	0.51 (1.7)	0.0 (0.0)	0.0 (0.0)	0.24 (0.8)	0.54 (1.8)
	N288	90/90	29.8	100	95.9-100.0	0.39 (1.3)	0.0 (0.0)	0.7 (0.2)	0.29 (1.0)	0.46 (1.5)
Low CT*	N96	180/180	31.0	100	97.9-100.0	0.71 (2.3)	0.12 (0.4)	0.02 (0.1)	0.37 (1.2)	0.78 (2.5)
	N288	180/180	31.4	100	97.9-100.0	0.62 (2.0)	0.0 (0.0)	0.0 (0.0)	0.21 (0.7)	0.64 (2.0)
High Negative	N96	88/90	N/A	97.8	92.3-99.4	N/A				
	N288	85/90	N/A	94.4	87.6-97.6	N/A				
True Negative	N96	179/180	N/A	99.4	96.9-99.9	N/A				
	N288	180/180	N/A	100	97.9-100.0	N/A				

Note: Avg= Average, SD= Standard Deviation, CV= Coefficient of Variation.
* Low level data pooled from two panel members, ** Agreement with expected results.

Table 6. NeuMoDx CT/NG Assay 2.0 Multi-site Reproducibility for NG

Vaginal Swabs										
			Overall			**SD (% CV)**				
Panel Member		No. of Correct/ Total No. of Tested	Avg Ct	% Agreement **	95% CI	Within Run	Between Run	Between Day	Between Site	Overall
Moderate CT	N96	90/90	27.6	100	95.9-100.0	0.64 (2.3)	0.0 (0.0)	0.22 (0.8)	0.11 (0.4)	0.67 (2.4)
	N288	90/90	27.7	100	95.9-100.0	0.50 (1.8)	0.0 (0.0)	0.19 (0.7)	0.35 (1.3)	0.60 (2.2)
Low CT*	N96	180/180	29.4	100	97.9-100.0	0.61 (2.1)	0.0 (0.0)	0.0 (0.0)	0.29 (1.0)	0.66 (2.2)
	N288	180/180	29.7	100	97.9-100.0	0.54(1.8)	0.0 (0.0)	0.04 (0.1)	0.40 (1.4)	0.63 (2.1)
High Negative	N96	42/90	N/A	46.7	36.7-56.9	N/A				
	N288	25/90	N/A	27.8	19.6-37.8	N/A				
True Negative	N96	180/180	N/A	100	97.9-100.0	N/A				
	N288	90/90	N/A	100	95.9-100.0	N/A				
Urine										
			Overall			**SD (% CV)**				
Panel Member		No. of Correct/ Total No. of Tested	Avg Ct	% Agreement **	95% CI	Within Run	Between Run	Between Day	Between Site	Overall
Moderate CT	N96	90/90	28.3	98	94.0-99.8	0.50 (1.8)	0.0 (0.0)	0.15 (0.5)	0.28 (1.0)	0.56 (2.0)
	N288	90/90	28.4	100	95.9-100.0	0.56 (1.9)	0.0 (0.0)	0.0 (0.0)	0.38 (1.3)	0.64 (2.3)
Low CT*	N96	180/180	30.0	100	97.9-100.0	0.51 1.7)	0.04 (0.1)	0.0 (0.0)	0.37 (1.3)	0.60 (2.0)
	N288	180/180	30.3	100	97.9-100.0	0.62 (2.0)	0.0 (0.0)	0.0 (0.0)	0.21 (0.7)	0.64 (2.0)
High Negative	N96	63/90	N/A	70.0	59.9-78.5	N/A				
	N288	85/90	N/A	94.4	87.6-97.6	N/A				
True Negative	N96	180/180	N/A	100	99.4-100.0	N/A				
	N288	180/180	N/A	100	97.9-100.0	N/A				

Note: Avg= Average, SD= Standard Deviation, CV= Coefficient of Variation.
* Low level data pooled from two panel members, ** Agreement with expected results.

Lot-to-lot reproducibility

Reproducibility between key NeuMoDx CT/NG Assay 2.0 reagent lots was evaluated using a three-member panel of CT and NG targets spiked at varied concentration into negative urine and vaginal swab/ UTV. Two runs of 10 replicates were conducted with each of the 3-reagent lot sets on two N288 systems, the results of which are shown below in Table 7.

