

## Introduction

*Chlamydia trachomatis* (CT) is the most prevalent bacterial sexually-transmitted infection worldwide, with an estimated 92 million new cases of genital CT infection occurring every year. CT can be effectively and easily treated with antibiotics, however at least 75% of women have no symptoms and often go undiagnosed and untreated, which may lead to severe health consequences. In women, if left untreated, Chlamydial infection can result in pelvic inflammatory disease, causing long-term complications such as chronic pelvic pain, ectopic pregnancy and infertility.

Early diagnosis and treatment are essential but many patients do not attend specialist genitourinary medicine (GUM) clinics for testing due to the



Fig. 1 – Atlas Genetics io™ System

asymptomatic nature of the infection and the stigma associated with these clinics. In an attempt to address these problems, programmes have been established in the UK, US and parts of Europe which aim to increase testing by promoting opportunistic screening at a variety of new venues such as family planning and other primary

healthcare clinics. However, turnaround times of 5-10 days continue to be a major factor in preventing effective treatment. This long delay in diagnosis, extended follow-up time and frequent failure to attend follow-up appointments contribute to the continued spread of the disease. The platform evaluated in this study, the Atlas Genetics io™, is capable of providing rapid, accurate and reliable Point of Care (POC) testing for CT, where the patient can be tested and treated in a single short visit – whether this is at the GUM, family planning, general practice, or high street pharmacy clinic. The Atlas Genetics io™ CT assay gives a result in around 30 minutes and offers the fastest molecular test available in either a POC or lab setting for this target. The novel electrochemical technology offers user benefits over fluorescent detection-based systems including simple and low-cost robust instrumentation and a high level of multiplex capability for future expansion of the test menu.

This preliminary evaluation compared the performance of the Atlas Genetics io™ POC CT test to routine diagnostic testing using the APTIMA Combo 2 (AC2®) test for the detection of CT.

## Materials and Methods

Two self-collected vulvo-vaginal swabs were obtained from 196 women presenting at a genitourinary medicine clinic. Samples were tested according to Figure 2 using the AC2® test (Hologic) and the Atlas Genetics io™ test. Any sample giving a discrepant result was retested using the residual buffer from the io™ CT assay using the *artus*® *C. trachomatis* Plus RG PCR assay (Qiagen).

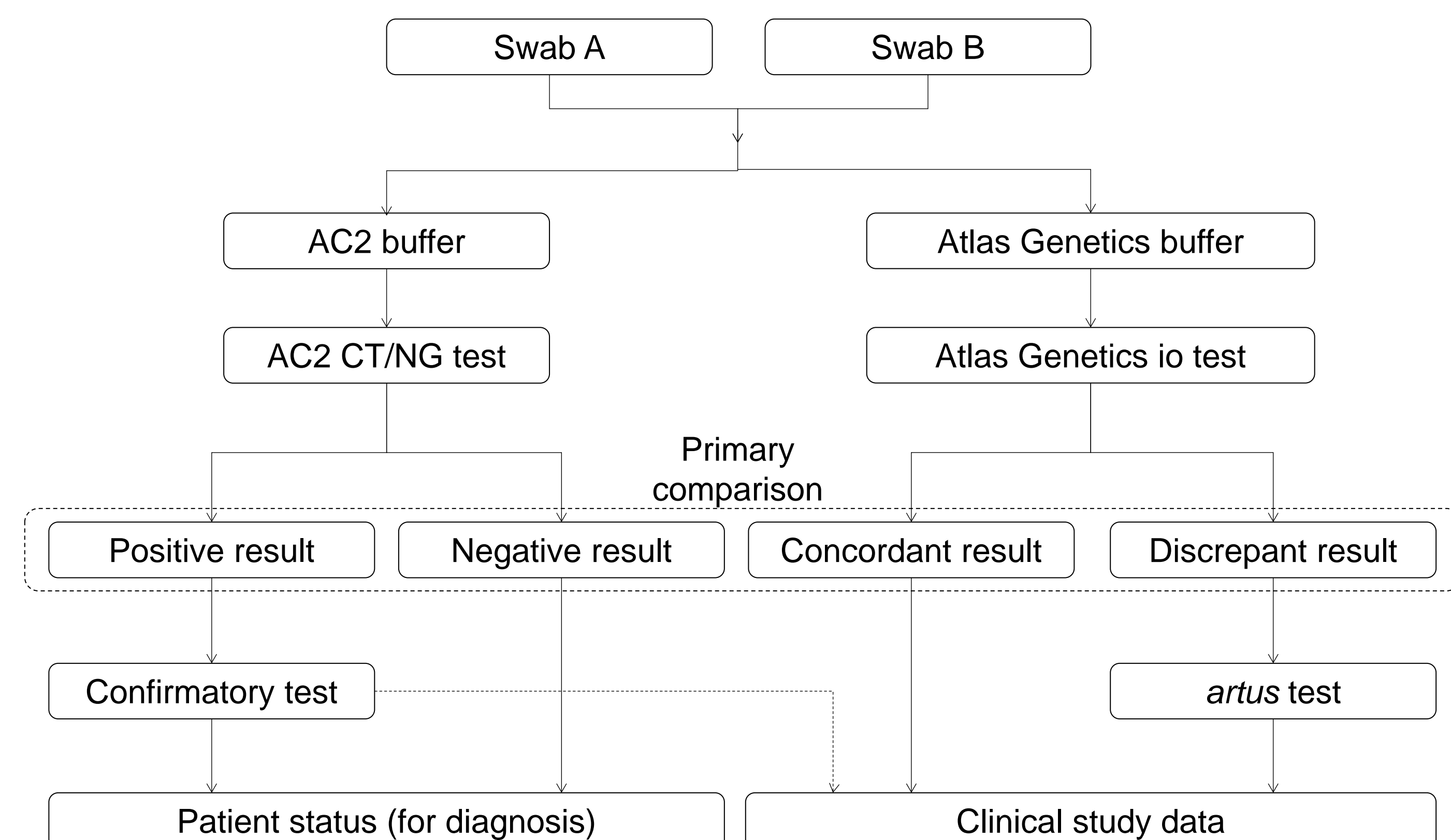


Fig. 2 – Sample Testing Flowchart

A true positive result was defined as a sample that was positive with at least two of the three tests.

## Results

Of the 196 paired samples obtained, four patient samples were withdrawn and six results were invalid for one or both of the io™ or AC2® tests, meaning 186 samples were available for analysis.

Eighteen samples were determined to be true positive results for *C. trachomatis*, of which one sample was positive with the AC2® and *artus*® CT test but negative with the io™ CT test. Three io™ false positive results were reported out of 168 samples that were negative when tested using the AC2® and *artus*® tests. Based on a provisional cut-off, the io™ assay demonstrated a sensitivity of 94.4% (17/18, 95% confidence interval: 72.7%-99.9%) and a specificity of 98.2% (165/168, 95% confidence interval: 94.9%-99.6%).

Table 1. Clinical Sample Testing Data

Result		Comparator (AC2/ <i>artus</i> )		Total
		Positive	Negative	
Atlas Genetics io	Positive	17	3	20
	Negative	1	165	166
Total		18	168	186

## Conclusions

- The Atlas Genetics io™ CT test delivered laboratory-equivalent results within 30 minutes
- With its rapid time to result, ease of use and applicability to a variety of testing venues, the Atlas Genetics io™ meets the requirements for a 'true' Point of Care device