Infinity CT/NG Assay – Chlamydia/GC

PRINCIPLE / PURPOSE: Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) are common, yet potentially harmful sexually transmitted diseases (STD). Left untreated, these bacteria can cause pelvic inflammatory disease (PID) in women; potentially leading to infertility.

The Infinity CT/NG Assay is an automated *in vitro* diagnostic test for qualitative detection and differentiation of DNA from CT and NG. The assay is performed on the Cepheid Infinity Instrument. The automated infinity system integrates sample purification, nucleic acid amplification, and detection of the target sequences in samples using real-time PCR and RT-PCR assays.

SCOPE: This procedure applies to testing and reporting of Infinity CT/NG Assay.

SPECIMEN:

DO NOT PERFORM TESTING ON PATIENTS LESS THAN 14 YEARS OF AGE.

Patient Preparation: Urine – Must be first catch (an “unclean” catch) or sometimes called “dirty” urine for both female and male patients.

Type: Urine, endocervical swab specimen, or self-collected vaginal swab.

Handling Conditions: Swabs and urine must be stored and transported in the appropriated reagent tubes. The urine is collected in the yellow top Infinity transport tubes and female endocervical samples are placed in the pink top Infinity transport tubes.

First catch female urine specimens must be transferred to the Xpert CT/NG Urine Transport Reagent tube (yellow top) within 24 hours of primary collection and is shipped and/or stored at room temperature.

First catch male urine specimens must be transferred to the Xpert CT/NG Urine Transport Reagent tube (yellow top) within 3 days of primary collection if shipped and/or stored at room temperature.

First catch male and female urine specimen NOT transferred to the Xpert CT/NG Urine Transport Reagent tube (unpreserved urine specimen) can be shipped and/or stored for up to 8 days at 4˚C.

Endocervical swabs collected should be inserted immediately into the Xpert CT/NG Swab Transport Reagent tube (pink top).

Storage:

First catch female urine specimen that is transferred to the Xpert CT/NG Urine Transport Reagent tube (preserved female urine specimen) can be stored up to 45 days to 2º C to 15º C or up to 3 days at 2º C to 30º C before testing with the Xpert CT/NG Assay.

First catch male urine specimen that is transferred to the Xpert CT/NG Urine Transport Reagent tube (preserved male urine specimen) can be shipped and/or stored up to 45 days at 2º C to 30º C before testing with the Xpert CT/NG Assay.

If the ER or Floor wants to add a CT/NG test to a urine specimen we already have in the lab, remember the following guidelines:

* The patient’s urine specimen must be a first catch (dirty catch) urine, which means the patient should not have urinated for at least 1 hour prior to specimen collection. You also cannot use clean catch or cath specimens.
* Make sure there is at least 7 ml of urine sample because you have to transfer approximately 7 ml of urine into the Xpert CT/NG Urine Transport Reagent tube using the disposable pipette provided in the kit. The correct volume of urine has been added when the level reaches the black dashed line on the label of the Xpert CT/NG Urine Transport Reagent tube.
* Make sure the Male or Female urine specimen meets the storage requirements above.
* The test Code to order for the sample to be processed at Alamance Regional Medical Center is “CHLMGC”

Endocervical swabs (Pink top) – Endocervical transport tubes are stable up to 60 days at 2 – 30ºC before testing with the Xpert CT/NG Assay.

If the ER wants to collect a male urethral swab then they will have to use the GEN-PROBE Aptima Unisex swab provided from LabCorp. They will have to order test code #183194. These specimens are stable for 60 days at 2ºC to 30ºC.

EQUIPMENT AND MATERIALS:

Equipment: Cepheid Infinity, gloves, lab coat, and splash guard or face shield.

Materials: CT/NG kit, transfer pipette, endocervical collection kit, and/or a urine collection kit, ethanol, and 4 x 4 gauze.

Performance Parameters: Cartridge must be used within 30 minutes after opening the cartridge lid.

Storage Requirements: Cartridges are stored at 2 - 28ºC.

CALIBRATION: Calibration of the individual modules is required annually and is performed by the Cepheid service rep.