Table 7. NeuMoDx CT/NG Assay 2.0 Inter-Lot Reproducibility Studies

Vaginal Swabs									
Lots	Panel Member	CT				NG			
		% Pos	Avg Ct	Ct SD	Ct % CV	% Pos	Avg Ct	Ct SD	Ct % CV
Lot Set #1	Negative	0 (0/40)	N/A			0 (0/40)	N/A		
	Moderate CT, Low NG	100 (40/40)	29.6	0.83	2.8	100 (40/40)	28.6	0.59	2.1
	Low CT, Moderate NG	100 (40/40)	31.4	0.84	2.7	100 (40/40)	27.0	0.58	2.1
Lot Set #2	Negative	0 (0/40)	N/A			0 (0/40)	N/A		
	Moderate CT, Low NG	100 (40/40)	29.7	0.59	2.0	100 (40/40)	28.8	0.52	1.8
	Low CT, Moderate NG	100 (40/40)	31.9	0.42	1.3	100 (40/40)	27.6	0.28	1.0
Lot Set #3	Negative	0 (0/41)	N/A			0 (0/40)	N/A		
	Moderate CT, Low NG	100 (40/40)	29.8	0.62	2.1	100 (40/40)	28.9	0.63	2.2
	Low Ct, Moderate NG	100 (40/40)	32.0	0.46	1.4	100 (40/40)	27.6	0.41	1.5
Total	Negative	0 (0/121)	N/A			0 (0/120)	N/A		
	Moderate CT, Low NG	100 (120/120)	29.7	0.69	2.3	100 (120/120)	28.8	0.59	2.1
	Low Ct, Moderate NG	100 (120/120)	31.8	0.66	2.1	100 (120/120)	27.4	0.51	1.8
Urine									
Lots	Panel Member	CT				NG			
		% Pos	Avg Ct	Ct SD	Ct % CV	% Pos	Avg Ct	Ct SD	Ct % CV
Lot Set #1	Negative	0 (0/40)	N/A			0 (0/40)	N/A		
	Moderate CT, Low NG	100 (40/40)	30.4	0.68	2.2	100 (40/40)	29.1	0.55	1.9
	Low CT, Moderate NG	100 (40/40)	32.2	0.98	3.1	100 (40/40)	27.6	0.62	2.2
Lot Set #2	Negative	0 (0/40)	N/A			0 (0/40)	N/A		
	Moderate CT, Low NG	100 (40/40)	30.0	0.85	2.8	100 (40/40)	29.0	0.78	2.7
	Low CT, Moderate NG	100 (40/40)	32.3	0.87	2.7	100 (40/40)	27.8	0.57	2.0
Lot Set #3	Negative	0 (0/41)	N/A			0 (0/40)	N/A		
	Moderate CT, Low NG	100 (40/40)	30.8	0.49	1.6	100 (40/40)	29.6	0.44	1.5
	Low Ct, Moderate NG	100 (40/40)	32.3	0.90	2.8	100 (40/40)	27.7	0.64	2.2

Total	Negative	0 (0/122)	N/A			0 (0/120)	N/A		
	Moderate CT, Low NG	100 (120/120)	30.4	0.76	2.5	100 (120/120)	29.2	0.64	2.2
	Low Ct, Moderate NG	100 (120/120)	32.2	0.91	2.8	100 (120/120)	27.7	0.64	2.3

Note: Avg= Average, Pos= Positive, SD= Standard Deviation, CV= Coefficient of Variation.

2. Linearity:

Not Applicable.

3. Analytical Specificity/Interference:

Cross-reactivity and Interference with other Microorganisms

NeuMoDx CT/NG Assay 2.0 was evaluated for cross-reactivity and microbial interference by spiking pooled urine and swab UVT media with relevant bacteria, fungi, 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 CT and/ or NG. The potential for cross-reactivity was evaluated with a panel of 143 microorganisms, using cultured organisms at high titers (0.02-0.03 McFarland standards) prepared in negative, pooled urine matrix and UVT medium (Table 8). These samples were then spiked with CT and NG at 3x LoD. Negative experimental control panels were prepared using negative urine and neat BD UVT, while positive experimental control panels were comprised of negative urine and BD UVT also spiked at 3x LoD. Each panel was tested in triplicate for each matrix type. No false positive results were obtained with CT and NG negative samples demonstrating no cross-reactivity. All pools tested in the presence e of CT and NG demonstrated no interference and yielded 100% detection for CT and NG in triplicate for both swab and urine matrix types. The table below lists all the organisms evaluated with the NeuMoDx CT/NG Assay 2.0.

