Datasheet
binx *io* Platform – CT/NG

FDA 510(k) cleared | Rapid | Easy to Use | Central Laboratory Performance

Technology	Rapid PCR combined with proprietary electrochemical detection
Regulatory designation	FDA 510(k) cleared Moderately complex with point of care designation CLIA-Waiver anticipated soon
Targets	Chlamydia (CT) genomic DNA, single target and gonorrhea (NG) genomic DNA, dual target • CT: evaluated against a panel of 15 serovars, including the new or Swedish variant (nvCT) • NG: evaluated against a panel of 32 different strains including strains from WHO, geographically diverse clinical isolates and strains with known mutations
Specimen types	**Female vaginal swab** • Clinician-collected • Self-collected by a patient in a clinical setting **Male first-catch urine** All specimen types are cleared for asymptomatic and symptomatic patients
Hands-on time	<1 minute
Precision pipetting	Not required
Turnaround time	~30 minutes
Results	Easy to understand qualitative results with no interpretation required (Detected/Not Detected output for CT/NG)

Clinical performance

	Female		Male	
Target	Sensitivity	Specificity	Sensitivity	Specificity
Chlamydia	96.1%	99.1%	92.5%	99.3%
Gonorrhea	100.0%	99.9%	97.3%	100.0%

Limit of Detection (LoD)

Genome equivalents/mL		
Organism	**Vaginal swab specimens**	**Male urine specimens**
CT serovar E (ATCC-VR-348B)	407.4	484.3
CT serovar F (ATCC-VR-346)	755.5	769.3
NG strain ATCC 49226	245.6	125.6
NG strain ATCC 700825	206.1	212.3

External controls	Commercially available through ZeptoMetrix (NATtrolTM Cat Nos. NATCT(434)-6MC, NATNG-6MC)
Internal controls	Included
Preventative maintenance	Not required
Calibration	Not required
Platform specifications	0.9 ft x 0.9 ft x 1.2 ft (H x W x D) 22.5 lbs
Cartridge storage	Refrigerated cartridge storage; ambient cartridge storage coming soon
Instrument storage	Ambient temperature
CPT Codes	Chlamydia: 87491 - Gonorrhea: 87591
Tests in development, including:	*Trichomonas vaginalis, Mycoplasma genitalium,* and SARS-CoV-2

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.

510(k) clearance does not constitute approval by FDA of a device.