Standard Preparation: Contact the local rep to schedule an appointment.

Calibration Procedure: Performed by the Cepheid Service Representative.

QUALITY CONTROL:

Each test includes a Sample Processing (SPC), a Sample Adequacy Control (SAC) and a Probe Check Control (PCC).

* SPC-Ensures the sample was correctly processed. The SPC contains genomic DNA of Bacillus globigii that is included in each cartridge. The SPC verifies that binding and elution of target DNA have occurred if the organisms are present and verifies that the sample processing is adequate. Additionally this control detects sample-associated inhibition of the real-time PCR assay. The SPC should be positive in an analyte negative sample and can be negative or positive in an analyte positive sample. The SPC passes if it meets the validated acceptance criteria.
* SAC- Ensures that the sample contains human cells or human DNA. This multiplex assay includes primers and probes for the detection of a single copy human gene. The SAC signal is only to be considered in an analyte negative sample. A negative SAC indicates that no human cells are present in the sample due to insufficient mixing of the sample or because of an inadequately taken sample.
* PCC-Before the PCR reaction starts, the Infinity instrument measures the fluorescence signal from the probes to monitor bead rehydration, reaction-tube filling, probe integrity and dye stability. PCC passes if it meets the validated acceptance criteria.
* External Controls-External controls (one positive for CT and one positive for NG and one negative for both) are performed with each new lot and/or shipment.

Chlamydia trachomatis Positive Control

Neisseria gonorrhoeae Positive Control

CT/NG Negative Control Negative Control

These controls are located in the Microbiology refrigerator.

Quality Assurance:

To ensure quality assurance, positive GC and Chlamydia results will be monitored weekly and monthly. Any increase in the expected positive rate (<10%) will be investigated and corrective action will be taken if the positive rate is >10%.

The total number of tests performed and the number of positive tests is used to calculate the percent positive. This number is charted and graphed weekly and monthly for a visual representation of the expected positive rate.

This is performed by the microbiology section leader (or other designee).

QC PROCEDURE - STEPWISE

Preparing the Cartridge- Important: Start the test within 30 minutes of adding the specimen and reagents to the cartridge.

To add the QC organisms and the reagents to the cartridge:

1. Remove the QC controls from the Microbiology refrigerator. They are located in a square box labeled NATtrol CT/NG Bundle.
2. Then remove one vial from a box labeled "NATtrol CT/NG Negative Control". Remove another vial from a box labeled "NATtrol *Neisseria gonorrhoeae* External Run Control Low" and another vial from a box labeled "NATtrol *Chlamydia trachomatis* External Run Control Low".
3. Remove from the new lot # or new shipment of CTNG assays, 3 cartridges and 3 sterile pipettes.
4. Using the bottle of ethanol, spray the area behind the plastic shield and using a

4 x 4 gauze clean the area to prevent contamination.

1. Then take off your gloves and wash and dry your hands.
2. Don a new pair of gloves
3. Place the 3 control vials, 3 pipettes, and 3 cartridges behind the plastic shield.
4. Gently invert the CT/NG Negative control 3 to 4 times to ensure adequate mixing of sample and transport matrix.
5. Unwrap the transfer pipette.
6. Open the control vial lid, compress the bulb of the transfer pipette, insert the pipette into the transport tube, and release the bulb to fill the pipette above the mark on the pipette shaft. Ensure the pipette is filled with no air bubbles present.