Table 8: Microorganisms Evaluated for Cross-reactivity and Microbial Interference with the NeuMoDx CT/NG Assay 2.0

Bacteria/Fungi/ Viruses	**Bacteria/Fungi/ Viruses**	**Bacteria/Fungi/ Viruses**
Acinetobacter baumannii	*Kingella denitrificans*	*Peptostreptococcus productus*
Acinetobacter calcoaceticus	*Kingella kingae*	*Plesiomonas shigelloides*
Acinetobacter lwoffii	*Klebsiella oxytoca*	*Propionibacterium acnes*
Actinomyces israelii	*Klebsiella pneumoniae*	*Proteus mirabilis*
Actinomyces pyogenes	*Lactobacillus acidophilus*	*Proteus vulgaris*
Aerococcus viridans	*Lactobacillus brevis*	*Providencia stuartii*
Aeromonas hydrophila	*Lactobacillus crispatus*	*Pseudomonas aeruginosa*
Alcaligenes faecalis	*Lactobacillus jensenii*	*Pseudomonas fluorescens*
Bacillus subtilis	*Lactobacillus lactis*	*Pseudomonas putida*
Bacteriodes fragilis	*Lactobacillus oris*	*Rahnella aquatilis*

Bacteroides caccae	*Lactobacillus parabuchnerri*	*Rhizobium radiobacter*
Bacteroides ureolyticus	*Lactobacillus vaginalis*	*Rhodospirillum rubrum*
Bergeriella denitrificans	*Lactococcus lactis cremoris*	*Saccharomyces cerevisiae*
Bifidobacterium adolescentis	*Legionella pneumophila*	*Salmonella minnesota*
Bifidobacterium breve	*Listeria monocytogenes*	*Salmonella typhimurium*
Bifidobacterium longum	*Micrococcus luteus*	*Serratia marcescens*
Brevibacterium linens	*Mobiluncus mulieris*††	*Staphylococcus aureus*
Campylobacter jejuni	*Moraxella catarrhalis*	*Staphylococcus epidermidis*
Candida albicans	*Moraxella lacunata*	*Staphylococcus saprophyticus*
Candida glabrata	*Moraxella osloensis*	*Streptococcus agalactiae*
Candida krusei	*Morganella morganii*	*Streptococcus anginosus* (group C)
Candida parapsilosis	*Mycobacterium smegmatis*	*Streptococcus bovis*
Candida tropicalis	*Mycoplasma genitalium*†	*Streptococcus dysgalactiae*
Chlamydia pneumoniae††	*Mycoplasma hominis*†	*Streptococcus equinus*
Chromobacterium violaceum	*Neisseria cinerea* (strain 194)	*Streptococcus mitis* (F0392)
Citrobacter freundii	*Neisseria elongata*	*Streptococcus mutans* (serogroup A)
Clostridium perfringens	*Neisseria flavescens*	*Streptococcus pneumoniae*
Corynebacterium genitalium	*Neisseria lactamica*	*Streptococcus pyogenes*
Corynebacterium xerosis	*Neisseria meningitidis* (serogroup A)	*Streptococcus salivarius*
Cryptococcus neoformans	*Neisseria meningitidis* (serogroup B)	*Streptococcus sanguinis*
Deinococcus radiodurans	*Neisseria meningitidis (serogroup C)*	*Streptomyces griseus*
Derxia gummosa	*Neisseria meningitidis (serogroup D)*	*Trichomonas vaginalis*
Eikenella corrodens	*Neisseria meningitidis (serogroup WL35)*	*Ureaplasma urealyticum**
Elizabethkingia miricola††	*Neisseria meningitidis (serogroup Y)*	*Veillonella parvula*
Enterobacter aerogenes	*Neisseria mucosa*	*Vibrio parahaemolyticus*
Enterobacter cloacae	*Neisseria perflava (strain 28)*	*Weissella paramesenteroides*
Enterococcus avium	*Neisseria perflava (strain 7078)*	*Yersinia enterocolitica*
Enterococcus faecalis	*Neisseria perflava (strain 831F)*	cytomegalovirus**

