

INITIAL EXPERIENCE WITH THE XPERT[®] CT/NG SYSTEM IN TAURANGA

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Background

- Antimicrobial stewardship's (AMS) concerns in sexual health medicine – specifically re Chlamydia (CT) and gonorrhoea (NG)
- Overuse and misuse of epidemiological and syndromic treatments
 - eg contacts of CT/NG who are given antibiotics before test results are available
 - particularly reporting contact > 2/52 before
 - also, patients with symptomatic urethritis given syndromic antibiotics before results are available
 - particularly stat azithromycin.

Our experience

- The Cepheid Xpert[®] CT/NG system is a rapid, point-of-care PCR test for CT and NG infections
- The system allows for the rapid (90' turnaround time), onsite DNA amplification diagnosis of CT and NG from a variety of clinical samples
- The size of the machine is comparable to a desktop computer with printer, and only requires a power point as the single-use cartridges are completely self-contained.

The beast



Cartridge Preparation

1



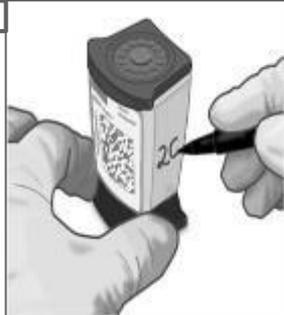
Obtain appropriately collected urine or swab specimen in Xpert Sample Collection Kit

2



Take one Xpert CT/NG cartridge and the provided transfer pipette

3



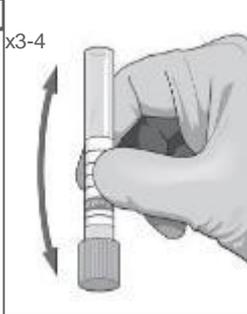
Label the side of the cartridge with the same ID as the collection tube

4



Open the cartridge lid

5



Gently mix by inverting the transport tube 3-4 times

6



Pipette at least 1 mL of the sample using the provided pipette*

7



Slowly empty the pipette into the sample chamber of the cartridge

8



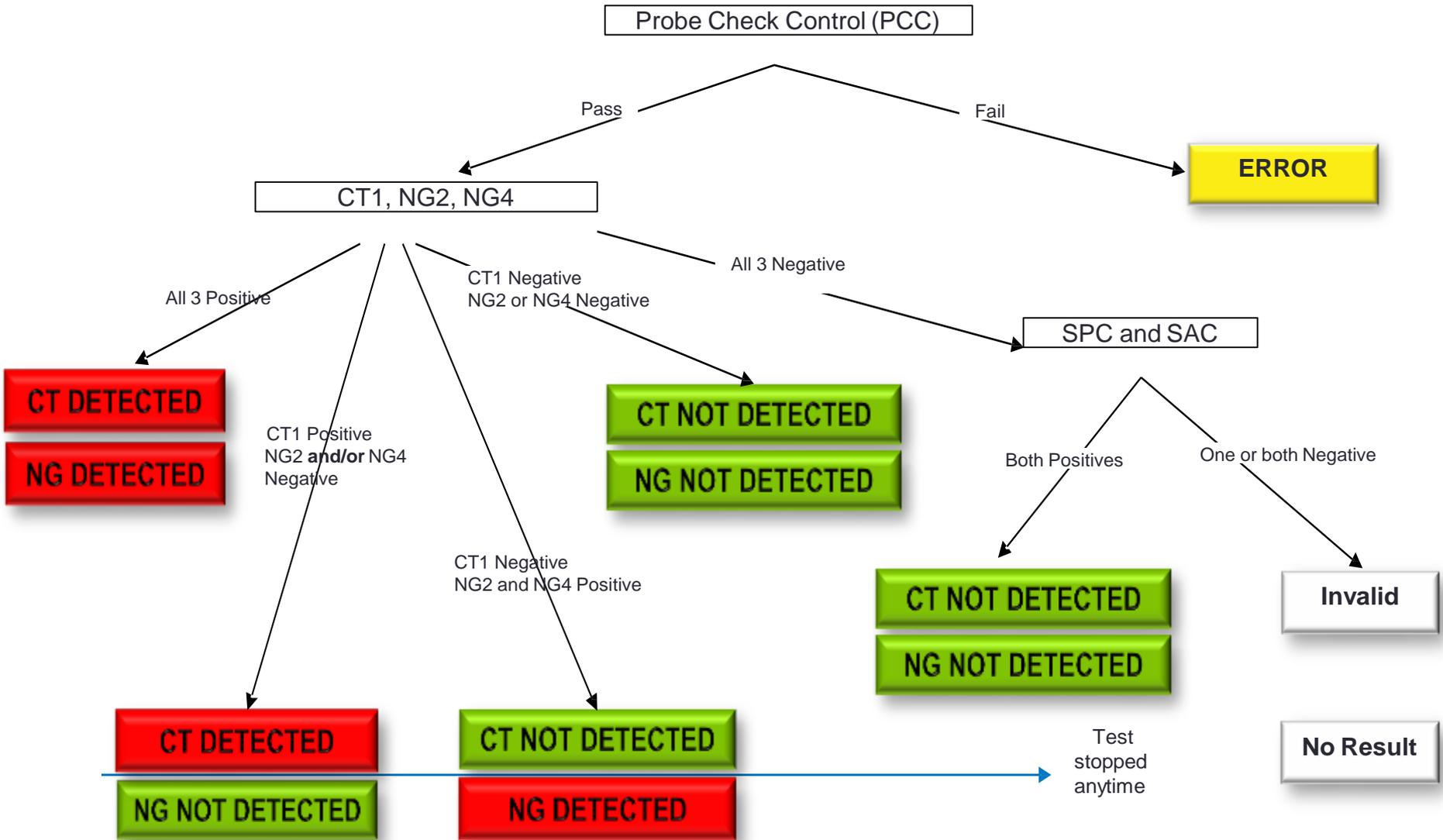
Close the lid firmly. Start the test within the time frame specified in the package insert.



