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# Use of the UriSwab collection device for testing of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: implications for a postal testing service

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**Summary:** In order to demonstrate the reliability of UriSwab, a trial was conducted using urine samples that had previously returned a detected result for *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*. Urine specimens (115 samples) were received from sexual health clinics and tested using the Roche Cobas 4800 CT/NG method. Concurrently, the urine samples were pipetted directly on to the sponge applicator of the UriSwab, simulating micturition, and the urine harvested from the UriSwab was tested using the Roche Cobas 4800 method. Of the 87 standard urine specimens that were *C. trachomatis* detected, 85 (98%) were also detected in the corresponding UriSwab specimen (sensitivity 97.7%, specificity 95.7%). Of the 34 standard specimens that were *N. gonorrhoeae* detected, 33 (97%) were also detected in the corresponding UriSwab specimen (sensitivity 97.1%, specificity 100%). The performance of the UriSwab in this trial was comparable with the testing of neat first-catch urine specimens for both *C. trachomatis* and *N. gonorrhoeae*.

**Keywords:** sexually transmitted infections, diagnosis, urine, nucleic acid amplification test, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, specimen collection, UriSwab

## INTRODUCTION

The ability to maximize convenience for persons requiring or seeking testing for sexually transmitted infections has been considered an important public health objective for their early identification and control.<sup>1,2</sup> Various strategies and technologies have sought to increase this convenience with respect to immediate or local access, privacy, reduced waiting times and reduced invasiveness.<sup>3-5</sup> Non-invasive testing through the use of a urine-based nucleic acid amplification test, community outreach and venue-based testing, point-of-care testing, Internet-facilitated testing and home-based specimen collection have all been piloted and evaluated as potentially effective strategies.<sup>6-9</sup>

The use of mailed specimens, both as swabs or urine, for testing of *Chlamydia trachomatis* has been one strategy of particular interest with a number of studies conducted worldwide.<sup>9-11</sup> One particular strategy developed in Queensland has been the use of an anhydrous transport media that desiccates urine, allowing urine specimens to be mailed through the postal system from home to laboratory, where it can be prepared for polymerase chain reaction (PCR) testing.<sup>12</sup> However, this system is limited by its bulk, multiple steps and cost.

Previous studies have demonstrated the suitability of the UriSwab for storage and transport of samples at room temperature and its application to the Roche Cobas Amplicor system (Branchburg, NJ, USA).<sup>13</sup> The UriSwab is simple to use, is

compact for easy storage and transportation and its stability at room temperature makes it an ideal candidate for an alternate postal collection kit.

In order to determine the reliability of the UriSwab, a methodological study was conducted to compare the standard urine and the UriSwab test results for *C. trachomatis* and *Neisseria gonorrhoeae* and to assess if the UriSwab collection method and its reduced test volume had an effect on the test results.

In addition, a comparison of the standard urine and the UriSwab samples kept at room temperature for seven days prior to testing was drawn. This was to identify if lengthy storage prior to adding urine to the Cobas PCR tube affects test results.

## METHOD

The UriSwab Urine Collection System (Copan, Brescia, Italy) utilizes a sponge applicator impregnated with preservatives (boric acid and sodium formate) to maintain microorganisms in urine specimens.<sup>14-16</sup> The hydrophilic sponge applicator, which is attached by a plastic wand to the cap of a plastic tube, can be inoculated by urinating directly on to the sponge or by dipping it into a specimen container. The sponge applicator holds a maximum of 2 mL of urine. On arrival at the testing laboratory the urine can be harvested from the sponge applicator by squeezing the flexible walls of the transport tube. The urine collected from the UriSwab can then be used for testing.

First-catch urine specimens that had previously returned a detected result for either *C. trachomatis*, *N. gonorrhoeae* or both using the Cobas 4800 system were collected from several

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Table 1. Results for *C. trachomatis* assay of standard urine specimens and UriSwab specimens.

<i>C. trachomatis</i>		The UriSwab specimen		
		Detected	Not detected	Total
Standard specimen	Detected	85	2*	87
	Not detected	1 <sup>†</sup>	22	23
	Total	86	24	110

Sensitivity 97.7% (95% confidence interval [CI]: 92.0%, 99.4%)  
 Specificity 95.7% (95% CI: 79.0%, 99.2%)  
 \*Detected in the standard method only – cycle thresholds 40 and 41  
 †Detected in the UriSwab method only – cycle threshold 39

Table 2. Results for *N. gonorrhoeae* assay of standard urine specimens and UriSwab specimens.

