binx *io* Point-of-Care System

FDA 510(k) Cleared | Fully Automated | Easy to Use | Central Laboratory Performance

Overview

- World's first and fastest rapid, FDA cleared, molecular point of care device platform for chlamydia and gonorrhea (CT/NG)
- Intended for use in point-of-care or clinical laboratory settings
- Designed to be 24-plex capable and widely extensible to other applications
- Single-use, assay-specific cartridge containing all reagents required to process female vaginal swab samples (no sample prep required);
- Internal quality control included, external controls commercially available
- Intuitive touch-screen operation; screen prompts start the test, no further user interaction necessary; fully automated
- Easy to understand results with no interpretation required (Detected/Not Detected output for CT/NG)
- No calibration or preventative maintenance necessary
- Ambient temperature cartridge storage
- Revenue opportunity for clinical practice

Sample Type

- Self- or clinician-collected vaginal swab in a clinical setting

Rapid Single-Visit Results

~30 min

Clinical Performance

In a 1,523 person, multi-center clinical study, 96% of patient samples processed on binx *io* by non-laboratorians pivotal in POC setting

Target	Sensitivity	Specificity
Chlamydia	96.1%	99.1%
Gonorrhea	100.0 %	99.9%

**Clinical performance measured against 3 standard of care molecular platforms.*

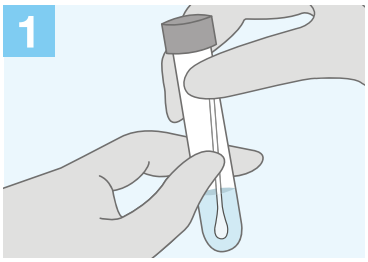
Regulatory Designations

- FDA 510(k) cleared
- Easy-to-use; designed for CLIA-Waiver. CLIA-study completion anticipated 2H 2020
- Moderately complex with point-of-care designation. 96% of patient samples in our clinical study were processed by non-laboratorians and office staff

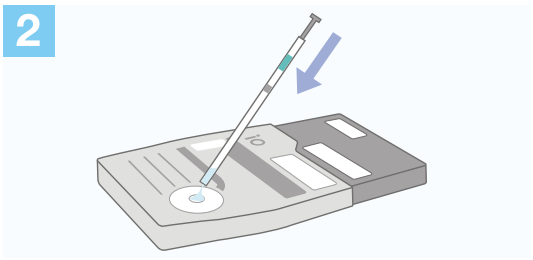
Device Specifications

Desktop size	10.91 in x 10.83 in x 15.12 in (H x W x D); 22.5 lbs	
Procurement options	- Instrument capital and cartridge purchase - Instrument placement under reagent rental	
Billable with established CPT codes	**CHLAMYDIA TEST** 87491	**GONORRHEA TEST** 87591

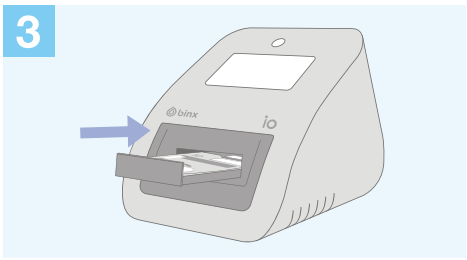
Processing Patient Samples is as Easy as 1, 2, 3



Collect: Place vaginal swab sample into specimen collection tube and shake



Prepare: Use the sample transfer pipet (included in the cartridge pouch) to transfer specimen from tube to cartridge



Test: Insert cartridge into *io* instrument and follow on screen prompts to get results in about 30 minutes

Published Evidence Supporting the binx io and Point-of-Care STI Testing

1. Widdice, Lea E., et al. "Performance of the Atlas Genetics Rapid Test for Chlamydia trachomatis and Women's Attitudes Toward Point-Of-Care Testing." *Sexually Transmitted Diseases.* 45.11 (2018): 723-727.
2. Turner, Katherine ME, et al. "An early evaluation of clinical and economic costs and benefits of implementing point of care NAAT tests for Chlamydia trachomatis and Neisseria gonorrhoea in genitourinary medicine clinics in England." *Sexually Transmitted Infection*. 90.2 (2014): 104-111.
3. Rönn, Minttu M., et al. "Potential for Point-of-Care Tests to Reduce Chlamydia-associated Burden in the United States: A Mathematical Modeling Analysis." *Clinical Infectious Diseases* (2019).
4. Rompalo, Anne M., et al. "Patterns of point-of-care test use among obstetricians and gynaecologists in the US." *Sexual Health.* 15.4 (2018): 318-324.

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