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

Problem

- 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

- COVID-19 continues to cause mass scale disruption to STD clinical services due to limited supplies and testing options for patients*

  Reference: *NCSD - Final Survey Report - May 2020

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

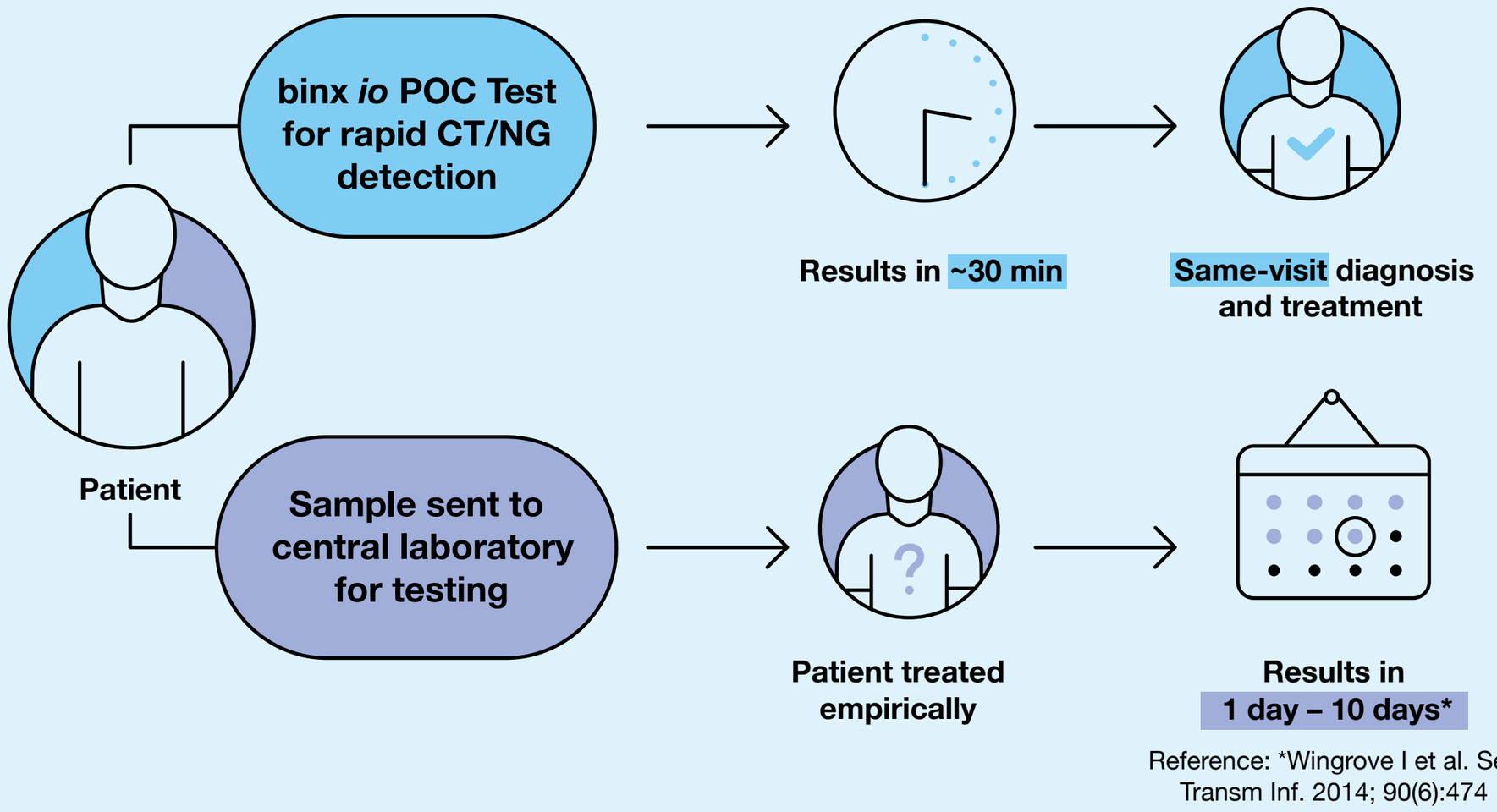
- Easy to use desktop-sized instrument that can be operated by non-laboratory trained personnel in CLIA-Waived settings
- Potential financial benefits for your healthcare practice

CLIA-Waived | Rapid | Easy to Use | Central Laboratory Performance

Impact on Patient Pathway

The *io* allows health care providers to provide diagnosis, a treatment plan, and counseling in a single patient visit*