Enterococcus faecium	*Neisseria polysaccharea*	epstein-Barr virus**
Erysipelothrix rhusiopathiae	*Neisseria sicca*	hepatitis B virus***
Escherichia coli	*Neisseria subflava*	*Flavobacterium meningosepticum*
Fusobacterium nucleatum	*Neisseria weaveri*	herpes simplex virus I**
Gardnerella vaginalis	*Pantoea agglomerans*	herpes simplex virus II**
Gemella haemolysans	*Paracoccus denitrificans*	human immunodeficiency virus 1***
Haemophilus ducreyi	*Peptoniphilus asaccharolyticus*	human papillomavirus 16††
Haemophilus influenzae	*Peptostreptococcus anaerobius*	human papillomavirus 18††
Neisseria subflava (strain CDN-1.7)	hepatitis C virus***	

* Tested at 1 x 10^6 CCU/mL, ** tested at 1 x 10^6 copies/mL, *** tested at 1 x 10^6 IU/mL, † tested at 1 x 10^6 CFU/mL, †† tested at 10 ng/mL purified DNA or RNA, CCU= color changing units, CFU= colony forming units.

Interference with Substances Potentially Present at the Anatomic Collection Site

The analytical performance of the NeuMoDx CT/NG Assay 2.0 was evaluated in the presence of a panel of potentially interfering substances that may be found in urogenital sites during urine or vaginal swab sample collection. Each potential interferent was spiked into pooled clinical, negative urine and pooled clinical negative vaginal swabs in UVT at clinically relevant concentrations indicated in Table 9. These samples were spiked with CT and NG at 3x LoD in urine or ≤ 3x LoD in pooled negative clinical swabs. All tests generated expected results with 100% detection of CT and NG, thereby demonstrating that the substances listed at the concentrations shown in the table below do not interfere with the performance of NeuMoDx CT/NG Assay 2.0.

Table 9: Endogenous/Exogenous Interfering Substances Tested

Substances in Urine	**CT**	**NG**
	Positive (pos/total)	**Positive (pos/total)**
7% Blood	4/4	4/4
PBMCs 10^5 Cells/mL	4/4	4/4
Acidic Urine pH 4.0	4/4	4/4
Alkaline Urine pH 9.05	4/4	4/4
Glucose 10.0 mg/mL	3/3*	3/3*
Albumin 10.5 mg/mL	4/4	4/4
Bilirubin 1.4 mg/dL	4/4	4/4
Progesterone Cream 7.5 mg/mL	4/4	4/4
Vagisil Deodorant Powder 3.6 mg/mL	4/4	4/4
Norforms Deodorant Supp. 2.8 mg/mL	4/4	4/4

Talcum Powder 12.0 mg/mL	4/4	4/4
Aspirin 40.0 mg/mL	4/4	4/4
Azithromycin 2.2 mg/mL	4/4	4/4
Doxycycline 4.5 mg/mL	4/4	4/4
Acetaminophen 3.8 mg/mL	4/4	4/4
5% Seminal Fluid	4/4	4/4

*One replicate was IND

Substances in Blood Concentration/Dosing Plan - Endogenous	**CT Positive (pos/total)**	**NG Positive (pos/total)**
Blood 3.5% v/v	4/4	4/4
Mucin (Saturated Swab)*	4/4	4/4
PBMCs 10^5 Cells/mL	4/4	4/4
Interference Samples- Concentration/Dosing Plan - Exogenous		
Seminal Fluid 25.1 mg/mL	4/4	4/4
Progesterone Cream 3.9 mg/mL	4/4	4/4
Vagisil Anti Itch Cream 3.9 mg/mL	4/4	4/4
Clotrimazole Vaginal Cream 6.3 mg/mL	4/4	4/4
Preparation H Hemorrhoidal Cream 6.9 mg/mL	4/4	4/4
Miconazole 37.1 mg/mL	4/4	4/4
Monistat 17.8 mg/mL	4/4	4/4
Abreva Cold Sore Cream 4.1 mg/mL	4/4	4/4

*Mucin dosed by swab from a 0.8% stock

4. Assay Reportable Range:

Not applicable

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

1. Internal Control

The full process internal control, Sample Process Control (SPC1), serves as both an extraction and PCR internal control. The primers and probe specific for SPC1 are included in each well of the NeuMoDx CT/NG Test Strip. The SPC1 target itself is encapsulated bacteriophage T7 that is incorporated into each well of the NeuMoDx Extraction Plate. The SPC1 is co-extracted with the DNA from each sample processed and enables monitoring of the performance of the entire test process (nucleic acid isolation and real-time PCR amplification/detection) and key process steps not monitored actively by the NeuMoDx Software. The NeuMoDx CT/NG Assay 2.0 incorporates the results of SPC1 amplification as part of the results processing algorithm.

