Assessment of pre-analytical sample storage parameters for accurate nucleic-acid based detection of Neisseria gonorrhoeae

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1. Background

- In 2020, Neisseria gonorrhoeae (NG) caused 82 million global cases of gonorrhoea, a sexually transmitted infection (STI); gonorrhoea notifications have risen in Australia, and globally.1
- Specimens for STI testing are collected by healthcare workers, or through self-collection and sent to laboratories for testing.
- Before processing self-collected samples, diagnostic laboratories must consider specimen transport conditions, the storage buffer/medium utilised, and the detection sensitivity of diagnostic platforms. There is limited data available on how these factors affect accurate nucleic-acid based N. gonorrhoeae detection.2
- Our project aimed to assess the effect of three storage parameters (time, temperature and sample storage buffer) on the analytical sensitivity of NG detection across an array of diagnostic assays.

3. Results

- Positive NG results were observed for the majority of processed samples (2,761/2,781; 99.3%).
- NG analytical sensitivity (non-significant sets/total sets tested across assays) can be maintained for up to 30 days (184/204; 90.2%), and at 37°C (230/255; 90.2%).
- The performance of storage buffers varies across diagnostic assays; commercial storage buffers are most consistent.

2. Methodology

- Known concentrations (CFU/mL) of NG (FA1090 strain) were spiked into commercial (Aptima Multitest Swab Transport Media, and Abbott Alinity transfer buffer) and generic (Amies Liquid Media, and Viral Transport Medium) storage buffers.
- Spiked samples were stored in triplicate at -20°C, 4°C, 25°C or 37°C for 2, 4, 7, 14 or 30 days. Baseline samples at 25°C were tested upon study commencement.
- Samples were processed using the Alinity m STI, Xpert CT/NG and Aptima Combo 2 nucleic acid amplification tests, and an in-house quantitative PCR (qPCR) assay.
- Two-way ANOVA statistical analysis was carried out relative to baseline samples.

4. Discussion

- Our data demonstrate that, in general, sample integrity for NG molecular testing was maintained across a range of sample-processing parameters.
- Importantly, our findings were applicable across a range of commercially available diagnostic platforms.
- These findings have relevance to transportation of self-collected samples for NG testing in a range of environmental conditions, and provide further support for the utility of sample self-collection.
- Future studies should aim to test direct clinical performance, as well as more extreme parameters (> 30 days & > 37°C).

Flexibility in sample storage allows diagnostic laboratories to accurately process a wider range of NG samples.

References:


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Original abstract title: Assessment of sample storage parameters for accurate nucleic-acid based detection of Neisseria gonorrhoeae – 14th to 15th March 2023