

patients with a diagnosed STD. EPT is legal for *Chlamydia trachomatis* (CT) infections in New York State. To guide EPT implementation at New York City STD (NYC STD) clinics, we estimated potential EPT use and EPT treatments to dispense.

Methods We analysed electronic medical record data for heterosexual patient visits to NYC STD clinics in 2009. To estimate potential EPT use, we measured: proportion clinic patients with presumptive diagnosis of mucopurulent cervicitis (MPC); nonspecific urethritis (NGU); contacts of both who tested positive for CT; patients with laboratory-confirmed genital CT infection; and proportion treated on day of visit. To guide policy on EPT treatments to dispense, we measured the median number of sex partners reported by CT-infected persons in the previous 3 months. To determine whether to route CT contacts to a physician (MD) visit (full STD evaluation) or an express visit (EV), we assessed STD diagnoses among CT contacts.

Results Among clinic patients with presumptive diagnoses of MPC, NGU, and contacts of both, CT prevalence was MPC, 14% (293/2144); MPC contact, 15% (38/257); NGU, 23% (1553/6744); and NGU contact, 17% (113/677). Of 40 099 patients tested for CT, 13% (5402/40 099) had a laboratory-confirmed CT infection. Of those, 79% (4288/5402) had been treated presumptively on day of visit. Males ($n=4551$) and females ($n=3186$) reported a median of two and one sex partners, respectively. Of 3561 contacts with CT diagnosis, 2339 (66%) were asymptomatic on day of visit and were routed to EV. Of those, 936 (40%) had >1 diagnosis other than CT; 22% of those (205) had a diagnosis of herpes simplex virus, human papillomavirus, trichomoniasis, or bacterial vaginosis.

Conclusion EPT is recommended only for heterosexual patients with laboratory-confirmed CT diagnosis because CT-prevalence was low among patients presumptively diagnosed with either MPC or NGU and their contacts. Approximately 20% of CT-infected persons qualify for EPT; the majority of CT-infected persons are treated on day of visit. EPT-eligible patients should be offered up to three treatments for sex partners. Asymptomatic CT contacts reporting they have taken EPT should be routed to EV; those who report not taking EPT should be routed to an MD visit regardless of symptoms. Symptomatic CT contacts should receive an MD visit.

P3-S1.11 PER CENT ADDITIONAL TEST POSITIVE FOLLOWING POSITIVE COMBO 2 CHLAMYDIA (CT) AND GONORRHOEA (GC) SPECIMENS: ASSESSING THE IMPACT OF PREVALENCE

doi:10.1136/sextrans-2011-050108.411

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Background The positive predictive value (PPV) of a screening test (ST) is a function of prevalence and ST specificity and is expected to decrease with decreasing prevalence unless ST specificity approaches 100%. Consequently, an additional test (AT) following positive STs may be indicated if prevalence is low. Our objective was to determine the impact of CT and GC prevalence on per cent AT positive following positive STs by Gen-Probe Combo 2 CT and GC using data from public clinics in the state of Mississippi.

Methods Based on CDC's electronic prevalence monitoring databases from 2005 to 2007, we stratified 126 clinics (with >400 females tested) served by Mississippi State Public Health Laboratory (MSPHL) based on ST positivity. We calculated the per cent AT positive among 6553 CT ST positive and 1841 GC ST positive specimens. We further examined the impact of the quantitative Combo 2 GC results (relative light units (RLU)) for a sample of 508 specimens from clinics with low (<2.0%, family planning) and high (>6.0%, STD) ST positivity by abstracting the RLU values from hard copy records.

Results Per cent CT AT positive declined significantly ($p<0.0001$) from 96.3% for specimens from clinics with >10.0% ST positivity to 90.9% for specimens from a single clinic with <6% ST positivity (see Abstract P3-S1.11 table 1). GC ST positivity was <6% for 109 (87%) of the clinics. In spite of the lower GC ST positivity, the per cent GC AT positive was also >90%, ranging from 95.4% for GC ST positivity <2% to 97.7% for GC ST positivity 3.0%–4.0%. However, the per cent GC AT positive was not associated with GC ST positivity ($p=0.17$). Discordant GC AT results were confined to GC ST positive specimens with RLU <1 million (results not shown). The per cent of ST specimens with RLU <1 million and the per cent AT negative among these lower RLU positives were also not associated with clinic ST positivity ($p=0.14$ and $p=0.78$, respectively).

