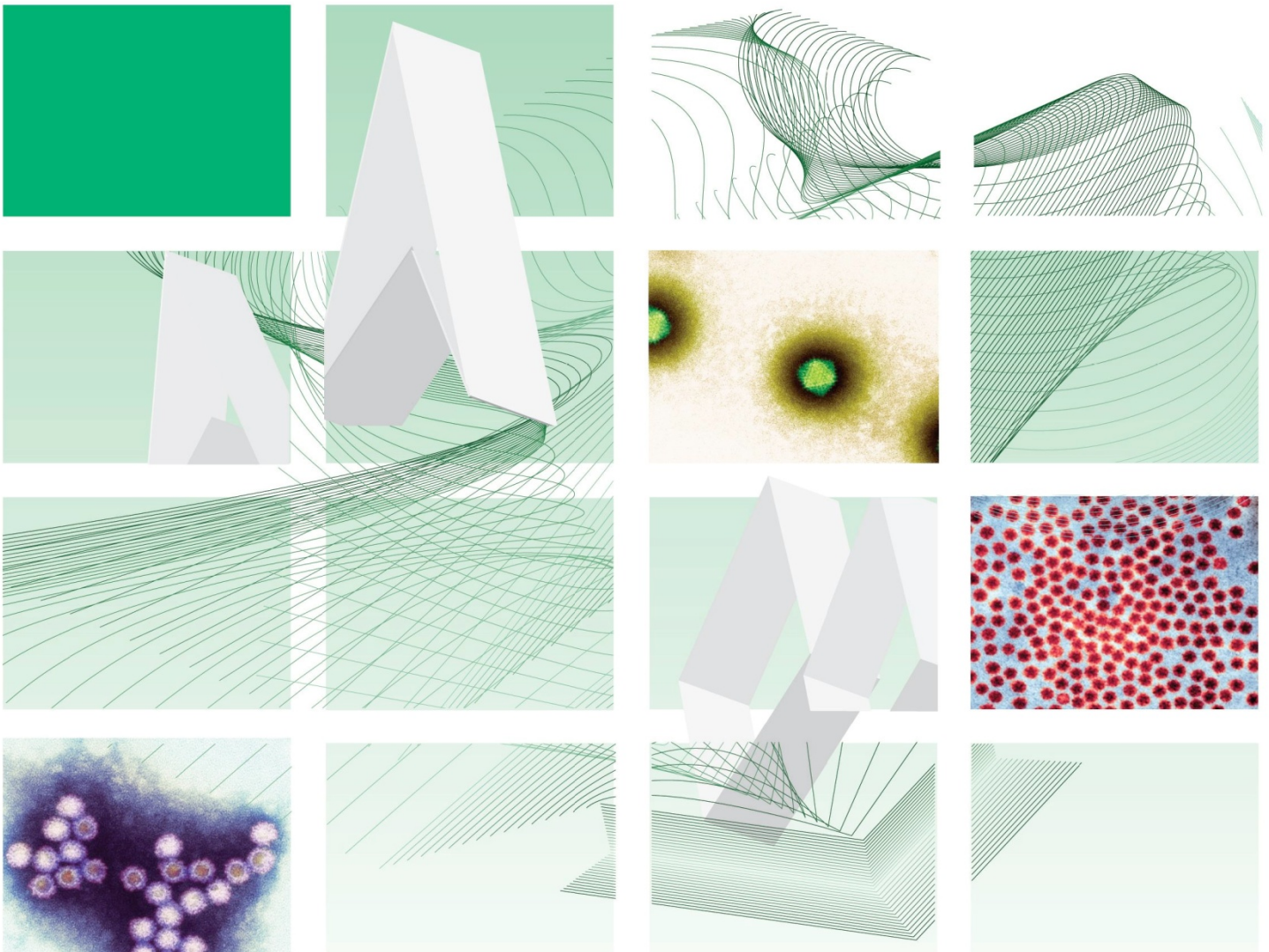




# UK Standards for Microbiology Investigations

## *Chlamydia trachomatis* Infection – Testing by Nucleic Acid Amplification Tests (NAATs)



## Acknowledgments

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UK Standards for Microbiology Investigations (SMIs) are developed under the auspices of Public Health England (PHE) working in partnership with the National Health Service (NHS), Public Health Wales and with the professional organisations whose logos are displayed below and listed on the website <http://www.hpa.org.uk/SMI/Partnerships>. SMIs are developed, reviewed and revised by various working groups which are overseen by a steering committee (see <http://www.hpa.org.uk/SMI/WorkingGroups>).

The contributions of many individuals in clinical, specialist and reference laboratories who have provided information and comments during the development of this document are acknowledged. We are grateful to the Medical Editors for editing the medical content.