2. External Controls

External controls are not provided with the NeuMoDx CT/NG Assay 2.0; however, testing of external positive and negative controls is recommended in the assay labeling. External controls should be tested in conformance with local, state, and/or federal regulations or accreditation requirements and each laboratory's standard quality control procedures.

3. Calibrators

Not Applicable.

4. Stability

The stability of urine and swab specimens was evaluated in an analytical study which used individual contrived positive samples in addition to negatives. Contrived positive CT/NG samples consisted of pooled negative clinical vaginal swabs and negative urine spiked with CT and NG at ≤3x LoD. Samples were stored onboard for up to 24 hours (h), or at 2-8°C for up to 7 days, before being processed separately on the N96 and N288. The positive samples remained positive and negative samples remained negative after storage at 2-8ºC up to 7 days and up to 8 h onboard N96 and N288 systems. The study results demonstrated no effect on stability of CT and NG detection and that urine and vaginal swab samples can be stored up to 7 days at 2-8ºC and up to 8 h when stored on NeuMoDx systems.

6. Detection Limit:

The limit of detection (LoD) of the NeuMoDx CT/NG Assay 2.0 on N96 and N288 was evaluated by testing spiked samples prepared in pooled negative clinical urine and vaginal swab matrix in UVT. The quantified stocks were diluted in pooled urine or swab matrix using a range of concentrations at five different levels (urine: 15 EB/mL to 0 EB/mL for CT and 2.5 cells/ mL to 0 cells/mL for NG; and vaginal swabs: 20 EB/mL to 0 EB/mL for CT and 5 cells/ mL to 0 cells/mL for NG). The LoD of the NeuMoDx CT/NG Assay 2.0 was initially estimated by testing separate dilutions of CT (serovar D) elementary bodies (EB) and NG (strain B5025) cells at five levels in both pooled clinical negative urine and vaginal swab matrix. Testing was performed on 20 replicates per level across multiple instruments, over three days, using three key reagent lots. The LoD is defined as the lowest concentration for each strain at which 95% (19/20) of replicates yield a positive result. Further testing included two CT Serovars (D, J) and two NG strains (B5025, NHI 1) for each system. The highest (least sensitive) LoD value was finalized by accepting the target level reaching ≥95% positivity for the assay across all system types and serovars/strains and reported as the final claimed LoD (Table 10).

Table 10. Claimed LoD of NeuMoDx CT/NG Assay 2.0 on N96 and N288 in CT serovars and NG strains

Specimen Type	***Chlamydia trachomatis*** **LoD (EB/ mL)**	***Neisseria gonorrhoeae*** **LoD (cells/ mL)**
Urine	7.08	0.68
Vaginal Swabs	12.54	0.87

Analytical Reactivity (Strain Inclusivity):

The ability of NeuMoDx CT/NG Assay 2.0 to detect 13 serovars of CT serovars, and 20 strains of NG was evaluated by spiking each of the serovars/strains into negative, pooled urine matrix and pooled UVT at within 2x claimed LoD concentrations. Each serovar or strain dilution was detected 100% with the NeuMoDx CT/NG 2.0 Assay in a minimum of 3 replicates. The CT serovars and NG strains tested in the study are listed in Table 11.

Table 11: Determination of Inclusivity for CT and NG on NeuMoDx CT/NG Assay 2.0

Chlamydia trachomatis Serovars	***Neisseria gonorrhoeae* Strains**
A	Strain 2686
B	MHD 446 [NCTC 10933]
Ba	ATCC 9793
C	Strain CDC Ng-98
E*	BDMS 8658 [CIP 104217]
F	83F0120 [DC-83-82]
H	Strain NCTC 8375 [B 5025]
I	Strain BDMS T4145 [CDC 83015965, Difco A0726] (Spectinomycin resistant)
K	Strain ODH 2915 [NCTC 10928]
LGV I	Strain 40836 (Uri)
LGV II	Strain B-1094
LGV III	Strain MHD 340 [NCTC 10929]
G	83F0091 [HWD 4345]
	WHO V [CDC 78-63856]
	76.061782
	F-18 [89-018314, CDC 10,001, P935]
	Strain FA1090 (Streptomycin resistant)
	83F0120 [DC-83-82]
	Strain C-58 [D-10]
	Strain CDC Ng-116
	Strain GC/CB/001 [CDC M-2]