Reference: *FDA - March 2021



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

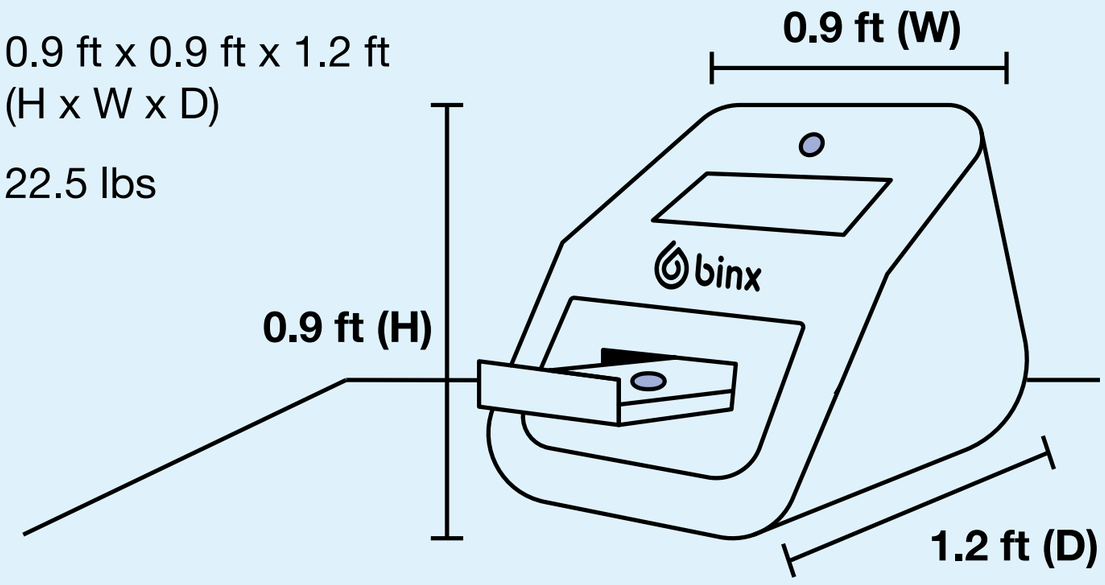
Sample Types

- Female vaginal swab
  - clinician-collected,
  - self-collected by a patient in a clinical setting
- Male first-catch urine
- Both sample types are cleared for **asymptomatic and symptomatic** patients

Platform Specifications

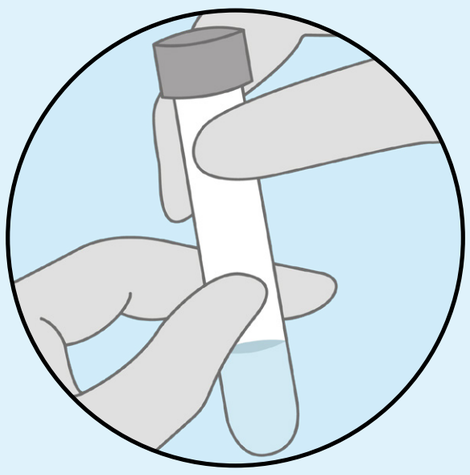
0.9 ft x 0.9 ft x 1.2 ft
(H x W x D)

22.5 lbs



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

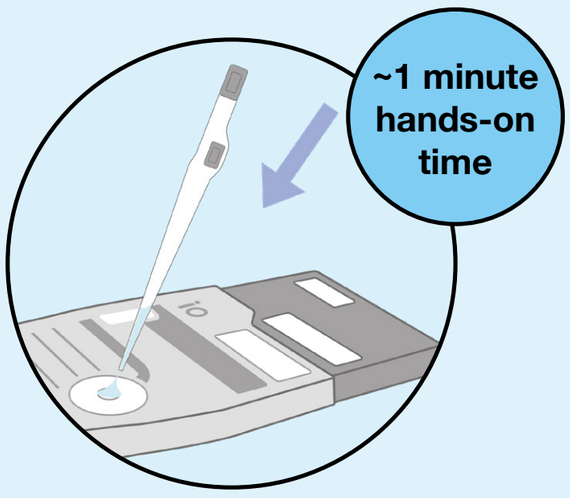
1



Collect sample

Vaginal swab or male first-catch urine

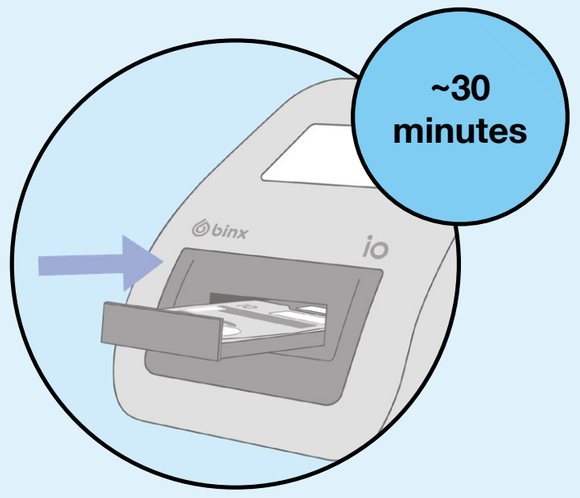
2



Prepare

Use the sample transfer pipet (included in the cartridge pouch) to transfer the sample from the collection tube to the cartridge

3



Prepare

Insert cartridge into *io* instrument and start the test. Actionable results will be ready in about 30 minutes

binx health *io* brings central lab equivalent performance for chlamydia & gonorrhea to CLIA-Waived POC Settings

- Ultra-rapid 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 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*

  *published in 2020 in JAMA Network Open
- 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	**INFECTIOUS AGENT, MULTIPLE ORGANISMS** 87801 | 87801-QW
Procurement options	Instrument capital and cartridge purchase Instrument placement under reagent rental		

Surgical Contact

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