Abstract P3-S1.11 Table 1 APTIMA additional test results among women by clinic Combo 2 positivity and organism Mississippi—2007

Organism	Clinic Combo 2 % positivity	APTIMA AT result				p Value
		Retested #	Positive #	%	95% CI	
CT	<6.0	11	10	90.9	58.7 to 99.8	<0.0001*
	6.0–<8.0	281	261	92.9	89.2 to 95.6	
	8.0–<10.0	799	745	93.2	91.3 to 94.9	
	10.0+	5462	5262	96.3	95.8 to 96.8	
	Total	6553	6278	95.8	95.3 to 96.3	
NG	<2.0	196	187	95.4	91.5 to 97.9	0.17*
	2.0–<3.0	459	442	96.3	94.1 to 97.8	
	3.0–<4.0	392	383	97.7	95.7 to 98.9	
	4.0–<6.0	177	171	96.6	92.8 to 98.8	
	6.0+	617	599	97.1	95.4 to 98.3	
Total		1841	1782	96.8	95.9 to 97.6	

*Cochran-Armitage trend test.

Conclusions Performing APTIMA CT or GC ATs added little to Combo 2 ST PPV, although the decrease in per cent AT positive with decreasing ST positivity observed in this study raises concern about Combo 2 PPV at CT prevalence levels lower than 6%. The lack of impact of GC prevalence on GC ST RLU or AT results is unexpected and might indicate that the Combo 2 ST PPV is very high even at the lower GC prevalence. In other words, most negative GC AT results are false rather than true negatives and the patients should be treated.

P3-S1.12 HIGH CONCORDANCE OF TEST RESULTS OF THE CHLAMYDIA TRACHOMATIS DETECTION AND GENOTYPING KIT COMPARED TO THE COBAS AMPLICOR CT/NG TEST

doi:10.1136/sextrans-2011-050108.412

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Background Improving diagnostic methods for the detection of *Chlamydia trachomatis* (CT), including genotyping, can contribute to control of CT by acquiring knowledge on epidemiology, transmission, sexual networks and pathogenicity. In the present study, we have compared the performance of the *Chlamydia trachomatis* detection and genotyping (Ct-DT) kit (Labo Bio-medical Products BV, Rijswijk, The Netherlands) with the COBAS Amplicor CT/NG (Roche Diagnostics Systems, Basel, Switzerland) in a well described female population consulting a sexually transmitted infection (STI) clinic.

Methods Self obtained vaginal swabs (SVS) were collected from females visiting a STI clinic. The presence of *Chlamydia trachomatis*

DNA was determined by the COBAS Amplicor CT/NG. In agreement with the manufacturer, 200 µl of processed COBAS Amplicor CT/NG medium was used for DNA isolation using the Qiagen DNA mini kit (Qiagen GmbH, Hilden, Germany). For the Ct-DT kit, 10 µl DNA was used. All CT positive samples were used for serovar typing. Discrepant samples were retested using COBAS TaqMan CT Test v2.0 (Roche Diagnostics Systems, Basel, Switzerland). A sample was considered CT positive (comparison standard) if both NAAT were positive or if one these NAAT and the retest was positive.

Results In all, 772 clients were included in the original study. COBAS medium was available from 71 CT positive clients and 179 CT negative samples were randomly selected. With the Ct-DT kit, 68 out of 71 CT positive samples (97%) tested positive and one borderline, leaving two discrepant results. Retesting of the latter two samples using the COBAS TaqMan assay resulted in two positive tests. All COBAS Amplicor CT negative samples were also negative with the Ct-DT kit. The sensitivity, specificity, positive and negative predictive value of the Ct-DT kit were 97%, 100%, 100% and 99%, respectively, if the borderline result is included in the positive results. Genotyping results are presented in Abstract P3-S1.12 table 1. Serovars D/Da, E and F were most prevalent. The serovar distribution is comparable to previously published Dutch data.

Abstract P3-S1.12 Table 1 Nucleic acid amplification test results, including serovar distribution

COBAS Amplicor	DEIA	RHA Serogroup	RHA Serovar	COBAS TaqMan	Final conclusion	N	
Positive	Positive	B	D/Da	NA	Positive	4	
			E	NA	Positive	37*	
		I	F	NA	Positive	18†	
			G/Ga	NA	Positive	3	
		C	I/Ia	NA	Positive	2	
			J	NA	Positive	1	
		None detected	None detected	Positive	Positive	1	
			None detected	Positive	Positive	1	
		Borderline	B	None detected	Negative	Positive	1
		Negative	NA	NA	Positive	Positive	2
Negative	Negative	NA	NA	NA	Negative	179	
					Total	250	

*One double infection with serogroup C, serovar K.

