A study to evaluate the correlation of the cobas 4800 CT/NG test with the Abbott m2000 CT/NG test

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This study is being conducted to provide performance evaluation data for the cobas 4800 CT/NG Test. This data will be used as part of the cobas 4800 CT/NG Test CE submission package. Comparison with a 'state of the art' technique (Abbott...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Chlamydial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33357

Source
ToetsingOnline

Brief title
cobas CT/NG test

Condition

- Chlamydial infectious disorders

Synonym
Chlamydia, STD

Research involving
Human

Sponsors and support

Primary sponsor: Roche Molecular Systems (RMS)
Source(s) of monetary or material Support: Roche Molecular Systems (RMS);Pleasanton;CA;USA

Intervention

Keyword: Chlamydia trachomatis, Neisseria gonorrhoea, Real time PCR, Sexually teransmitted disease

Outcome measures

Primary outcome

The statistical analyses will be performed separately for each type of specimen. The positive correlation, negative correlation and overall agreement (total concordance) of the cobas 4800 CT/NG Test to the Abbott m2000 CT/NG Test will be calculated along with the 95% confidence intervals. Calculations will be done with initial results as well as final resolved results.

The cobas 4800 CT/NG Test and the Abbott m2000 CT/NG Test shall be considered equivalent by having the exact 95% (one-sided) confidence bound for percent Chlamydia trachomatis positive specimen greater than 90%.

The cobas 4800 CT/NG Test and the Abbott m2000 CT/NG Test shall be considered equivalent by having the exact 95% (one-sided) confidence bound for percent Neisseria gonorrhoeae positive specimen greater than 90%.

In the event that the final samples sizes for the endocervical swab CT and/or NG positive specimens falls below 50, an overall cobas 4800 CT/NG Test positive correlation of at least 95% must be met for both CT and NG to show equivalence to the Abbott m2000 CT/NG Test.

Secondary outcome

n.a.

Study description

Background summary

Chlamydia trachomatis (CT) and Neisseria gonorrhoea (NG) are the most prevalent sexual transmitted diseases worldwide and and a serious public health problem. Detection of CT/NG infections are currently carried out by molecular techniques in routine molecular laboratories. The most commonly used clinical specimens are urine and vaginal/endocervical swabs.
Development in the field of molecular detection apparatus is moving rapidly and new requirements for high specificity and sensitivity are being implemented in new generation machines. In addition, new variants as well as reduced NG specificity (as a conscequency of improved detection methods) has lead to the development of a new cobas 4800 system by Roche to replace the first generation cobas amplicor system. This study is being conducted to provide performance evaluation data for the cobas 4800 CT/NG test which meet the present requirements for molecular diagnostic tests.

Study objective

This study is being conducted to provide performance evaluation data for the cobas 4800 CT/NG Test. This data will be used as part of the cobas 4800 CT/NG Test CE submission package. Comparison with a 'state of the art' technique (Abbott m2000 system) will provide the data needed for registration of this new cobas 4800 system and use in patient care.

Study design

This non-clinical study is designed to obtain a clinical specimen correlation analysis between the cobas 4800 CT/NG Test and the Abbott m2000 CT/NG Test. This study will include the co-collection of vaginal as well as endocervical swab specimens for both the Abbott m2000 CT/NG Test and the cobas 4800 CT/NG Test, each requiring test-specific collection devices. This study will also include the collection of male and female urine specimens, in which the single specimen will be used with the appropriate collection devices for both testing methods. The VU University Medical Center will receive urine and vaginal swab specimens from the Groningen Laboratory of Infectious Disease and endocerviacl swabs specimen from the USA. All clinical specimens collected into the Roche specimen collection devices will be stored at 2-8°C and tested at the VU University Medical Center using the cobas 4800 CT/NG Test. Swab and urine clinical specimens collected into the Abbott specimen collection devices will be stored at -20°C and tested at the site of collection as part of routine diagnostics using the Abbott m2000 CT/NG Test. All invalid specimens will be retested at the initial testing site using an additional aliquot of the original clinical specimen. All specimens found to be discrepant between the

Roche and Abbott tests will be analyzed at the VU University Medical Center using an in-house home brew CT/NG test, the results of which will be used for final resolution. All specimen retains at the Abbott testing site will be stored at that site and made available for additional testing if required. All specimens collected into the Roche collection devices will be stored at the VU University Medical Center and made available for retesting if required.
Retains from the specimens collected into Roche collection devices will be sent to Roche at the completion of the study.
After testing is completed, the remaining testing materials will be returned to Roche. All test results from both testing systems will be de-linked from patient identification and transferred to Roche Molecular Systems, Assay Development in Pleasanton, California. Electronic raw data files from the cobas 4800 CT/NG testing together with Abbott m2000 CT/NG results will be transferred to Roche for analysis and comparison for each specimen tested.

Study burden and risks

The nature and extent of the burden and risks associated with participation will be almost zero. For urines residual specimen can be used and for vaginal and endocervical co-collection a second swab will be taken in 1200 patiënts/ swab type during routine speciemen colllection for detection of CT and/or NG infection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Suspected for STD

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2009
Enrollment:	1200
Type:	Actual

Ethics review

Approved WMO Date:	08-07-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL28074.029.09