Procedure for Performing the binx health *io*® *Chlamydia trachomatis / Neisseria gonorrhoeae* Test - CLIA Waived

Use of the binx health *io* CT/NG Cartridge for the qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA using the binx *io* Instrument

Please read these instructions in full before performing the test. Refer to the package insert for full information about this test. Refer to the *io* Instrument operator manual for instructions on how to use the *io* Instrument. A Certificate of Waiver is required to perform this test in a CLIA-waived setting. Failure to follow the manufacturer's instructions, or changing the instructions, will mean that the test will not meet the requirements for CLIA waiver.

Sample preparation

1

Remove the cartridge from the pouch. and place on a clean surface.

Do not press the perforated areas or the isolation valve.

1. Perforated areas (DO NOT PRESS)

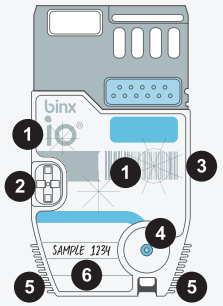
2. Isolation valve (DO NOT PRESS)

3. Barcode

4. Sample port

5. Handle here

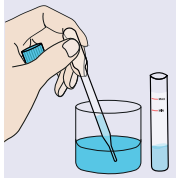
6. Space provided to label Cartridge



2 **Follow the steps below dependent on the type of specimen collected, either a male urine specimen or a female vaginal swab specimen**

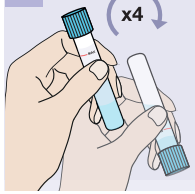
Male Urine Specimens

a



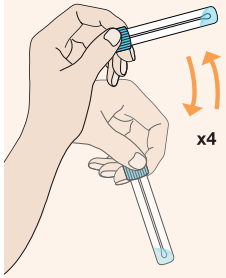
Using the provided Transfer Pipet transfer the urine to the collection tube. You will need to do this two times so that the liquid level is between the "min" and "max" lines on the tube.

b



Make sure the tube is tightly closed and mix the specimen by inverting four times.

Female Vaginal Swab Specimens



Make sure the tube is tightly closed. Hold the vaginal swab specimen tube by its cap and shake it four times downwards with quick movements of the wrist. This helps to make sure the specimen is released from the swab.

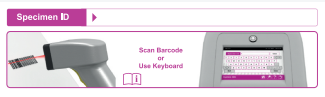
MAKE SURE THAT THE SPECIMEN IS FULLY MIXED BEFORE USE.

Running a Cartridge on the *io* Instrument

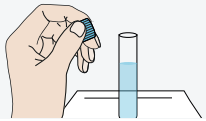
Turn the *io* Instrument on. Refer to the Instrument Operator Manual on how to log in. The *io* Instrument screen shows how to load the Cartridge and run the specimen.

3 On the touchscreen, select "Run/Cancel Test" from the *io* Instrument main menu.

4 Enter the Specimen ID using the touchscreen or by scanning a barcode on the sample tube.

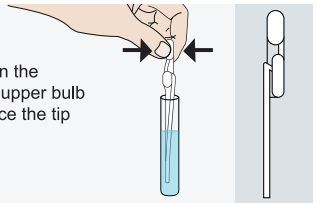


5 Remove the cap of the specimen tube.

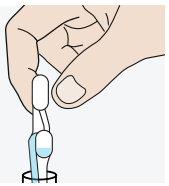


Transfer the sample from the collection tube to the sample port on the Cartridge using the Sample Transfer Pipet

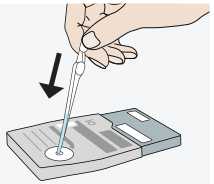
6 A Sample Transfer Pipet is supplied in the Cartridge pouch. Firmly squeeze the upper bulb of the Sample Transfer Pipet and place the tip into the specimen.



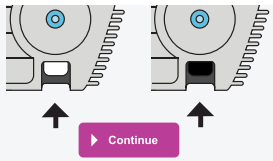
7 Keep the tip of the pipet in the specimen. Slowly release the bulb to fill the pipet. Excess liquid will flow into the lower overflow bulb.



8 As shown on the screen of the *io* Instrument, push the pipet tip into the center of the Cartridge sample port until the tip of the pipet touches the base of the port. Squeeze the upper bulb of the pipet slowly to empty all of the liquid in the shaft of the pipet into the Cartridge.

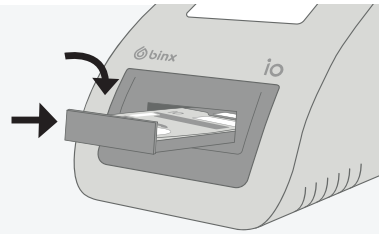


9 Check that the sample indicator has changed from white to black as shown on the *io* Instrument screen. Then select 'Continue' on the screen. If the indicator window does not turn black, load the sample onto a new Cartridge.

