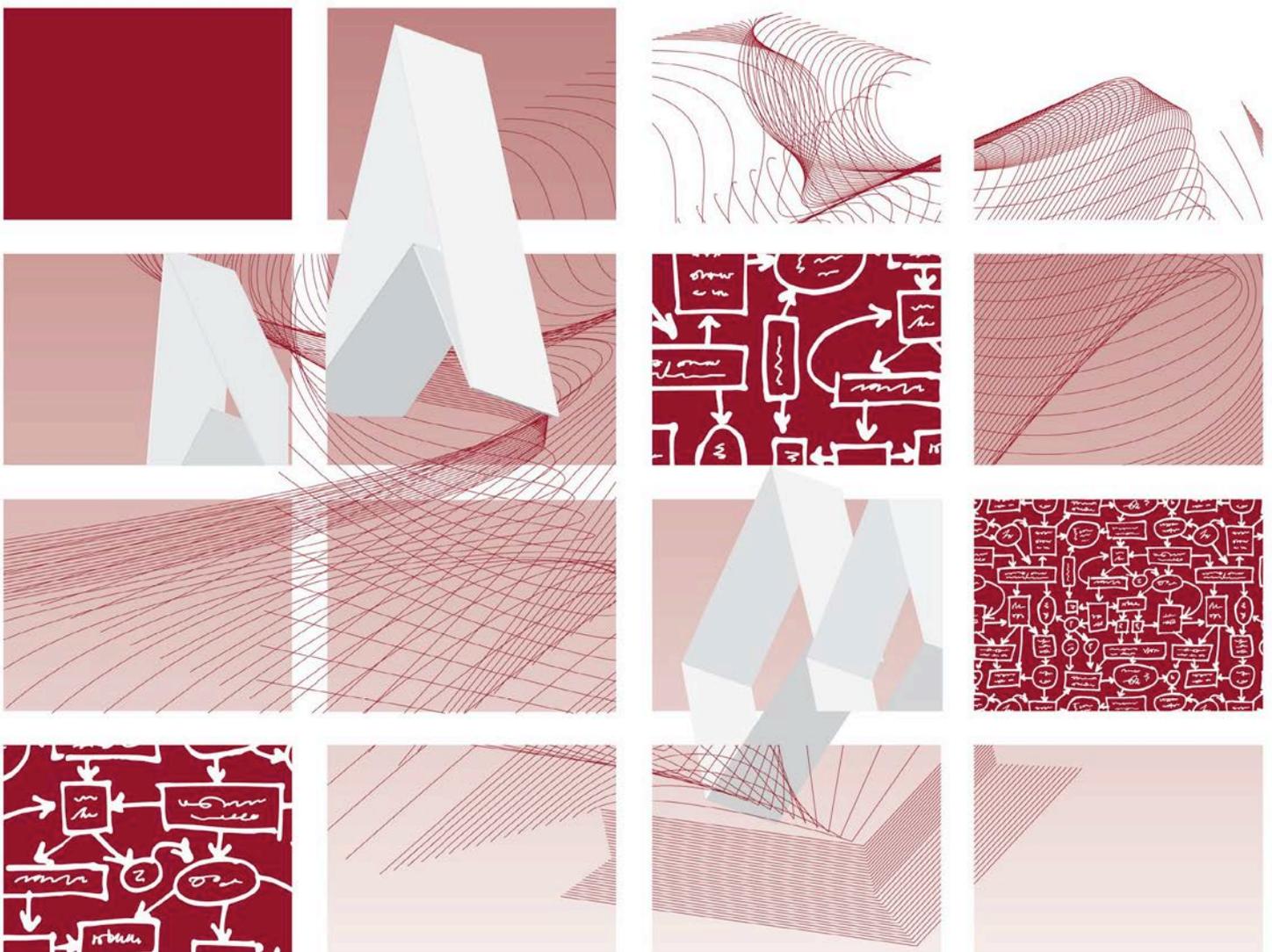




UK Standards for Microbiology Investigations

Sexually Transmitted Infections



Acknowledgments

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.

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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.

For full details on our accreditation visit: 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.

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

Amendment No/Date.	2/01.11.13
Issue no. discarded.	1.1
Insert Issue no.	1.2
Section(s) involved	Amendment
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.	1/28.09.12
Issue no. discarded.	1
Insert Issue no.	1.1
Section(s) involved	Amendment
Flowchart.	Related document Q 62 has now become P 6.