<i>N. gonorrhoeae</i>		The UriSwab specimen		
		Detected	Not detected	Total
Standard specimen	Detected	33	1*	34
	Not detected	0	76	76
	Total	33	77	110

Sensitivity 97.1% (95% confidence interval [CI]: 85.1%, 99.5%)  
 Specificity 100% (95% CI: 95.2%, 100%)  
 \*Detected in the standard method only – cycle threshold 40

clinical sites located in regional areas (Townsville, Cairns and Mt. Isa) and transported directly to the Pathology Queensland Central Laboratory. Samples were collected from patients attending local sexual health clinics who had been tested reactive for either *C. trachomatis* or *N. gonorrhoeae*. All the samples were de-identified. Transit time between collection, initial diagnosis and arrival at the Pathology laboratory varied but all the samples were refrigerated or frozen for 1–2 weeks prior to transport to the laboratory. While each sample had been selected for testing based on a previous reactive test result, the samples were de-identified and labelled only with the clinical site and a number. Therefore the initial test result and any patient detail was unknown on arrival at the Central Laboratory.

A total of 115 urine specimens were received from sexual health clinics and kept frozen until they could be tested.

The urine samples were analysed by two different methods. Firstly, urine specimens were prepared for testing on the Cobas 4800 by thawing, mixing and adding urine to the Cobas tube as specified in the test method. Addition of urine to the Cobas PCR tube varied from 4.3 to 6.3 mL. The dilution of urine to PCR medium ranged from 1/2 to 3/5 for standard testing.

A matching urine specimen was pipetted on to the UriSwab until it was fully soaked, to simulate urination, and the swab returned to the transport tube. The urine was squeezed from the UriSwab by pressing the sides of the transport tube. The specimen harvested from the UriSwab was added to the Cobas PCR tube, the tube capped and inverted five times. The amount of urine harvested from the UriSwab and added to the Cobas PCR tube ranged from 1.0 to 1.2 mL. The dilution of urine to PCR medium was approximately 1/5.

The final 34 urine specimens received from clinical sites also had the UriSwabs prepared in parallel that were held at room temperature for seven days prior to testing. Both standard urine specimen and its UriSwab counterpart were tested on day 7 to assess stability during prolonged storage at room temperature.

Table 3. Results for *C. trachomatis* assay of standard urine specimens and UriSwab specimens stored for seven days at room temperature.

<i>C. trachomatis</i>		The UriSwab 7 days at RT specimen		
		Detected	Not detected	Total
Standard specimen	Detected	25	1*	26
	Not detected	1 <sup>†</sup>	7	8
	Total	26	8	34

Sensitivity 96.2% (95% confidence interval [CI]: 81.1%, 99.3%)  
 Specificity 87.5% (95% CI: 52.9%, 97.8%)  
 \*Detected in the standard method and the UriSwab method but not in the UriSwab after seven days – cycle thresholds 40 and 39  
 †Detected in the UriSwab method and in the UriSwab after seven days only – cycle thresholds 39 and 39

Table 4. Results for *N. gonorrhoeae* assay of standard urine specimens and UriSwab specimens stored for seven days at room temperature.

<i>N. gonorrhoeae</i>		The UriSwab 7 days at RT specimen		
		Detected	Not detected	Total
Standard specimen	Detected	10	1*	11
	Not detected	0	23	23
	Total	10	24	34

Sensitivity 90.9% (95% confidence interval [CI]: 62.3%, 98.4%)  
 Specificity 100% (95% CI: 85.7%, 100%)  
 \*Detected in the standard method and in the UriSwab method but not in the UriSwab after seven days – cycle thresholds 39 and 37

## RESULTS

One hundred and fifteen first-catch urine specimens were tested by the Cobas 4800 CT/NG Test *in vitro* nucleic acid amplification test for qualitative detection of *C. trachomatis* and *N. gonorrhoeae*.

All these specimens were tested as standard specimens and UriSwab specimens. Four specimens had insufficient urine remaining for testing as standard specimens and were not included in the trial. Another specimen was inhibitory when tested by the standard method and was not included in the trial.

Thirty-four specimens also had duplicate UriSwab specimens prepared and stored at room temperature for seven days prior to testing and compared with corresponding standard urine specimens.

Consequently, 110 urine specimens were tested and their results compared. The results are summarized in Tables 1–4.

Of the 87 standard urine specimens that were *C. trachomatis* detected, 85 (98%) were also detected in the corresponding UriSwab specimen (Table 1).

Of the 34 standard specimens that were *N. gonorrhoeae* detected, 33 (97%) were also detected in the corresponding UriSwab specimen (Table 2).

The 23 and 76 standard urine samples that were not detected for *C. trachomatis* and *N. gonorrhoeae*, respectively, were also not detected in the corresponding the UriSwab except for one specimen had detected for *C. trachomatis* in the UriSwab specimen but not the standard specimen.

Of the 34 urines that had duplicate UriSwabs prepared and held at room temperature for seven days, 26 specimens were

detected for *C. trachomatis* using the standard method on day 0. Twenty-five specimens were detected by the UriSwab on day 7. Another specimen was detected in the UriSwab specimen after seven days but not in the initial neat urine (Table 3).

Of the 34 urines that had duplicate UriSwabs prepared and held at room temperature for seven days, 11 specimens were detected for *N. gonorrhoeae* as standard urines. One specimen of the 11 was not detected when tested from the duplicate UriSwab seven days later (Table 4).