*E_{nv} (Swedish variant) was also evaluated and tested positive

Competitive Inhibition:

Due to potential of co-infection of CT and NG, where one target may be at a disproportionately higher concentration than the other (and adversely impact the detection of target at a lower concentration), detection of coinfection of CT at target levels near 3x LoD were chosen in the presence of competing co-infection of 10^6 cells/ mL NG, or for NG at target levels near 3x LoD in the presence of 10^6 EB/ mL CT. Competitive analyses revealed 100% detection of lower concentration pathogen in the presence of high concentration of competing pathogen. The results of the study demonstrated no impact to sensitivity for either target in combinations of high and low levels, respectively.

7. Assay Cut-Off:

Assay result from each test is determined by a cut-off based on the end point ratio (EPR), end point signal (EP), and cycle threshold (Ct). A test may be negative, positive, invalid, or unresolved as determined by these measurements for the detection of CT and NG DNA.

8. Accuracy (Instrument):

Not applicable.

9. Carry-Over:

A two-part analytical study was conducted on N96 and N288 to evaluate potential carryover contamination while performing a within and across run study. High-positive CT/NG samples were prepared with spiking pooled negative urine and neat UVT media at 10^6 EB/mL for CT and 10^6 cells/mL for NG. Negative samples were pooled negative urine or UVT without spiking with CT and NG. The first part of the study involved the processing of high positive CT/NG samples alternated with negative samples in an alternating, checkerboard arrangement. The second part of the study involved a full run of high positive samples processed in one run on an instrument followed by a full run of negative samples processed immediately after the high positive run across the same instrument. The study included 4 runs (2 alternating checkerboard, 1 positive followed by a negative run).

The overall carryover rate of the NeuMoDx CT/NG Assay 2.0 for urine and swab specimens on the N288 and N96 was 0% (100% agreement with expected results) when testing high titers of target concentration of CT and NG adjacent to negative samples processed within the same run or in alternate runs.

10. Matrix Equivalence:

A matrix equivalency study was conducted to demonstrate the equivalence of samples contrived in neat BD UVT used in analytical testing to samples collected in clinical negative vaginal swab matrix (collected in BD UVT) when testing with the NeuMoDx CT/NG Assay 2.0. Performance of each matrix was assessed in parallel using moderate positive (5x LoD), low positive (2x LoD), and negative samples.

CT/ NG targets were dosed together in positive samples. Negative samples consisted of only the matrix being evaluated. Each matrix was tested in replicates of n=10 at 5x LoD and n=30 at 2x LoD. Ten replicates were tested in each matrix lacking both analytes, in neat BD UVT and negative clinical vaginal swab matrix (collected in BD UVT).

The 5x LoD and 2x LoD level produced rates of 100% positivity in both the CT and NG targets. Negative samples in both matrices resulted in no amplification of the CT or NG targets, with valid negative results achieved at a rate of 100%. These results demonstrated matrix equivalency.

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 NeuMoDx CT/NG Assay 2.0 was evaluated in a prospective, multi-center study conducted at 14 collection sites. The participating testing sites, at geographically diverse locations across the U.S., included family practice, obstetrics/gynecology practice, public health clinics, STD and family planning clinics, college campus and teen clinics, and emergency room/urgent care locations. A single neat urine from each male and female subject and one self-collected vaginal swab (collected in a clinical setting) and two clinician-collected vaginal swabs were collected from each female subject. All evaluable samples were tested with the NeuMoDx CT/NG Assay 2.0 in accordance with package insert instructions for use. The samples were split between three external laboratories and tested on N96 and N288 systems. The comparator testing was performed at a separate reference laboratory.

A total of 4017 participants with a mean age of 31±10 years (median: 29; range:15–77 years) were enrolled in the study, including 1825 males and 2192 females. Among the 1825 males enrolled in the study, five participants were excluded after consent because of not meeting eligibility criteria (n=3), previous enrollment (n=1), or withdrawal owing to insufficient urine collection (n=1), which resulted in 1820 valid male participants. Among the 2192 females enrolled, 36 were excluded after consent, with reasons including ineligibility or unconfirmed eligibility (n=13), withdrawal from the study (n=4), and samples evaluable by the NeuMoDx CT/NG Assay 2.0 not collected (n=19), leaving 2156 females included in the study.

