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	Positive	Positive	1
		None detected	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

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[1]B de Barbeyrac, [1]V Mehats, [2]A Papaxanthos, [1]C Bébéar. *[1]Inra-Université de Bordeaux, Bordeaux, France; [2]CHU Bordeaux, Bordeaux, France*

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

	Ct values			
Serial dilutions of CT-infected cells	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 PLATEFORM COBAS® 4800 CT/NG TEST FOR DETECTING *CHLAMYDIA TRACHOMATIS* IN UROGENITAL SAMPLES

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B de Barbeyrac, V Mehats, M Clerc, C Le Roy, C Bébéar. *Inra-Université de Bordeaux, Bordeaux, France*

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

from urine specimens prepared by adding 4.5 ml to 4.5 ml of cobas® PCR media, and from swabs discharged in 1.0 ml of the same media. The cobas® 4800 system loaded extracted DNA, controls and amplification reagents into 96-well amplification plates. Plates were then covered and placed into the cobas® z480 real-time PCR instrument. Retesting in both cobas® 4800 and TaqMan 48 assays was performed to further investigate specimens providing discrepant results.

Results A total of 708 clinical specimens (293 male urines and 415 swab specimens, of which 356 self-collected vaginal swabs, 45 swabs from cervix and 14 swabs from male urethra) were analysed. The results were concordant in 98.5% of cases (697/708). Out of 708 samples, 50 provided positive results (17 men, 33 women). Three urine specimens and eight vaginal swabs provided discrepant results. Out of five specimens providing positive results in the reference CT assay, four were false-negative in the cobas® 4800 CT test. Out of six positive results by the cobas® 4800 assay, five were false-positive. After discrepancy analysis, the prevalence of the CT infection was 7.7% (55/708). The sensitivity and specificity of the cobas® 4800 CT/NG test were 92.7% (urine specimens 94.1%, swab specimens 92.1%) and 99.2%, respectively. The three false-negative results in swabs could be explained by the procedure not consistent with the manufacturer's instructions. Indeed, swabs were not inserted directly into the cobas® media vials.

Conclusion The cobas® 4800 CT/NG test is suitable for high through-put identification of the *C trachomatis* infection.

P3-S1.15 THE MOLECULAR DIAGNOSIS OF RECTAL GC AND CT INFECTIONS USING THE FTA ELUTE CARD FOR SPECIMEN COLLECTION AND THE REAL-TIME MULTIPLEX PCR FOR DETECTION

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K H Chi, C Y Chen, T Ye, E Nachamkin, R Ballard. *CDC, Atlanta, USA*

Background To evaluate the potential use of the Whatman Indicating FTA Elute Micro Card for collection, transport, and storage of rectal swab specimens for subsequent detection of STD pathogens in MSM using a TaqMan-based real-time multiplex PCR.

Methods Two rectal swabs were obtained by the physician from each participant in a study to determine carriage of STD pathogens among MSM. One of the swabs was placed into a tube containing 1 ml of Genelock transport medium and while the other swab was firmly pressed onto an FTA Card with three side to side motions held at approximately 60° angle each time. Genomic DNA was eluted from three discs (3 mm diameter) punched out of each card after storage at room temperature for up to 6 months and tested by a real-time multiplex PCR assay which simultaneously detects *lymphogranuloma venereum* (LGV), non- LGV, *Chlamydia trachomatis* (CT), and *Neisseria gonorrhoeae* (GC), and human DNA control. For comparison, an aliquot of sample from genelock tube was extracted using the Qiagen DNA mini kit and tested with same real-time multiplex PCR assay.

Results Using purified DNA obtained from the Genelock specimens, the real-time multiplex PCR assay detected nine GC and 17 non-LGV CT; while 7 GC and 15 non-LGV CT were detected in DNA samples eluted from the FTA Cards and used directly for PCR. There were three GC and non-LGV co-infections and no LGV was detected using both specimen collection methods. A substantial number of specimens were found to be PCR inhibitory either collected in Genelock (18.3%) or on FTA Cards (15.4%).