For further information please contact us at:

Standards Unit  
Microbiology Services  
Public Health England  
61 Colindale Avenue  
London NW9 5EQ

E-mail: [standards@phe.gov.uk](mailto:standards@phe.gov.uk)

Website: <http://www.hpa.org.uk/SMI>

UK Standards for Microbiology Investigations are produced in association with:



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NICE has accredited the process used by Public Health England to produce Standards for Microbiology Investigations. Accreditation is valid for 5 years from July 2011. More information on accreditation can be viewed at [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

For full details on our accreditation visit: [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

## Amendment Table

Each SMI method has an individual record of amendments. The current amendments are listed on this page. The amendment history is available from [standards@phe.gov.uk](mailto:standards@phe.gov.uk).

New or revised documents should be controlled within the laboratory in accordance with the local quality management system.

Amendment No/Date.	4/16.04.14
Issue no. discarded.	3.1
Insert Issue no.	3.2
<b>Section(s) involved</b>	<b>Amendment</b>
Whole document.	<p>Document has been transferred to a new template to reflect the Health Protection Agency's transition to Public Health England.</p> <p>Front page has been redesigned.</p> <p>Status page has been renamed as Scope and Purpose and updated as appropriate.</p> <p>Professional body logos have been reviewed and updated.</p> <p>Standard safety and notification references have been reviewed and updated.</p> <p>Scientific content remains unchanged</p>

Amendment No/Date.	3/29.01.13
Issue no. discarded.	3
Insert Issue no.	3.1
<b>Section(s) involved</b>	<b>Amendment</b>
Contents page.	Accreditation logo added.
References.	Hyperlink removed.

## UK Standards for Microbiology Investigations<sup>#</sup>: Scope and Purpose

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### Users of SMIs

- SMIs are primarily intended as a general resource for practising professionals operating in the field of laboratory medicine and infection specialties in the UK.
- SMIs provide clinicians with information about the available test repertoire and the standard of laboratory services they should expect for the investigation of infection in their patients, as well as providing information that aids the electronic ordering of appropriate tests.
- SMIs provide commissioners of healthcare services with the appropriateness and standard of microbiology investigations they should be seeking as part of the clinical and public health care package for their population.

### Background to SMIs

SMIs comprise a collection of recommended algorithms and procedures covering all stages of the investigative process in microbiology from the pre-analytical (clinical syndrome) stage to the analytical (laboratory testing) and post analytical (result interpretation and reporting) stages.

Syndromic algorithms are supported by more detailed documents containing advice on the investigation of specific diseases and infections. Guidance notes cover the clinical background, differential diagnosis, and appropriate investigation of particular clinical conditions. Quality guidance notes describe laboratory processes which underpin quality, for example assay validation.

Standardisation of the diagnostic process through the application of SMIs helps to assure the equivalence of investigation strategies in different laboratories across the UK and is essential for public health surveillance, research and development activities.

### Equal Partnership Working

SMIs are developed in equal partnership with PHE, NHS, Royal College of Pathologists and professional societies.

The list of participating societies may be found at <http://www.hpa.org.uk/SMI/Partnerships>. Inclusion of a logo in an SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing SMIs. Nominees of professional societies are members of the Steering Committee and Working Groups which develop SMIs. The views of nominees cannot be rigorously representative of the members of their nominating organisations nor the corporate views of their organisations. Nominees act as a conduit for two way reporting and dialogue. Representative views are sought through the consultation process.

SMIs are developed, reviewed and updated through a wide consultation process.

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<sup>#</sup>Microbiology is used as a generic term to include the two GMC-recognised specialties of Medical Microbiology (which includes Bacteriology, Mycology and Parasitology) and Medical Virology.



## Quality Assurance

NICE has accredited the process used by the SMI Working Groups to produce SMIs. The accreditation is applicable to all guidance produced since October 2009. The process for the development of SMIs is certified to ISO 9001:2008.

SMIs represent a good standard of practice to which all clinical and public health microbiology laboratories in the UK are expected to work. SMIs are NICE accredited and represent neither minimum standards of practice nor the highest level of complex laboratory investigation possible. In using SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. SMIs also provide a reference point for method development.

The performance of SMIs depends on competent staff and appropriate quality reagents and equipment. Laboratories should ensure that all commercial and in-house tests have been validated and shown to be fit for purpose. Laboratories should participate in external quality assessment schemes and undertake relevant internal quality control procedures.

## Patient and Public Involvement

The SMI Working Groups are committed to patient and public involvement in the development of SMIs. By involving the public, health professionals, scientists and voluntary organisations the resulting SMI will be robust and meet the needs of the user. An opportunity is given to members of the public to contribute to consultations through our open access website.

## Information Governance and Equality

PHE is a Caldicott compliant organisation. It seeks to take every possible precaution to prevent unauthorised disclosure of patient details and to ensure that patient-related records are kept under secure conditions.