†One double infection with serogroup C (no serovar detected).

Conclusion Compared with COBAS Amplicor CT/NG, the *Chlamydia trachomatis* detection and Ct Genotyping RHA Kit combination is a sensitive and highly specific assay to detect *Chlamydia trachomatis*. Moreover, it is a more rapid and easy to perform method to detect the most commonly detected serotypes compared to PCR-RFLP typing.

P3-S1.13 ESTABLISHMENT OF A PROTOCOL FOR THE DETECTION OF *CHLAMYDIA TRACHOMATIS* IN SEMEN SPECIMENS USING THE COBAS® 4800 CT/NG TEST

doi:10.1136/sextrans-2011-050108.413

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Background In addition to common urogenital samples, semen specimens are used to detect *Chlamydia trachomatis* (CT). In France, testing of semen specimens is mandatory by law in context of donors and in vitro fertilisation. However, semen specimens are known to show significant inhibition in PCR assays. Analysis of cycles of threshold (ct) values can be used to determine inhibition and limits of detection of assays.

Objective To establish a suitable protocol for the highly sensitive detection of CT in semen specimens using the fully automated cobas 4800® CT test.

Materials and Methods We evaluated inhibition rates and limits of detection (LOD) for different semen sample volumes by ct value analysis in the cobas® 4800 CT test. Semen samples were obtained from 100 patients visiting the reproduction biology department of the Bordeaux University hospital. Between 5 and 67 replicates of semen ranging from 1 to 50 µl were each added to 4.5 ml of cobas® PCR media and run in the cobas® 4800 CT test. The inhibition rate was compared to the inhibition rate obtained in 323 urogenital swabs and 278 urines using the ct values of the internal control (IC). Thereafter, semen volumes that showed the lowest inhibition rates were selected to determine the LOD, by comparing mean ct values for the target in the cobas® 4800 CT test using semen specimens spiked with different concentrations of CT.

Results Mean IC ct values in semen volumes ranging from 1 to 40 µl did not differ from those obtained in urogenital swabs and urines, whereas semen volumes of 50 µl resulted in a marked increase in IC ct values indicating inhibition. Therefore, semen volumes of 25, 40, and 50 µl diluted in 4.5 ml of cobas® PCR media were tested to determine the LOD. Mean ct values generated by the target CT are shown in Abstract P3-S1.13 table 1. Ct values were similar in samples of 25 µl semen and controls, but were higher or even negative in 40 and 50 µl semen volumes indicating that a semen volume of 25 µl showed the lowest LOD (10–5) combined with a low inhibition rate.

Abstract P3-S1.13 Table 1 Comparison of ct values in different semen sample volumes spiked with serial dilutions of CT-infected cells

Serial dilutions of CT-infected cells	Ct values			
	Control sample	25 µl semen	40 µl semen	50 µl semen
10 ⁻¹	31	30.2	30.6	32.6
10 ⁻²	33.2	33.3	32.8	35.8
10 ⁻³	35.7	36.8	35.3	37.5
10 ⁻⁴	37.9	37.1	38	40.5
10 ⁻⁵	40	40.0	neg	neg

Conclusion Semen specimens can be tested in the cobas® 4800 CT test applying our easy to perform, highly sensitive, and low inhibition protocol.

P3-S1.14 EVALUATION OF THE PLATFORM COBAS® 4800 CT/NG TEST FOR DETECTING *CHLAMYDIA TRACHOMATIS* IN UROGENITAL SAMPLES

doi:10.1136/sextrans-2011-050108.414

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Objectives To assess the performance of the Roche fully automated cobas® 4800 CT/NG test for the detection of *C trachomatis* (CT) infection in clinical specimens compared to the current routine practice.

Methods Consecutive clinical specimens sent to the Bacteriology department of the Bordeaux University Hospital, Bordeaux, between July and September 2010 were included. Results of the cobas® 4800 CT/NG test were compared with those obtained with the cobas® TaqMan CT 48 assay (Roche). For the latter, DNA from 200 µl of urine or swab resuspended in transport medium, (2SP or universal transport medium) was extracted on the MagNA Pure using the DNA I isolation kit (Roche) and amplified on the TaqMan 48 automates. The cobas® 4800 CT/NG performed DNA extraction