1. Empty the pipette’s content into the sample (S) chamber of the cartridge.



1. Close the cartridge lid.
2. Turn on the computer, and then turn on the Infinity instrument if it is not already on.
3. On the Windows® desktop, double-click the Infinity shortcut icon. If the computer is already on this step will not need to be performed.
4. Log on to the Infinity System software using your user name and password. Please see the Microbiology Section leader is you do not have a user name or password or have forgotten them.
5. In the Infinity window, click Orders and Order Test. Scan the barcode or manually enter the ID.
6. In the Sample ID box, type the control ID "neg ctng, control lot # on the vial, lot # of the new lot # or new shipment of CT/NG assays. For example, "neg ctng 310886 (this is the lot # for the control) for 05808 (this is the lot # of the kit)". Make sure you type the correct control ID. The control ID is associated with the test results and is shown in the View Results window and all the reports.
7. Scan the barcode on the Xpert CT/NG Assay cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and expiration Date.
8. Click Start Test. In the dialog box that appears, type your password if the analyzer asks for it.
9. Open the instrument module door with the blinking green light and load the cartridge.
10. Close the door. The test starts and the green light stops blinking.
11. Proceed to the positive Chlamydia trachomatis control vial.
12. Using the bottle of ethanol, spray the area behind the plastic shield and using a

4 x 4 gauze clean the area to prevent contamination.

1. Remove your gloves and wash and dry your hands.
2. Don a new pair of gloves.
3. Gently invert the positive Chlamydia trachomatis control 3 to 4 times to ensure adequate mixing of sample and transport matrix.
4. Unwrap the transfer pipette.
5. Open the transport tube lid, compress the bulb of the transfer pipette, insert the pipette into the transport tube, and release the bulb to fill the pipette above the mark on the pipette shaft. Ensure the pipette is filled with no air bubbles present.



1. Empty the pipette’s content into the sample (S) chamber of the cartridge.



1. Close the cartridge lid.
2. In the Infinity window, click Order Test. A window pops up that says “Please scan sample ID barcode”. So using the mouse, left click on the “Manual Entry” box.
3. In the Sample ID box, type the control ID "pos CT, control lot # on the vial, lot # of the new lot # or new shipment of CT/NG assays. For example, "pos CT 312164 for 05808". Make sure you type the correct control ID.
4. Scan the barcode on the Xpert CT/NG Assay cartridge.
5. Click Start Test. In the dialog box that appears, type your password if needed.
6. Open the instrument module door with the blinking green light and load the cartridge.
7. Close the door. The test starts and the green light stops blinking.
8. Proceed to the positive Neiserria gonorrhoeae control vial.
9. Using the bottle of ethanol, spray the area behind the plastic shield and using a

4 x 4 gauze clean the area to prevent contamination.

1. Take off your gloves and wash and dry your hands.
2. Don a new pair of gloves
3. Gently invert the positive Neisseria gonorrhoeae control 3 to 4 times to ensure adequate mixing of sample and transport matrix.
4. Unwrap the transfer pipette.
5. Open the transport tube lid, compress the bulb of the transfer pipette, insert the pipette into the transport tube, and release the bulb to fill the pipette above the mark on the pipette shaft. Ensure the pipette is filled with no air bubbles present.



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1. Empty the pipette’s content into the sample (S) chamber of the cartridge.



1. Close the cartridge lid.
2. In the Infinity window, click Order Test. A window pops up that says “Please scan sample ID barcode”. So using the mouse, left click on the “Manual Entry” box.
3. In the Sample ID box, type the control ID "pos GC, control lot # on the vial, lot # of the new lot # or new shipment of CT/NG assays. For example, "pos GC 312165 for 05808". Make sure you type the correct control ID.
4. Scan the barcode on the Xpert CT/NG Assay cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and expiration Date.
5. Click Start Test. In the dialog box that appears, type your password if needed.
6. Open the instrument module door with the blinking green light and load the cartridge.
7. Close the door. The test starts and the green light stops blinking.
8. When all tests are completed, the light turns off.
9. If any of the quality control vials do not work then repeat with a new vial of control. See a section lead if any quality control does not work after the second time.

PATIENT PROCEDURE:

Preparing the cartridge:

1. Using the bottle of ethanol, spray the area behind the plastic shield and using a

4 x 4 gauze clean the area to prevent contamination.