The development of SMIs are subject to PHE Equality objectives [http://www.hpa.org.uk/webc/HPAwebFile/HPAweb\\_C/1317133470313](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317133470313). The SMI Working Groups are committed to achieving the equality objectives by effective consultation with members of the public, partners, stakeholders and specialist interest groups.

## Legal Statement

Whilst every care has been taken in the preparation of SMIs, PHE and any supporting organisation, shall, to the greatest extent possible under any applicable law, exclude liability for all losses, costs, claims, damages or expenses arising out of or connected with the use of an SMI or any information contained therein. If alterations are made to an SMI, it must be made clear where and by whom such changes have been made.

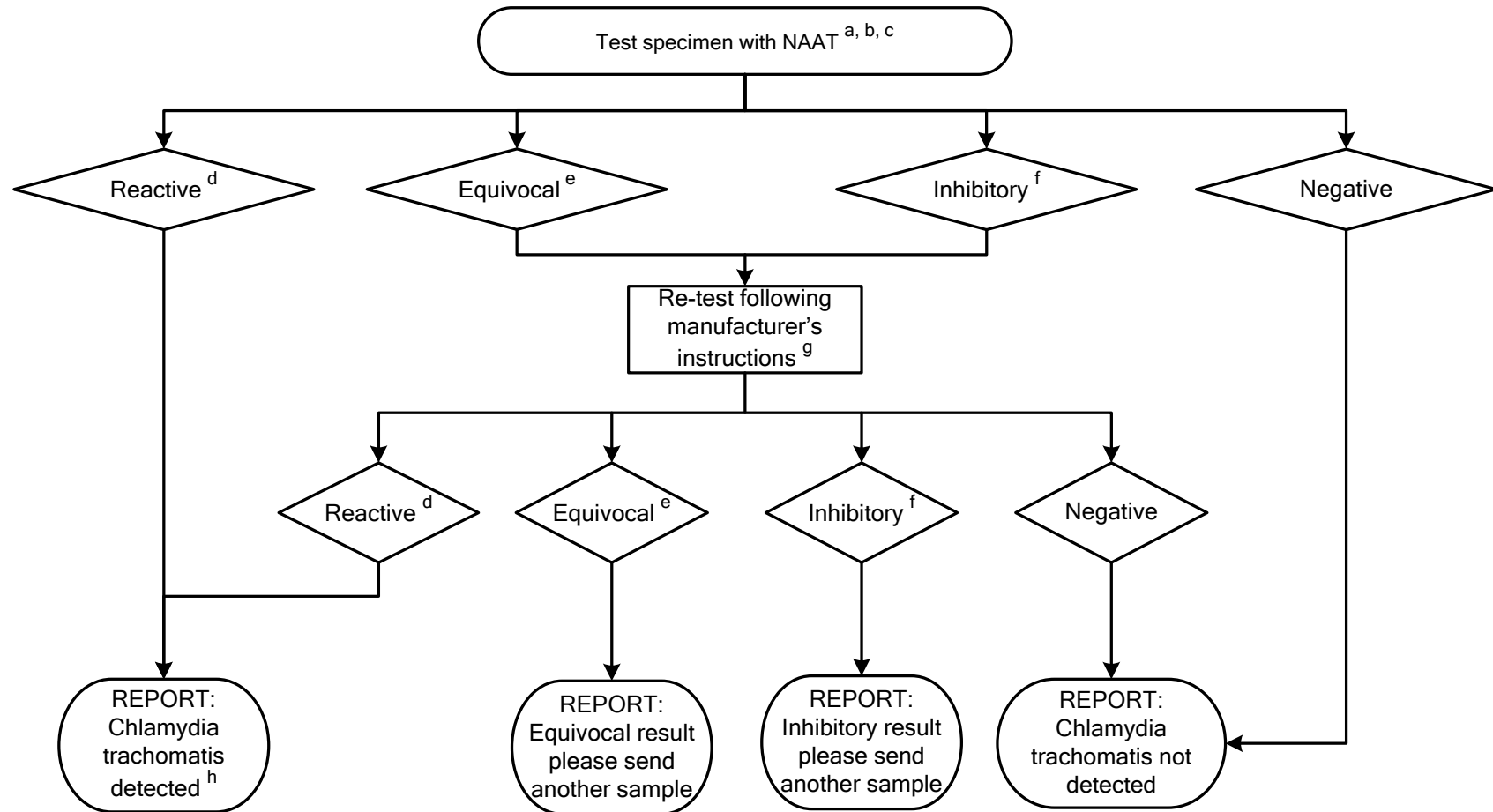
The evidence base and microbial taxonomy for the SMI is as complete as possible at the time of issue. Any omissions and new material will be considered at the next review. These standards can only be superseded by revisions of the standard, legislative action, or by NICE accredited guidance.