Automated Xpert Protocol

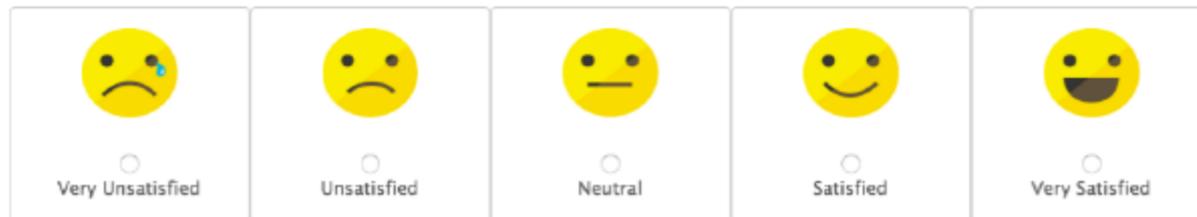


Result Interpretation Algorithm



Results – staff satisfaction

- We have assessed the staff satisfaction using the test, by administering a 5-item questionnaire using a 5-point, semi-quantitative visual Likert scale (very unsatisfied, unsatisfied, neutral, satisfied, very satisfied)
 - items: (1) overall satisfaction; (2) specimen collection and processing; (3) set up of the machine; (4) time taken by the test to run; (5) format of the results
- Staff satisfaction was high, as the score was, for all items and all questionnaires, either 4 or 5 (satisfied or very satisfied).



Who and what did we actually test?

- We were given by Cepheid 50 free cartridges to try
- To keep things simple, we chose to use only male urines (FVU) – the leftover after collecting the standard lab-based PCR test for CT/NG
- We tested two groups of men:
 - Asymptomatic contacts of CT and/or NG, reporting contact $> 2/52$ prior \Rightarrow the outcome was avoiding unnecessary use of epidemiological antibiotics if they agreed to wait for the Xpert[®] results before being treated
 - asymptomatic contacts $< 2/52$ prior were excluded as still in the window period
 - Symptomatic men with urethritis \Rightarrow looking at whether the test could direct us to use the right antibiotics from the start.

The teething problems

- Although we were very satisfied with the test, we discovered after performing the first 18 tests that we were only selecting the test for CT
 - hence no results for NG on those first 18 patients (but they still had the right tests done at the lab)
- We had one NR (No Result)
 - the correct procedure would have been to repeat the test with a new cartridge, but we elected to wait for the lab-based PCR instead.

Did we avoid unnecessary antibiotic use?

- 32 asymptomatic men, reporting contact with a CT and/or NG case > 2 weeks prior
- 30 accepted to wait 2 hours for the results of the Xpert[®] CT/NG test before being given antibiotics
 - 29 tested negative and unnecessary antibiotics were avoided
 - 1 had No Result (NR) and still elected to wait for the lab-based PCR test the day after => negative, no antibiotics given
- 1 NG contact declined to wait and was treated epidemiologically => neg on FVU with both Xpert[®] CT/NG and the lab-based PCR; tested pos for NG on both rectal & throat swabs with the lab-based PCR
- 1 CT contact declined to wait => given azithromycin 1g stat, all neg on both Xpert[®] CT/NG and the lab-based PCR.

Did we use the right antibiotics from the start?

- 6/18 symptomatic patients had acute anterior urethritis with purulent discharge on examination (NG) => they were treated with ceftriaxone/azithromycin without even waiting for the Xpert[®] CT/NG results
 - all confirmed by Xpert[®] and/or lab-based PCR
- 13/18 had non-gonococcal urethritis (NGU) on examination
 - 7 had doxycycline x 1/52
 - 5 were pos for CT with the Xpert[®] CT/NG, all confirmed at the lab
 - 2 had a neg Xpert[®] CT/NG => 1 was CT pos at the lab, the other was diagnosed as non-specific urethritis (NSU)
 - 4 had azithromycin 1g stat
 - 3 had NSU (neg for CT/NG)
 - 1 had CT
 - 1 NGU patient declined syndromic antibiotics and elected to wait => left the clinic, had CT on both Xpert[®] and lab-based PCR, never came back for treatment despite repeated attempts.

Discussion

- We feel the greatest value of this preliminary experience with a POC test was the avoidance of unnecessary use of epidemiological antibiotics (30/32)
 - we were actually pleasantly surprised by how the discourse of avoiding unnecessary antibiotics resonates with the public, when the choice is given to have a sound microbiology result in 2 hours - *most frequent comment was “yeah, it kind of makes sense”*
- The results were a bit more blurred when it comes to directing the initial antibiotics
 - all gonorrhoea diagnosis were actually made on clinical grounds and could have been confirmed microbiologically with a Gram stain in 5 minutes - *if only we had a microscope!*
 - we also failed to stick to the best practice in 4 patients with NGU/NSU, who were given azithromycin despite the data showing better efficacy of doxycycline.

Next steps

- We would like to keep the machine :-)
 - possibly by submitting a business case leveraging on the avoidance of unnecessary antibiotic use
- We need to fine tune our syndromic approach to urethritis incorporating in a better way microscopy (*in the new location?*) and POC test
- We would like to try pooling the samples so we can use one cartridge for multisite CT/NG tests
 - this will make the price competitive with 3 x lab-based PCRs.

Acknowledgements

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