1. Doff your gloves and wash and dry your hands.
2. Don a new pair of gloves
3. Remove one CT/NG cartridge and one sterile pipette located within the kit and place them behind the plastic shield.
4. Label the patient’s specimen with the barcode accession label lengthwise making sure to match the name and the medical record number.
5. Using one of the small accession labels, without the barcode, place it on the side of the cartridge.
6. Using another one of the small accession labels, without the barcode, place it on the Infinity patient log under the column accession number.
7. Fill in the date beside the accession number label.
8. Place a U for a urine specimen and a S for swab specimen under the “Urine or Swab (U or S)” column on the Infinity patient log.
9. Gently invert the patient’s transport specimen 3 to 4 times to ensure adequate mixing of sample and transport matrix.
10. Unwrap the transfer pipette.
11. Open the control vial lid, compress the bulb of the transfer pipette, insert the pipette into the transport tube, and release the bulb to fill the pipette above the mark on the pipette shaft. Ensure the pipette is filled with no air bubbles present.



1. Empty the pipette’s content into the sample (S) chamber of the cartridge.



1. Close the cartridge lid.
2. Turn on the computer, and then turn on the Infinity instrument if it is not already on.
3. On the Windows® desktop, double-click the Infinity shortcut icon. If the computer is already on this step will not need to be performed.
4. Log on to the Infinity System software using your user name and password.
5. In the Infinity window, click Orders and Order Tests. Scan the patient’s barcode accession number. If you need to manually enter the patient’s accession number or if the barcode accession number is not reading then use the mouse and left click on the “Manual Entry” box. Type the accession number and click on “OK”
6. Make sure you type the correct sample ID. The sample ID is associated with the test results and is shown in the View Results window and all the reports.
7. Scan the barcode on the Xpert CT/NG Assay cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and expiration Date.
8. Click Start Test. In the dialog box that appears, type your password if needed.
9. Open the instrument module door with the blinking green light and load the patient’s cartridge.
10. Close the door. The test starts and the green light stops blinking. It takes approximately 90 minutes to obtain results.
11. Then proceed to the next patient making sure to clean the work area behing the plastic shield with ethanol and changing gloves. Your hands must be washed between glove changes.
12. After the test is completed then fill in the columns with the Chlamydia trachomatis and Neisseria gonorrhoeae results and place a check under the column labeled “Result in LIS”.

INTERPRETATION & REPORTING RESULTS:

Reference Ranges: Negative

Procedures for Abnormal Results: Report as positive in LIS. Report positive results to the appropriate Health Department within 24 hours. Refer to [MICRO-315-CH](https://conehealth.sharepoint.com/:w:/t/armc-lab/ETxcrYSmVWlAl69kZrfc0YcBdkV51Bagnt92L_hwjXoPzQ?e=etSZyn) for detailed instructions.

Reporting Format: Results are interfaced.

Record results in LIS AND on patient log.

INTERFACE RESULT ENTRY:

\*If BOTH organisms are not detected, results will automatically cross over to patient’s chart. If either CT or NG is detected, results will need to be released.

1. Select Result Entry tab.
2. Select Interface as the resulting mode.
3. Enter ARGXP as the method code in the Select Methods field and click Add.
4. Once the method is activated, select Results at the bottom right of the screen.
5. Select the binocular icon from the bottom of the the page to access the search window.
6. Use the barcode scanner to scan the CID and access patient results.
7. Review the results and check for QA failures. Detected CT/NG results are not criticals and do not need to be called.
8. Select save.

MANUAL RESULT ENTRY:

NODT – NOT DETECTED

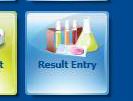
DT - DETECTED

INVPCR – INVALID, UNABLE TO DETERMINE THE PRESENCE OF TARGET

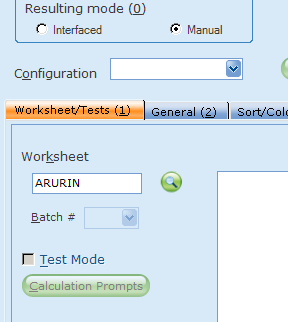
DNA DUE TO SPECIMEN INTEGRITY, RECOLLECTION REQUESTED.