Of the remaining 1820 male participants, a male urine (MU) specimen was collected from each, but 119 specimens were excluded from analysis owing to protocol deviation, collection or instrument device events, and other specimen testing issues which prevented a final result from being obtained by NeuMoDx CT/NG Assay 2.0 or comparator method, which left data from a total of 1701 male subjects included in the study.

Of the 1701 MU specimens, for CT, there were 10 cases where either a valid NeuMoDx CT/NG Assay 2.0 result could not be determined (n=2) or where the PIS result could not be determined (n=8), therefore there were 1691 MU specimens included in the primary analysis of performance for CT. Similarly, for NG, there were 3 cases where a valid NeuMoDx CT/NG Assay 2.0 result could not be determined, therefore there were 1698 MU specimens included in the primary analysis of performance for NG.

Among the evaluable specimens collected from the 2156 female participants, 138 female urine (FU) specimens and 140 self-collected vaginal swab (SCVS) specimens (in a clinical setting) were excluded due to protocol deviations, collection device events, instrument device events, and other events which prevented a final result from being obtained by either NeuMoDx CT/NG Assay 2.0 or comparator, allowing for 2018 and 2016 female subject specimens to be included in the study for FU and SCVS respectively.

Of the 2018 FU specimens, there were 11 cases where a valid NeuMoDx CT/NG Assay 2.0 result could not be determined for the CT target and 12 cases where a valid result was not obtained for the NG target; therefore, there were 2007 FU specimens included in the primary analysis for CT and 2006 for NG.

Of the 2016 SCVS specimens, all produced valid results for CT and NG with the NeuMoDx CT/NG Assay 2.0 and comparator test; these subjects are included in the primary data analysis.

Clinical Sensitivity and Specificity

The clinical performance of the NeuMoDx CT/NG Assay 2.0 was assessed by comparing the test results obtained with the NeuMoDx CT/NG Assay 2.0 to a Patient Infected Status (PIS) for each subject. For female participants, the PIS was established from the results of FU and SCVS in a clinical setting tested by two FDA-cleared NAAT comparator assays. Females were classified as infected if at least one positive result was obtained by each assay. Any other combination of results was considered a non-infected status. Male subjects were classified as infected if both comparator urine NAAT results were positive. If the MU results were conflicting (*i.e.*, one positive and one negative), a third FDA-cleared NAAT method was performed as a tie-breaker to male PIS.

The clinical sensitivity and specificity of the NeuMoDx CT/NG Assay 2.0, when used with SCVS and urine specimens, was calculated in comparison with the PIS along with prevalence rates observed during the clinical study in the tables 12 and 13 below.

Table 12. NeuMoDx CT/NG Assay 2.0 Performance vs PIS for CT Detection

Specimen Type	Symptom Status	n	TP	FP	TN	FN	Prev.	Sensitivity (95% CI)	Specificity (95% CI)
SCVS	Asymp	1052	43	2	1007	0	4.1%	100.0% (91.8%, 100.0%)	99.8% (99.3%, 99.9%)
	Symp	964	58	7	896	3	6.3%	95.1% (86.5%, 98.3%)	99.2% (98.4%, 99.6%)
	All	**2016**	**101**	**9**	**1903**	**3**	**5.2%**	**97.1% (91.9%, 99.0%)**	**99.5% (99.1%, 99.8%)**
FU	Asymp	1054	40	1	1010	3	4.1%	93.0% (81.4%, 97.6%)	99.9% (99.4%, 100.0%)
	Symp	953	56	3	889	5	6.4%	91.8% (82.2%, 96.4%)	99.7% (99.0%, 99.9%)
	All	**2007**	**96**	**4**	**1899**	**8**	**5.2%**	**92.3% (85.6%, 96.1%)**	**99.8% (99.5%, 99.9%)**
MU	Asymp	1227	102	0	1123	2	8.5%	98.1% (93.3%, 99.5%)	100.0% (99.7%, 100.0%)
	Symp	464	82	1	377	4	18.5%	95.3% (88.6%, 98.2%)	99.7% (98.5%, 100.0%)
	All	**1691**	**184**	**1**	**1500**	**6**	**11.2%**	**96.8% (93.3%, 98.5%)**	**99.9% (99.6%, 100.0%)**

FU = Female Urine, SCVS = Self-Collected Vaginal Swab (in a clinical setting), MU = Male Urine, Prev. = Prevalence, Asymp= Asymptomatic, Symp=Symptomatic, TP = True Positive, FP = False Positive, TN = True Negative, FN = False Negative.

