

## Testing for Chlamydia trachomatis

**SKUP-statement, December 2005**

1. *Infection with Chlamydia trachomatis*

Chlamydia trachomatis is an intracellular organism, primarily affecting the genital mucous membrane. The diagnosis of genital chlamydial infections has evolved rapidly from the 1990s. In principle, the detection of Chlamydia trachomatis is tantamount to infection. The ideal detection method has 100 % sensitivity (detects all infections) and 100% specificity (no false positive). This method does not exist, of course.

2. *The “gold standard” or the criterion standard test*

The gold standard for a method is a diagnostic test that is regarded as definitive. The gold standard for Chlamydia trachomatis is cultivating the sample in a cell culture. This method is good under optimal conditions, but because C. trachomatis dies during transport, the method is rarely used to day.

3. *Methods in the departments of microbiology*

The methods for detection of Chlamydia trachomatis in the departments of microbiology are nucleic acid amplification tests (NAAT). NAAT for Chlamydia may be performed on swab specimens collected from the cervix (women) or urethra (men), on self-collected vaginal swabs or on voided urine. These methods are far more sensitive than the previous ELISA (antigen – antibody) tests. The ELISA tests moreover are unsuited for noninvasive samples.

4. *Near patient testing in primary health care*

There is no situation in primary health care with the need of an acute Chlamydia test answer. If the test still is carried out in general practise, one has to demand the same analytical quality for these tests as for the methods used in hospitals. All the commercial rapid tests intended for use in primary health care are based on the ELISA technique.

5. *Quality goals*

The suggested quality goals are based on expert recommendations. The SKUP quality goal for rapid testing of Chlamydia trachomatis implies a sensitivity of 85% and a specificity of 95%. A positive test result must be confirmed in a hospital laboratory.

6. *Expert statement*

Experts in microbiology in Denmark, Norway and Sweden do not expect that commercial point-of-care-tests for Chlamydia, based on ELISA techniques, can meet the necessary quality goals.

7. *SKUP statement, December 2005*

**For the time being, SKUP will not take on assignments with evaluations of rapid tests for Chlamydia trachomatis.**