UK Standards for Microbiology Investigations[#]: Scope and Purpose

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.

[#]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. 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. (2013). Sexually Transmitted Infections. UK Standards for Microbiology Investigations. S 6 Issue 1.2. <http://www.hpa.org.uk/SMI/pdf>.

Scope of Document

UK Standards for Microbiology Investigations (SMIs) comprise a collection of recommended algorithms for initial test selection and testing methods and confirmatory strategies. UK SMIs also contain guidance notes that describe the recommended standard set of investigations consistent with current good practice in different infective disease presentations, as well as examples of standard laboratory practice and general information on clinical syndromes.

The syndromic algorithms form part of the pre-analytical stage of the investigative process and are intended to guide clinicians and diagnostic laboratory staff in the choice of the correct pathway for the investigation of a sample based upon the clinical context. It is recognised that clinical details are essential to the optimal processing of samples and the documents perform best when sufficient, relevant, clinical details are provided at the time of sample submission. The algorithms are presented in flowchart format to give a clear overview of how to proceed with the testing of specimens and the possible outcomes using the clinical history provided. If the primary testing set does not identify a causative pathogen, secondary testing should be performed if clinical and/or epidemiological features support such testing. Laboratories may wish to undertake second line tests either after, or at the same time as, the primary testing set according to the clinical and local epidemiological setting and laboratory operational capabilities. The flowcharts are intended to reflect current recommended practice, accounting for prevalence of infections in the UK, public health needs, and availability of tests, with references and links to more detailed guidance. National surveillance programmes for specific organisms should be taken into consideration when using the algorithms.

This document should be read in conjunction with relevant SMIs for laboratory processing and reporting of target organisms and public health actions.

S 6 – Sexually Transmitted Infections: Scope

The intended scope of this document is to describe which infections, and relevant associated tests, should be considered according to the different clinical presentations consistent with sexually transmitted genital tract/rectal infection. Extra genital samples, except blood are excluded.

The syndromes included have been selected to reflect the common presenting complaints of patients with sexually transmitted infections (STIs), including ulcers and vesicles, proctitis, lumps, dysuria, discharge (urethral and vaginal), testicular and pelvic pain.

The target organisms include:

- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- *Treponema pallidum*
- Human immunodeficiency virus (HIV)
- Herpes simplex virus
- Human papillomavirus

- *Trichomonas vaginalis*
- *Candida* species

Although not specifically classed as sexually transmitted diseases, additional organisms are covered as their clinical presentation may show cross-over with the classical STIs, for example, *Candida* species.

This approach covers the signs and symptoms resulting from direct infection of the genitourinary tract, rectum, external genitalia and oropharynx. It is also recognised however that the associated infections may result in additional features such as rashes, arthralgia, and neurological illness which are beyond the scope of this document.

The recommendations for testing relate to first presentations or possible re-infections; in the setting of likely recurrences (genital warts/herpes simplex infection), a more restricted approach would be valid.

Decisions on test selection priority should take account of local prevalence data. Decisions on additional tests may be made in light of a risk assessment, eg pharyngeal swabbing for *N. gonorrhoeae*.

Individuals who are at increased risk of any STI, or those with a diagnosed STI are at risk of multiple STIs. Therefore, a screening approach should be undertaken to account for possible asymptomatic, subclinical, or past unrecognised infections eg HIV, hepatitis B and syphilis and other infections in selected cases with additional risk factors¹.

Note: this document does not cover the following:

- Other infections or illnesses that are not sexually transmitted but may present together with involvement of the GU tract, such as rashes, cellulitis, uncomplicated urinary tract infection and pharyngitis
- Management of asymptomatic individuals presenting for a sexual health screen after perceived risk or after notification through contact tracing
- Child health or protection issues
- Specific issues relating to pregnancy or contraception
- Treatment

1 Notification to PHE^{2,3} or Equivalent in the Devolved Administrations⁴⁻⁷

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.