Table 13. NeuMoDx CT/NG Assay 2.0 Performance vs PIS for NG Detection

Specimen Type	Symptom Status	n	TP	FP	TN	FN	Prev.	Sensitivity (95% CI)	Specificity (95% CI)
SCVS	Asymp	1052	24	0	1028	0	2.3%	100.0% (86.2%, 100.0%)	100.0% (99.6%, 100.0%)
	Symp	964	20	2	941	1	2.2%	95.2% (77.3%, 99.2%)	99.8% (99.2%, 99.9%)
	All	**2016**	**44**	**2**	**1969**	**1**	**2.2%**	**97.8% (88.4%, 99.6%)**	**99.9% (99.6%, 100.0%)**
FU	Asymp	1053	22	0	1029	2	2.3%	91.7% (74.2%, 97.7%)	100.0% (99.6%, 100.0%)
	Symp	953	20	1	931	1	2.2%	95.2% (77.3%, 99.2%)	99.9% (99.4%, 100.0%)
	All	**2006**	**42**	**1**	**1960**	**3**	**2.2%**	**93.3% (82.1%, 97.7%)**	**99.9% (99.7%, 100.0%)**

MU	Asymp	1231	11	1	1219	0	0.9%	100.0% (74.1%, 100.0%)	99.9% (99.5%, 100.0%)
	Symp	467	81	1	384	1	17.6%	98.8% (93.4%, 99.8%)	99.7% (98.5%, 100.0%)
	All	**1698**	**92**	**2**	**1603**	**1**	**5.5%**	**98.9% (94.2%, 99.8%)**	**99.9% (99.5%, 100.0%)**

FU = Female Urine, SCVS = Self-Collected Vaginal Swab (in a clinical setting), MU = Male Urine, Prev. = Prevalence, Asymp= Asymptomatic, Symp=Symptomatic, TP = True Positive, FP = False Positive, TN = True Negative, FN = False Negative.

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Expected Values

The spread 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 rate of the NeuMoDx CT/NG Assay 2.0 in females and males during the clinical study are shown below in Table 14.

Table 14. NeuMoDx CT/NG Assay 2.0 Positivity Rate for CT and NG Detection by Clinical Sites

	Chlamydia trachomatis % Positivity rate			***Neisseria gonorrhoeae*** % Positivity rate		
Study Site	**SCVS**	**MU**	**FU**	**SCVS**	**MU**	**FU**
1	9.72	15.43	8.92	4.17	17.24	4.23
2	11.11	5.26	0.0	0.0	10.53	0.0
3	3.53	N/A	3.53	2.35	N/A	2.35
4	7.19	11.59	5.98	3.70	7.30	3.30
5	2.54	11.84	2.56	1.69	9.21	1.71
6	2.78	10.04	2.86	0	7.34	0
7	8.73	19.55	9.21	3.06	4.55	3.08
8	5.99	16.67	6.06	1.80	1.67	1.82
9	0.88	2.12	0.59	1.18	0.42	0.88
10	4.61	13.74	4.57	0.46	1.53	0.46
11	0.0	3.45	0.0	0.0	0.0	0.0
12	7.69	13.64	7.69	0.0	4.55	0.0
13	0.0	5.71	0.0	0.0	0.0	0.0
14	2.25	2.99	1.14	0.0	1.49	0.0
All sites	**5.46**	**11.01**	**4.98**	**2.28**	**5.54**	**2.14**

N/A- Samples not enrolled at site.

Indeterminate or Unresolved Result Rates

Invalid (indeterminate or unresolved) rates were calculated for each of the N96 and N288 systems, and for combined. Among all specimen types, instrument models, targets, and symptom status, 1/5738 (0.0%; 95% CI 0.0% to 0.1%) were Indeterminate (IND) and 12/5738 (0.2%; 95% CI 0.1% to 0.4%) were Unresolved (UNR).

VIII Proposed Labeling:

The labeling is acceptable and 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.