Conclusions The FTA Elute Micro Card allows stable storage and convenient transport of rectal swab specimens at room temperature. DNA can be eluted from the card with simple processes instead of numerous purification procedures for downstream real-time PCR amplification and aetiology detection. This preliminary evaluation shows the potential use of FTA Card for rectal specimen collection and PCR testing, and may also provide a cost-saving alternative to expensive international shipping of specimens on dry ice from remote study sites.

P3-S1.16 COMPARISON OF THE ABBOTT M2000 REALTIME CT ASSAY FOR *CHLAMYDIA TRACHOMATIS* MONITORING IN TANZANIA COMPARED TO THE ROCHE AMPLICOR CT ASSAY

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[1]P Agreda, [1]L Dize, [1]S West, [2]J A Williams, [2]B Van Der Pol, [1]C A Gaydos. *[1]Johns Hopkins University, Baltimore, USA; [2]Indiana University USA*

Background The Abbott m2000 RealTime CT assay was evaluated as a new option for the detection of *Chlamydia trachomatis* in specimens obtained from Tanzania, and its performance was compared to the performance of the Roche Amplicor CT Assay.

Methods Duplicate swab specimens were collected from villages throughout Tanzania. 304 duplicate samples were shipped to the Johns Hopkins STD laboratory at 2–8°C for the detection of *C trachomatis*. All swab specimens were shipped in a dry state, expressed in 1 ml of sterile molecular grade DEPC water upon arrival, and analysed using the Roche Amplicor CT assay. Prior to Roche Amplicor amplification and detection, DNA extraction was performed using the Roche Magna Pure LC robot. The duplicate swab specimens were shipped to Indiana University for Abbott m2000 RealTime CT assay analysis. The bacterial load was measured by the DC value of the m2000 RealTime CT.

Results Of 304 specimens, 44 (14.5%) were positive for CT via Roche Amplicor CT assay, and 53 (17.4%) were positive for CT via Abbott m2000 RealTime CT assay. The relative quantitation for the m2000 assay ranged from DC 0.62 to DC 22.16. If the Roche PCR assay was considered to be the reference standard, the Abbott m2000 RealTime CT assay sensitivity was 44/44 (100%), specificity was 251/260 (96.53%), positive predictive value was 251/251(100%), and negative predictive value was 44/53 (83.01%). The κ score was 0.890. Discordant specimens, which were determined to be negative by Roche Amplicor and positive by Abbott m2000 RealTime, were tested by Gen-Probe TMA. Of nine discordant tests, two were positive, five were negative, and two were of insufficient volume for retesting. After discordant testing, there appeared to be five samples that were graded to be false positives by m2000. The Abbott m2000 RealTime CT assay sensitivity remained 100%, while specificity increased to 256/258 (99.2%). The negative predictive value increased to 46/48 (95.83%). The κ score was 0.9748 after discordant results were further analysed.

Conclusions Abbott m2000 RealTime CT assay demonstrates excellent sensitivity and specificity compared to the Roche Amplicor CT Assay for the detection of *C trachomatis*. It may be advantageous to be able to measure the relative concentration for CT in some epidemiologic studies.

P3-S1.17 SYNDROMIC MANAGEMENT OF CERVICITIS AND VAGINAL DISCHARGE AT A STI CLINIC IN JAMAICA: LOW CURE RATES FOR CHLAMYDIAL INFECTION AND TRICHOMONIASIS

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[1]M Hobbs, [2]C Anderson, [2]T Hylton-Kong, [2]S Eastman, [1]K Rich, [3]M Gallo, [3]J Legardy-Williams, [4]E Costenbader, [4]M Steiner, [3]L Warner. *[1]University of North Carolina, Chapel Hill, USA; [2]Comprehensive Health Centre, Center of Excellence, Kingston, Jamaica; [3]Centers for Disease Control and Prevention, USA; [4]Family Health International, Research Triangle Park, USA*

Background Management of cervicitis and abnormal vaginal discharge in Jamaica is based on the syndromic approach recommended by the