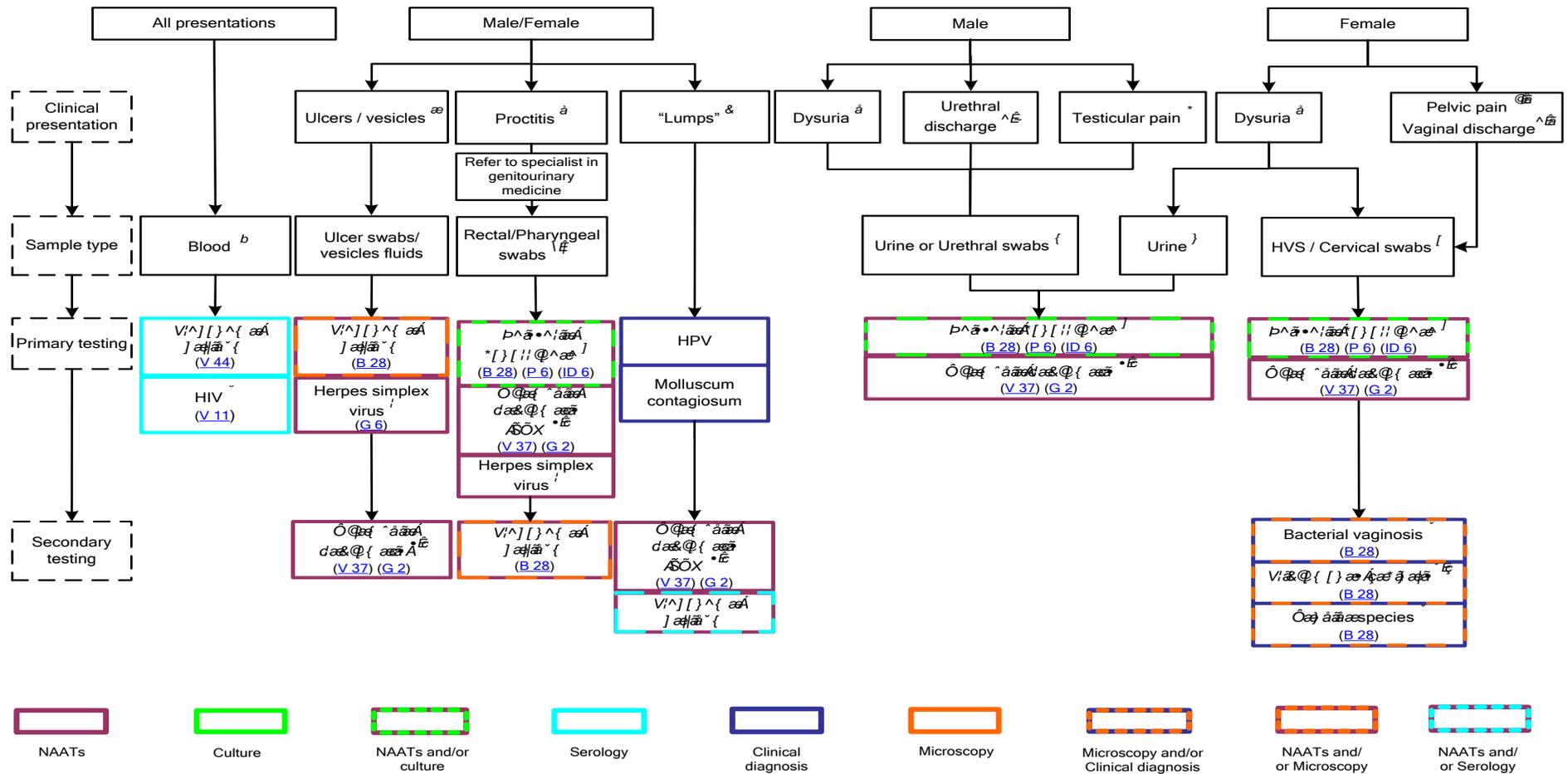
For the purposes of the Notification Regulations, the recipient of laboratory notifications is the local PHE Health Protection Team. If a case has already been notified by a registered medical practitioner, the diagnostic laboratory is still required to notify the case if they identify any evidence of 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 HIV & STIs, HCAs and CJD under 'Notification Duties of Registered Medical Practitioners': it is not noted under 'Notification Duties of Diagnostic Laboratories'.

Other arrangements exist in Scotland^{4,5}, Wales⁶ and Northern Ireland⁷.