(All invalid results must be verified by repeat testing and called to the appropriate personnel which will be documented. The test must then be cancelled)

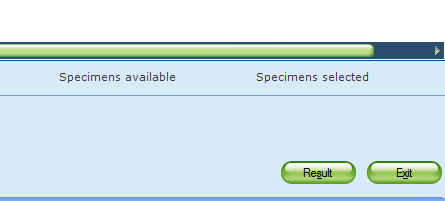
1. SIGN INTO SUNQUEST
2. SELECT “RESULT ENTRY”



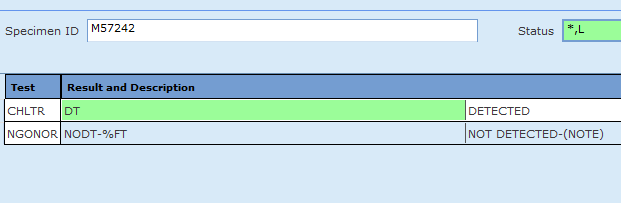
1. SELECT “MANUAL”
2. ENTER WORKSHEET “ARURIN”
3. “TAB”



1. CLICK “RESULT”



1. ENTER ACCESSION
2. “TAB”
3. ENTER CHLAMYDIA RESULT (DT OR NODT)
4. “TAB”
5. ENTER NGC RESULT (DT OR NODT)
6. “TAB”



1. “SAVE”
2. REVIEW RESULTS
3. “ACCEPT”

PROCEDURE NOTES:

* For invitro diagnostic use.
* Pathogenic microorganisms, including hepatitis viruses and Human Immunodefiency Virus, may be present in clinical specimens. Use universal precautions with all specimens and quality controls
* For collection of endocervical swab specimens, use only the Xpert CT/NG Vaginal/Endocervical Specimen Collection Kit.
* For urine specimens, use only the Xpert CT/NG Urine Specimen Collection Kit or unpreserved urine.
* Under or over dispensing of urine into Urine Transport Reagent tubes may affect assay performance.
* Endocervical vaginal swab specimens and urine specimens must be collected and tested before the expiration date of the Xpert Transport Reagent Tube.
* Do not substitute Xpert CT/NG Assay reagents with other reagents.

Rebooting:

Shutdown:

1. Click on the RED “X” in the top right corner.
2. Click on the windows icon in the bottom left corner.
3. Click on “shutdown”.

Startup:

1. Turn on computer tower.
2. Double click on the FilmArray icon.

RELATED PROCEDURES:

Specimen Collection and Processing.

Specimen Processing and Labeling.

QM-195 Proficiency Testing.

LIMITATIONS OF THE PROCEDURE:

* The Xpert CT/NG Assay has only been validated with the following specimen types, collected with the Cepheid Xpert CT/NG Vaginal/Endocervical or Urine Specimen Collection Kit.
* Because the detection of CT and NG is dependent on the DNA present in the sample, reliable results are dependent on proper sample collection, handling, and storage.
* With endocervical specimens, assay interference may be observed in the presence of blood and/or mucus.
* With urine specimens, assay interference may be observed in the presence of blood, mucus, or vagisil feminine powder.
* A negative test result does not exclude the possibility of infection because test result may be affected by improper specimen collection, technical error, specimen mix-up, concurrent antibiotic therapy, or the number of organisms in the specimen which may be below the sensitivity of the test.

SUPPLEMENTAL MATERIALS/ADDENDUM:

Specimen Collection and Processing

REFERENCES:

1. CLSI Publication M29. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. (Refer to latest edition).
2. Center for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories.
3. Cepheid Xpert CT/NG Package Insert.

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| Medical Director Approval –  ARMC Cancer Center  ARMC Main Lab | Original hardcopy signed |  |

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| Review Date | Signature | Mgmt. | Director |
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HISTORY PAGE

SOP Number: MICRO-721-CH

SOP Title: CTNG / Chlamydia GC

Written By: Jacee Farmer

Manual in which Hard Copy of this SOP is located: Microbiology Manual

Distribution: Sharepoint

Supersedes Procedure:

SOP CHANGE CONTROL

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|  | Approvals | |  | Action | In |
| Mgmt. | Date | Director | Date |  | Effect |
| J FARMER | 2/19/19 |  |  | Added “Report positive results to the health dept.” | 2/19/19 |
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