SMIs are Crown copyright which should be acknowledged where appropriate.

### **Suggested Citation for this Document**

Public Health England. (2014). *Chlamydia trachomatis* Infection – Testing by Nucleic Acid Amplification Tests (NAATs). UK Standards for Microbiology Investigations. V 37 Issue 3.2. <http://www.hpa.org.uk/SMI/pdf>.

## ***Chlamydia trachomatis* Infection – Testing by Nucleic Acid Amplification Tests (NAATs)**





## Footnotes

- a) First catch urine or urethral swab for men and vaginal swab (which may be self-collected) or endocervical swab for women are the recommended specimen types. The testing of first catch urine specimens from women may result in lower sensitivity and is not recommended by national or European guidelines<sup>1,2</sup>. Where extra-genital specimens are being tested, local validation should be carried out (see [Q 1 – Commercial and In-House Diagnostic Tests: Evaluations and Validations](#) for further information). In all cases laboratories should follow manufacturer's instructions regarding individual specimen types. Laboratories should ensure that their assay is capable of detecting the new variant *C. trachomatis* (nvCT).
- b) Laboratories using dual nucleic acid amplification tests (NAATs) capable of detecting both *C. trachomatis* and *N. gonorrhoeae* should follow nationally agreed algorithms and confirmatory strategy for the *N. gonorrhoeae* component of the test. In women, urine is not the optimal sample for *N. gonorrhoeae*/*C. trachomatis* combined NAATs<sup>2,3</sup>.
- c) Laboratories should follow good laboratory practice in molecular testing. Good laboratory practice for *C. trachomatis* should include environmental swabbing. See [Q 2 – Quality Assurance in Diagnostic Virology and Serology Laboratory](#) and [Q 4 – Good Laboratory Practice when Performing Molecular Amplification Assays](#) for further information.
- d) As per national and international guidelines, where the PPV is less than 90%, and for specimens from extra-genital sites (eg rectal swabs), confirmatory testing for persons with a positive *C. trachomatis* screening test should be considered, taking into consideration local evaluation and validation data<sup>1,2</sup>. In laboratories where confirmatory testing results are found to be consistently concordant following audit, confirmatory testing may be deemed unnecessary.
- e) The term 'equivocal' may be different for various platforms eg 'indeterminate'.
- f) The term 'inhibitory' may be different for various platforms eg 'invalid'.
- g) Some manufacturers work to a consensus algorithm of the best of three results. This has reagent and staff cost implications.
- h) The primary sample container should be checked before reporting to ensure sample confirmation is not required.

### **Additional footnote for information, not stated in the flowchart:**

- i) Where results are likely to have medicolegal significance, specimens should be handled in accordance with Royal College of Pathologists' guidance<sup>3,4</sup>. Legal precedent is limited, but laboratories should consider confirmatory testing with an assay of equal sensitivity and an alternative gene target in the case of a reactive result.
- j) The detection of *C. trachomatis* may be positive in patients with LGV<sup>5</sup>. Definitive diagnosis of LGV to distinguish LGV serovars from non-LGV serovars is done by PCR.

## Notification to PHE<sup>6,7</sup> or Equivalent in the Devolved Administrations<sup>8-11</sup>

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The Health Protection (Notification) regulations 2010 require diagnostic laboratories to notify Public Health England (PHE) when they identify the causative agents that are listed in Schedule 2 of the Regulations. Notifications must be provided in writing, on paper or electronically, within seven days. Urgent cases should be notified orally and as soon as possible, recommended within 24 hours. These should be followed up by written notification within seven days.

For the purposes of the Notification Regulations, the recipient of laboratory notifications is the local PHE Health Protection Team. If a case has already been notified by a registered medical practitioner, the diagnostic laboratory is still required to notify the case if they identify any evidence of an infection caused by a notifiable causative agent.

Notification under the Health Protection (Notification) Regulations 2010 does not replace voluntary reporting to PHE. The vast majority of NHS laboratories voluntarily report a wide range of laboratory diagnoses of causative agents to PHE and many PHE Health Protection Teams have agreements with local laboratories for urgent reporting of some infections. This should continue.

**Note:** The Health Protection Legislation Guidance (2010) includes reporting of Human Immunodeficiency Virus (HIV) & Sexually Transmitted Infections (STIs), Healthcare Associated Infections (HCAs) and Creutzfeldt–Jakob disease (CJD) under 'Notification Duties of Registered Medical Practitioners': it is not noted under 'Notification Duties of Diagnostic Laboratories'.

<http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/HealthProtectionRegulations/>

Other arrangements exist in [Scotland](#)<sup>8,9</sup>, [Wales](#)<sup>10</sup> and [Northern Ireland](#)<sup>11</sup>.

## References

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