USE OF THE STARSWAB MULTITRANS COLLECTION AND TRANSPORT SYSTEM FOR DETECTION OF *CHLAMYDIA TRACHOMATIS* (CT) AND *NEISSERIA GONORRHOEAE* (GC) WITH APTIMA® COMBO 2™, APTIMA CT AND APTIMA GC ASSAYS

John Harrison, Michelle Garassi, Sara Wierzbicki, William LeBar
Hospital Consolidated Laboratories-Providence Hospital, Southfield, MI,

Abstract

There are currently three FDA approved nucleic acid amplification tests (NAAT) for the detection of C. trachomatis and N. gonorrhoeae. Each of these tests has its own assay specific collection and transport device. Laboratories may receive multiple NAAT transport devices that have not been validated for use with their particular assay. The APTIMA® Combo 2™ (AC2), APTIMA CT (ACT), and APTIMA GC (AGC) are target amplification nucleic acid probe tests that utilize target capture, transcription mediated amplification and hybridization protection to detect rRNA. ACT and AGC utilize different target sequences than AC2 and thus may be used for confirmation of positive NAAT results, as well as stand-alone tests. In an ongoing study were are evaluating the Starswab Multitrans Collection and Transport system (MT) for use with the AC2, ACT and AGC assays. To date, 125 specimens have been collected in both MT and M4 transport medium and tested by AC2, ACT, AGC. There has been total agreement with the results obtained using each transport system. CT was detected in 12 specimens and GC in 6 specimens from both MT and M4 by AC2 , ACT and AGC. Negative results were obtained in 106 specimens from both transports. These preliminary results demonstrate that MT is a suitable transport medium for the APTIMA Combo 2, APTIMA CT and APTIMA GC assays. Further testing is warranted to establish the validity of the use of this transport with AC2, ACT and AGC.

Chlamydia trachomatis **and** ***Neisseria gonorrhoeae*** **infections are the most common reportable sexually transmitted infections in the United States today. It is estimated that over 3 million *C. trachomatis* infections occur annually among adolescents and young adults while in 2003, *N. gonorrhoeae* was second in frequency with 318,411 cases reported. One of the keys to the prevention of these infections rests on the ability to make a diagnosis based on accurate laboratory testing. There are currently three FDA approved nucleic acid amplification tests (NAAT) for the detection of *C. trachomatis* (CT) and *N. gonorrhoeae* (GC). Each of these tests has its own assay specific collection and transport device. Laboratories may receive multiple NAAT transport devices that have not been validated for use with their particular assay. The APTIMA® Combo 2™ (AC2), APTIMA CT (ACT), and APTIMA GC (AGC) are target amplification nucleic acid probe tests that utilize target capture, transcription mediated amplification and hybridization protection to detect rRNA. The purpose of this study was to evaluate the *Starplex Multitrans* medium for use with the AC2, ACT and AGC assays.**

Methods

Endocervical samples (n =191) were obtained from patients presenting at an Emergency Department with symptoms of genital tract disease or at an OB/GYN clinic presenting for routine gynecologic care. Samples were placed into M4 and Starswab Multitrans transport tubes.

The Starswab Multitrans system is a collection and tranportation system for viruses, chlamydia, mycoplasma and ureaplasma.

Each system consists of a blue screw cap, 10ml polypropylene tube containing transport medium with anitbiotics and glass beads, packaged with a scored plastic shafted, dacron tipped swab in a peel pouch. approved for room temperature storage for up to one year prior to use.

We previously validated the use of M4 medium for use with the The APTIMA® Combo 2™ (AC2), APTIMA CT (ACT), and APTIMA GC (AGC) assays. The target capture portion of the AC2 assay was performed with 400 µl of sample from the *Starplex Multitrans* tubes. The remainder of the target capture, amplification, selection and detection assays were performed according to instructions for the AC2 assay. Confirmatory testing of positive CT and GC results was performed with the ACT and AGC assays as described above.

AC2, ACT and AGC results are automatically interpreted by the assay software and presented as individual results. A result may be negative, equivocal, positive or invalid as determined by the assay type and total RLU detected.

Results

A total of 191 specimens collected in M4 and the Starswab Multitrans were tested by APTIMA® Combo 2™ . There was complete agreement in assay results between the two transport systems 189/191 sample pairs. One hundred fifty five samples were negative and 44 samples were positive for either CT or GC in the AC2 on initial testing. Two samples in the Starplex tube initially tested equivocal (1 CT and 1 GC)in the AC2 assay. Repeat AC2 tests of these two samples were negative.The distribution of the RLU values from the 155 negative samples is shown in Table 1 below

Total RLU (x1000)	Number of Samples
1	78
2	56
3	8
4	6
5	4
8	1
18	1
20	1

Table 1. Distribution of RLU values for negative Starplex samples in the APTIMA Combo 2 Assay. (The negative cutoff value for the assay is <85, 000 RLU)

The distribution of RLU values for samples positive for CT and GC is shown in Table 2.

Total RLU (x1000)	CT	GC
500	1	
600	2	
700		1
800	2	1
900	4	3
1,000 – 1,500	10	5
1,500 – 2,000	1	1
>2,000	1	1

Table 2. Distribution of RLU values for positive Starplex samples in the APTIMA Combo 2 Assay. (The positive cutoff value ≥1,000 for the assay is 250 - <4,500 RLU)

All specimens initially positive in the AC2 were tested in the individual ACT and AGC assays. All CT and GC positive specimens tested in the discreet assays, had results that fell within the expected range of 5,000 – 12,000 RLU (x1000).

Conclusion

Our results demonstrate that the *Starplex Multitrans* is a suitable transport medium for the detection of *Chlamydia* trachomatis and *Neisseria* gonorrhoeae in the APTIMA® Combo 2™, APTIMA CT and APTIMA GC assays.