

## Comparison between (UTM-RT) and M4RT kits for the collection of clinical specimens for the detection of Chlamydia trachomatis with COBAS® TaqMan® 48 CT Test.

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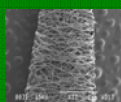
**Background.** *Chlamydia trachomatis* (CT) is the most common agent associated with sexual transmitted diseases that can occur asymptotically. The diagnosis of CT infections is done with nucleic acid amplification assays mainly; quality and stability of the clinical specimen are essential for the performance of the molecular assays.

**Objective.** To compare the flocked swabs and Universal Transport Medium (FS+UTM-RT) (Copan Italia spa) to the M4RT® (MicroTest Culture Transport System, Remel) for the detection of *Chlamydia trachomatis* with the Roche COBAS® TaqMan® 48 CT Test v2.0 on clinical specimens.

### Materials



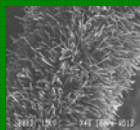
3 ml MRT4 Medium with female and male rayon swabs



Rayon Swab



3 ml UTM-RT With Female regular flocked swab 519CS01 and male flocked swab 525CS01



Flocked swab

SWABS	females	males	tot
A-SW	1	10	11
E-SW	46	/	46
U-SW	1	29	30
tot	48	39	87

Tab.1

**Methods.** For this study, 2 clinical specimens were collected in random order from patients attending a sexual transmitted diseases clinic. One specimen was collected with a flocked swab stored in a tube of UTM-RT medium, the second one was collected with a rayon swab and stored in a tube of M4RT medium.

All specimens were analysed with the COBAS® TaqMan® 48 CT assay as per manufacturer testing procedure.

The kit positive control (LowCP) was tested in duplicate, one with the kit recommended M4RT medium and the other with the UTM-RT medium.

For each specimen test and control the qualitative result (pos/neg) and the threshold Cycle (Ct) of the internal Quality Standard (QS) and of the target were recorded.

To date 87 patients were tested (48 females and 39 males) with double specimens (174 specimens): 46 endocervical swabs (E-SW), 30 urethral swabs (U-SW) and 11 anal swabs (A-SW) were collected (Tab.1). The study is still in progress.

**Results.** In the 87 specimens, collected in the SF+UTM-RT, 10 CT positive e 77 negative were found, while 8 CT positive and 79 negative were found in the specimens collected in the M4RT (Tab.2).

85 patients (98%) had concordant results in both collection systems. The 2 discordants (2%) were repeated and confirmed positive in FS+UTM-RT and negative in M4RT (Fig. 1).

30 LowCP were tested in duplicate, one in M4RT and the other in UTM-RT. The Ct average of the target is 0.7 lower in the LowCP-UTM-RT (Ct = 37.3) compared to the LowCP- M4RT (Ct= 38) (Fig.2).

In the CT positive specimens, the target Ct average is 2.23 lower for the specimens in UTM-RT (Ct = 28.77) compared to the specimens in M4RT (Ct = 31) (Fig 2). Positive specimens were found in each anal, endocervical and urethral swabs (Tab.3).

No results were found inhibited in any of the two collection systems.

In the CT negative specimens, the Ct average of the QS was equal (M4RT Ct = 36,21 UTM-RT Ct =36.15) (Fig.3).

		UTM-RT			tot
		POS	NEG	invalid	
M4RT	POS	8	0	0	8
	NEG	2	77	0	79
	invalid	0	0	0	0
tot		10	77	0	87

Tab.2

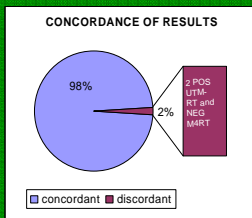


Fig.1

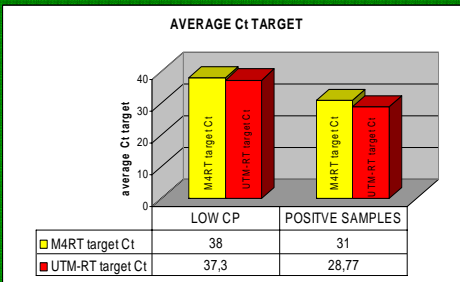


Fig.2

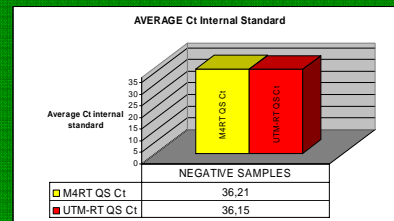


Fig.3

SWABS	A-SW	E-SW	U-SW	tot
POS	2	6	2	10
NEG	9	40	28	77
tot	11	46	30	87

Tab.3

**Conclusions.** The Copan FS+UTM-RT collection system detected 2 CT infected patients that were missed by the M4RT collection system; there are not inhibitors, confirmed by the Internal Quality Standard that had similar Ct in both collection systems. For the FS+UTM-RT collection system, the fluorescent signal has a lower Ct average, demonstrating a better amplification efficiency due to less interference found in the medium used. The Ct-Target analysis of the positive specimens in FS+UTM-RT system seem to partially increase the Roche COBAS® TaqMan® 48 CT assay sensitivity, probably also due to the major quantity of sample collected with the flocked swab.