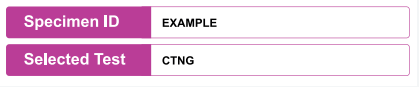


Insert the Cartridge and run test

10 The drawer will automatically open. Load the Cartridge into the Instrument drawer and push the drawer shut.



11 On the screen, check the test type (CT/NG assay) and specimen ID are correct.



12 Select "Run Test". The test will take about 30 minutes. The time left is shown on the *io* Instrument screen.

13 At the end of the test, select the "View Results" button and view the results on the screen.

14 The used Cartridge will be ejected from the *io* Instrument. Dispose of the Cartridge and used specimen collection kit in accordance with federal, state, or local requirements.

io Instrument Operating Conditions and Maintenance

The *io* Instrument must be be operated on a level surface between 10-35°C, 0-80% relative humidity. The Instrument requires no calibration or preventative maintenance. For routine cleaning of the Instrument (or in the case of spills) first disconnect the power then clean the outer casing using 70% isopropyl alcohol (isopropanol). If a specimen is spilled onto a Cartridge, clean the spill using a tissue and dispose of the tissue. If you suspect a sample leak inside the Instrument, disconnect the power and contact binx health technical support.

See the other side of this sheet for interpretation of results, warnings and precautions, specimen collection/handling and QC procedures.

For technical support call 1-844-MYBINX-1 (1-844-692-4691)

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Viewing Results

Specimen ID	EXAMPLE		
Test Type	CTNG	**Cartridge LOT**	97490000000
Test Result			

CT	DETECTED
NG	NOT DETECTED

Test results will show whether chlamydia (CT) and gonorrhea (NG) DNA are detected or not detected or if the test is invalid. An example of a CT positive/NG negative test result is shown above.

io CT/NG Assay Result	Interpretation
CT Not Detected **NG Not Detected**	Negative Test for chlamydia and gonorrhea. *DNA from chlamydia and gonorrhea was not detected.*
CT Detected **NG Not Detected**	Positive test for chlamydia, negative test for gonorrhea. *DNA from chlamydia was detected. DNA for gonorrhea was not detected.*
CT Not Detected **NG Detected**	Positive test for gonorrhea, negative test for chlamydia. *DNA for gonorrhea was detected. DNA from chlamydia was not detected.*
CT Detected **NG Detected**	Positive test for chlamydia and gonorrhea. *DNA from chlamydia and gonorrhea was detected.*
Test Invalid	The presence or absence of chlamydia and gonorrhea could not be determined. Repeat the test using the same patient specimen and a new cartridge*.
User Aborted	The assay was canceled by the user. No result is given. Repeat the test using the same patient specimen and a new cartridge*.
Error	A fault ocurred. Repeat the test using the same patient specimen and a new cartridge*.

*There is enough liquid in the specimen collection kit tubes to re-run a sample using a new Cartridge up to two additional times following “Test Invalid”, “User Aborted” or “Error” results. If three 'Test Invalid', 'User Aborted' or 'Error' results are obtained, obtain and test a new patient sample.

External Quality Control Procedure

External quality control materials are not provided with the test and need to be ordered separately. External quality control samples recommended are manufactured by ZeptoMetrix Corp., Buffalo, NY. There are two controls: a CT positive control (Cat. No. NATCT(434)-6MC) which also acts as a NG negative control and a NG positive control (Cat. No. NATNG-6MC) which also acts as a CT negative control. Controls should be shaken vigorously for five seconds before use. A control can then be loaded onto the *io* CT/NG Cartridge as if it were a patient sample, using the Sample Transfer Pipet. The external quality controls must be run whenever a new operator is introduced to the testing process or whenever a new lot of *io* CT/NG Cartridges is received. If the controls do not perform as expected, please contact binx on 1-844-MYBINX-1 (1-844-692-4691) or support@mybinxhealth.com.

Warnings and Precautions

1. For *in vitro* diagnostic use.
2. This Assay is for use with female vaginal swab and male urine specimens collected using the binx Vaginal Swab or Male Urine Specimen Collection Kits.
3. Do not use expired *io* CT/NG Cartridges.
4. Do not freeze male urine samples prior to use.
5. Do not use if the Cartridge packaging has been damaged, ruptured or opened for an indeterminate period prior to use. Dispose of any unused Cartridges as hazardous waste.
6. Cartridge contains guanidine thiocyanate (H302: harmful if swallowed, H312: harmful for contact with skin, H332: harmful if inhaled, H412: harmful to aquatic organisms; long-term effects, P273: do not disperse in environment).
7. Cartridge contains ethanol (H225: highly flammable liquid and vapor, P210: keep away from heat/sparks/open flames/hot surfaces, no smoking).
8. Specimens and used Cartridges may be infectious. Wear appropriate personal protective equipment (PPE) when handling these. Wash hands thoroughly afterwards. Wear disposable gloves and change gloves between specimens. Keep the bench area clean by wiping with a 10% bleach solution. Wipe all spills and change gloves afterwards. Appropriate precautions for disposal of biohazardous materials should be established in line with local or national policies and practices.
9. For additional warnings and precautions relating to the use of the *io* Instrument and for cleaning and decontamination procedures, please refer to the binx health *io* Instrument Operator Manual.

Specimen Collection and Handling

Proper specimen collection and handling is critical to make sure accurate results are returned (see the Vaginal Swab and Male Urine Specimen Collection Kits' Instructions for Use for more details). **Specimens should not be tested if they have been kept at room temperature for more than 24 hours or if they have been kept in the refrigerator (between 2-8°C) for more than one week. It is essential that the specimen is fully mixed before testing.**

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