Sexually Transmitted Infections



To view associated SMI documents please access from: <http://www.hpa.org.uk/SMI>

Footnotes

- a) Ulcers include genital, perianal, anal and oral. Vesicles and crusts are also covered under this section.
- b) Proctitis is characterised by rectal pain, discharge, constipation and tenesmus¹.
- c) “Lumps” include warts, papules and lymphadenopathy. HSV may be associated with lymphadenopathy. If the presenting complaint is lymphadenopathy of the groin only, the first recommended tests are syphilis and lymphogranuloma venereum (LGV) ([G 2 – Microbiological Investigation of Patients with Acute Lymphadenopathy and Fever](#)).
- d) UTI has been excluded. Dysuria is characterised by pain or burning on passing urine. Itching may also be present. The Primary Care Guidance for symptoms of UTI should be followed for diagnosis of UTI in primary care⁸.
- e) In the GUM clinic microscopy supports early therapeutic approach and should be done where possible.
- f) Men who have sex with men and at high risk of STI should be offered rectal and pharyngeal swabbing for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.
- g) Mumps may cause epididymitis and testicular pain.
- h) Symptoms consistent with PID (pelvic pain, dyspareunia, PV bleeding and discharge).
- i) If additional symptoms with vaginal discharge are consistent with PID, testing for bacterial vaginosis is not necessary. The investigation for vaginal discharge is set within the context of STI and other guidelines should be followed for investigation of vaginal discharge in other clinical settings⁹.
- j) If treponemal infection is first diagnosed by detection of antibody in blood, testing a CSF sample may be indicated ([V 44 – Serological Diagnosis of Syphilis](#)).
- k) Although not licensed for these sites, NAATs may be used and potentially give valid results from pharyngeal and rectal specimens. This should be validated locally for the individual platforms used^{10,11} ([V 37 – Chlamydia trachomatis Infection – Testing by Nucleic Acid Amplification Tests \(NAATs\)](#)).
- l) Individuals considered at high risk for STI should be offered rectal and pharyngeal swabbing to detect *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.
- m) Both urine and urethral swab samples perform equally well and choice of sample can be guided by patient preference¹².
- n) Urine is collected for urinalysis if clinically indicated (www.hpa.org.uk/SMI/pdf/Bacteriology). In women, urine is not the optimal sample for *Neisseria gonorrhoeae* / *Chlamydia trachomatis* combined nucleic acid amplification tests (NAATs) even in the presence of dysuria^{10,13}.
- o) Self-taken vulvo-vaginal swabs are considered equivalent to standard clinician-taken genital swabs for *Neisseria gonorrhoeae* / *Chlamydia trachomatis* (NAATs)¹⁴.

- p) Although detection of *Neisseria gonorrhoeae* by NAATs is more sensitive than culture, culture allows confirmatory identification and antimicrobial susceptibility testing¹². A culture should be taken in all cases of gonorrhoea diagnosed by NAATs¹². Local GUM clinics should inform laboratories about samples specifically requiring culture.
- q) Consider testing for other bloodborne viruses including HIV, syphilis, hepatitis B and C¹.
- r) The detection of herpes simplex virus can be performed by culture ([V 17- Isolation of Herpes Simplex Virus Associated with Herpes genitalium](#)) but NAATs is preferable due to the increase in sensitivity^{15,16}. Herpes simplex type specific serology is useful in confirming the stage of newly diagnosed lesions (primary or non-primary)^{17,18}.
- s) Samples taken from patients with LGV will be positive in Chlamydia trachomatis NAATs testing. LGV is sought in rectal swabs positive for Chlamydia trachomatis, rather than pharyngeal swabs. Definitive diagnosis of LGV to distinguish LGV serovars from non-LGV serovars is done by NAATs¹⁹. The HPA laboratory policy for LGV testing is available at http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1214291242961.
- t) Where results are likely to have medicolegal significance, specimens should be handled in accordance with Royal College of Pathologists' guidance^{10,20,21}. 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.
- u) Microscopy can include wet prep for *Trichomonas vaginalis*, yeasts and clue cells or Gram stain for clue cells and *Candida* species. Culturing of *Trichomonas vaginalis* and *Candida* species may be used in some clinical settings.
- v) NAATs and rapid antigen tests are available for the detection of *Trichomonas vaginalis*.

Additional footnote for information, not stated in the flowchart:

- w) Ureaplasma and Mycoplasma are not covered in this algorithm due to the lack of clinical significance in PID and vaginal discharge²².
- x) The detection of *Klebsiella granulomatis* previously known as *Calymmatobacterium granulomatis* (the cause of Donovanosis) is not covered in this algorithm as it is rare in the UK but should be considered in patients with appropriate travel history to the tropics and sub tropics including Western New Guinea (Papua), the Caribbean, Southern India, South Africa and Southeast Asia. Diagnosis can be performed by specialist 16S PCR²³.
- y) *Haemophilus ducreyi* is rare in the UK and declining worldwide²⁴.

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