## DISCUSSION

Our results demonstrate the potential efficacy of the UriSwab as a tool for collecting urine samples for detection of *C. trachomatis* and *N. gonorrhoeae* by nucleic acid amplification testing. When compared with the testing of neat urine samples, urine collected via the UriSwab was 97.7% and 97.1% sensitive for *C. trachomatis* and *N. gonorrhoeae*, respectively. A high correlation between the two methods of sample collection indicates that the UriSwab could be as effective as testing whole urine.

A smaller substudy of the UriSwabs left at room temperature for seven days prior to testing demonstrated the effectiveness of the collection device in areas of remoteness where long travel times may be anticipated between collection and laboratory processing.

It should be noted that four specimens were not included in our final analysis due to insufficient neat urine remaining to be tested by the standard method and a fifth specimen was discounted due to the presence of inhibitory substances in the neat sample. Nonetheless, in all these samples, the UriSwab-collected samples were reactive.

The Cobas 4800 Operators Manual<sup>17</sup> states that at target levels for *C. trachomatis* of 0.2 inclusion forming units (IFU), i.e. below the limit of detection of the assay, the mean cycle threshold is 37.8 with a coefficient of variation of 1.86%. Cycle thresholds could then vary between samples of the same specimen by +0.7/−0.7. The limit of detection of the assay for urine is 0.75 IFU for 100% recovery.

Similarly for *N. gonorrhoeae* at 0.5 colony forming units (CFU), the cycle threshold is stated at 37.6 with a coefficient of variation of 1.76%. The cycle threshold could then vary between samples of the same specimen by +0.7/−0.7. The limit of detection of the assay is 2.3 CFU with 100% recovery.

At cycle thresholds above 37 when there are low levels of test organisms the likelihood of a 'not detected' result increases and this would explain our discrepant results. The results from this study show that the specimens affected would be those that have levels of the test organism below the limit of detection of the assay.

Our study should be regarded as a 'proof of concept' trial, given that the number of specimens tested was low and that testing with human subjects was not conducted. Actual collection of samples in the field would be the next step in validating this methodology. However, limited use by people in outreach settings since our initial methodological trial has demonstrated strong acceptance and easy use by participants (results unpublished).

Based on our initial trial, comparison of the *C. trachomatis* and *N. gonorrhoeae* results for the urines prepared using the standard method and the UriSwab collection procedure demonstrate that the sensitivities and specificities are all above 95%

and that the reduced test volume of urine from the UriSwab has little effect on the test results.

The sensitivity of the UriSwab holds great potential for initiatives that seek to simplify the accessibility of testing. Previous studies have described the use of an anhydrous gel as the basis for a postal system of urine collection and transport.<sup>12</sup> This system has been operating successfully for a number of years and has facilitated convenient sample collection and testing for persons across Queensland.<sup>18</sup>

However, the use of this transport gel for chlamydia testing by mail does have limitations. Currently, this system is reliant on a number of multiple steps – urination into a specimen container, followed by pipetting of a portion of the sample into a second, smaller transport tube, which is then placed into the return mail envelope. While each step is simple in itself, the combination of these can be considered cumbersome and time consuming, particularly for people attempting to collect specimens in venues that are not completely private.

In addition, a number of components are required – urine specimen container, pipette and transport tube. This not only contributes to the expense of the kit, but also its bulk, placing demands on storage space and postage to requesting clients. Bulky materials used in postal kits can make retrieval difficult for clients if such kits cannot be accommodated in private mail boxes, compelling them to obtain these packages from local post offices. Therefore, potential for the UriSwab to replace the transport gel within these chlamydia postal kits is significant given its greater simplicity of use, and reliance on fewer pieces of equipment. Less equipment results in lower production costs, lower mailing costs and lower demands on storage space. Disadvantages with the UriSwab system include the smaller volumes available for analysis and the need to squeeze the swab to extract urine. However, these are only disadvantages when compared with standard urine testing using jars. As a replacement for the current system of transport gel used in chlamydia postal kits, the UriSwab provides comparable specimen volumes and simpler processing.

A previous study identified the potential for another swab, the flocced swab, to facilitate easier transport of urine samples.<sup>19</sup> However, this study required collection of urines into a standard urine collection container, into which the flocced swab is dipped. Our study progressed swab-based urine collection further by collecting the urine directly onto the UriSwab.

There are several limitations to our study. Our number of clinical samples, particularly for *N. gonorrhoeae* detection was limited. Secondly, as this was a methodological trial, we were unable to assess the performance of the test within 'real-world' conditions. Finally, specimens that were used had been de-identified by the collecting laboratory and therefore patient details such as age and gender were not available. Though a number of specimens did provide these details, this was not consistent, and therefore was omitted from the analysis.

## CONCLUSION

The use of the UriSwab as a simple, home collection method for remote and rural use does appear to compare favourably with standard urine collection for *C. trachomatis* and *N. gonorrhoeae*.

Therefore, the UriSwab could provide an acceptable alternative to the current system of 'gel transport' tubes which forms the basis of Queensland's Chlamydia Postal Testing program.

The UriSwab requires no additional equipment, is less expensive to post and places lower demands on storage space.

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