The first CLIA-Waived molecular point-of-care solution for the rapid detection of chlamydia & gonorrhea

Rapid | Easy to Use | Central Laboratory Performance

Problem

- Approximately 50% of eligible women seen in a healthcare setting are not screened for chlamydia (CT) and gonorrhea (NG) in accordance with CDC guidelines

  Reference: Khosropour CM et al. Sex Transm Dis. 2014;41(11):665-670

- 19% rise in CT and 63% rise in NG since 2013 in the US

  Reference: CDC (2018)

- Current CT/NG testing pathways may cause suboptimal outcomes due to potential inappropriate empiric treatment, limited patient compliance, and delay in treatment as patients can wait up to 10 days for laboratory results

  Reference: Wingrove I et al. Sex Transm Inf. 2014; 90(6):474

Solution: The binx *io* Platform

- First ever FDA 510(k), CLIA-Waived CT/NG molecular test for males and females, enabling same-visit diagnosis and treatment
- Gives results comparable to a laboratory-based test for chlamydia and gonorrhea in about 30 minutes rather than days or weeks

  Reference: FDA - March 2021

- Easy to use desktop-sized instrument that can be operated by non-laboratory trained personnel in CLIA-Waived settings
- Potential financial benefits for your healthcare practice

binx *io* brings central lab equivalent performance for chlamydia & gonorrhea to CLIA-Waived point of care (POC) Settings

» Ultra-rapid polymerase chain reaction (PCR) combined with proprietary electrochemical detection enabling sensitivity and specificity equivalent to central lab performance

» With CLIA Waiver, the binx *io* expands access to laboratory-based quality testing in near-patient settings holding CLIA-certificates of waiver such as primary care offices, urgent cares, community clinics, emergency rooms, and retail pharmacies

Clinical Performance

» 2,445 person (1,523 females; 922 males) multi-center clinical study

» Clinical performance measured against three FDA cleared standard-of-care molecular platforms

	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%

As published in JAMA Network Open
Van Der Pol, B. et al. Evaluation of the Performance of a Point-of-Care Test for Chlamydia and Gonorrhea. JAMA Network Open 3(5) (2020): e204819

Established guidelines for CT/NG testing combined with reimbursement enables a new clinic revenue stream

Billable with established CPT codes

Chlamydia Test **87491** & Gonorrhea Test **87591**

or

Infectious Agent, Multiple Organisms **87801 | 87801-QW**

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.

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