



SEXUALLY TRANSMITTED BACTERIA REFERENCE LABORATORY

The Centre for Infections Health Protection Agency provides various areas of specialist and reference microbiology and information on these can be found at: <http://www.hpa.org.uk/srmtests>

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Table of Contents

Director's Foreword	3	Specialist and Reference Services	
Help Us to help you	4	• Gonorrhoea	10
Request Forms	5	• Treponemal	11
Faxing and emailing reports	6	• Genital Ulcer Disease	12
Specimen and sample submission guidelines	7	• <i>Chlamydia trachomatis</i>	13
Urgent specimens	8	Molecular Epidemiology/Surveillance	
STBRL Contact Details	9	• GRASP	14
		Retention Policy	15
		Compliance with Human Tissue Act	16
		Quality Assurance: EQA and IQA	17
		Caldicott Recommendations	18

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Sexually Transmitted Bacteria Reference Laboratory Director's Foreword

The Sexually Transmitted Bacteria Reference Laboratory (STBRL) is situated in the Centre for Infections (CfI) Division of the Health Protection Agency (HPA), Colindale, London. STBRL is a national reference laboratory for a number of bacteria responsible for sexually transmitted infections and receives bacterial isolates from the Health Protection Agency, National Health Service and commercial laboratories throughout the UK. The diagnostic and reference samples received are analysed by a wide range of methodologies in accordance with customer needs

STBRL is an expanding laboratory that provides specialist and reference services for the bacterial sexually transmitted pathogens, *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Treponema pallidum*, *Haemophilus ducreyi* and *Mycoplasma genitalium*. STBRL currently provides a full reference service for the identification and typing of *N. gonorrhoeae*, serological confirmation of treponemal infection, molecular diagnostics for *C. trachomatis*, *T. pallidum*, *H. ducreyi* and *M. genitalium*. Molecular typing for *T. pallidum* and *C. trachomatis* is under development.

Professor Catherine Ison
Director STBRL

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HELP US TO HELP YOU

LABELLING AND PACKAGING

- The HPA Centre for Infections receives over 300 packages containing pathological specimens every day.
- To ensure that specimens are processed as rapidly as possible, the receiving laboratory at HPA Centre for Infections Colindale should be clearly identified on the address label.
- To ensure that specimens are not subjected to needless postal delays, please always follow the National and International Postal Regulations 2007 – IATA Dangerous Goods Regulations. Biological substance, Category B, must be transported following packing instructions 650.

Postal Address:

Sexually Transmitted Bacteria Reference Laboratory (STBRL)
Health Protection Agency Centre for Infections
61 Colindale Avenue
London NW9 5HT

DX Address:

HPA Colindale
Cfi (STBRL)
DX 6530014
Colindale NW

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USER MANUAL**



REQUEST FORMS

- Full clinical information on the accompanying request forms will ensure that all required tests and interpretations are provided. Please use the appropriate request form for the desired test where possible and complete all relevant sections. Instructions on how to complete forms are on the website : <http://www.hpa.org.uk/srmtests>
- Laminated request forms suitable for repeated photocopying and PDFs on a disc have been sent to many of our customers. To help ensure accurate data entry onto our Laboratory information management system the forms are pre-addressed and bar-coded. This also ensures reports are dispatched to the appropriate address.

If you have not received or require additional laminated request forms, please contact Tony McNiff on 020 8327 6533 or e-mail: tony.mcniff@hpa.org.uk

Alternatively all STBRL request forms, *N. gonorrhoeae*, *C. trachomatis*, *T. pallidum*, & *M. genitalium* may be downloaded from the HPA website at <http://www.hpa.org.uk/srmtests>

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USER MANUAL**



Faxing and emailing reports containing patients' data.

It is our policy that reports containing patient data should not be sent by E-mail.

E-mails cannot be relied on to guarantee security of patient data because they can be intercepted by a third party on route.

In some circumstances STBRL can send results by fax. In this case the following conditions must be adhered to after discussion with the Laboratory. Refer also to the document "Cfl recognition of Caldicott recommendations".

The report must be sent to a "safe haven" fax machine. This means that, if the location is in general use, consideration must be given to ensuring that unauthorised personnel are unable to read reports, accidentally or otherwise. Also, the room housing the fax machine must be in a secure location, which is locked if it is likely to be unattended at the time the fax is sent.

Assurance must be sought from the intended recipient of the faxed report, preferably in writing, that the receiving fax machine is a safe-haven. If it is essential to fax patient identifiable information to STBRL please speak to the Director's PA who will arrange for someone to receive the fax.

Confirmation must always be sought from the intended recipient that the fax is expected and has been received.

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SPECIMEN AND SAMPLE SUBMISSION GUIDELINES

All Specimens **MUST** be labelled with the following:-

- Surname/Forename or other Unique Patient Identifier
- Date of Birth
- Sender's Sample Number

Request Forms **MUST** match and include the above information on the sample
Plus Name and contact information of requester (vital for urgent requests)

- Tests required
- Specimen type and site
- Sender's Sample Number
- Consultant or GP (if applicable)
- Date of dispatch
- Sex
- Relevant clinical information
- Date of onset
- NHS number
- Date and time of collection of specimen

Please complete the forms in **BLACK** or **BLUE** pens (**NOT RED** or any other colour).

Further information is included in a video to be found at http://www.hpa.org.uk/cfi/packaging_video.htm

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URGENT SPECIMENS

- If a specimen result is required urgently, prior telephone contact with the receiving unit or Laboratory Director or Laboratory Manager will ensure priority. **Also clearly mark 'URGENT' on the request form.**

Key factors affecting specimen performance

- The time taken to perform bacterial identification and typing tests is dependent on the receipt of pure cultures. Cultures that require purification or that cannot be retrieved because they are no longer viable and necessitate a second isolate may increase turnaround time significantly.
- Lysed blood or heavily bloodstained samples can interfere with serological testing for syphilis.
- DNA in specimens requesting molecular tests may degrade if stored for too long before referral.
- If a specimen is received in STBRL, which is unsuitable for examination, we will endeavour to contact the sender to discuss the problem.
- If a specimen is submitted to STBRL for an investigation that we do not offer we archive the sample/isolate and issue a report to the sender explaining the reasons for the samples rejection.
- For further information concerning services or matters of interest consult our newsletters:
<http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListDate/Page/1200660009616?p=1200660009616>

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STBRL CONTACT DETAILS

Opening hours 9am to 5.30pm
Cfl Switchboard 020 8200 4400

STBRL Fax No. 020 8327 6474
Email: stbrl@hpa.org.uk

Enquiries and Director's PA Mrs Mary Bryan Tel: 0208 327 6464 mary.bryan@hpa.org.uk	Director Professor Catherine Ison Tel: 0208 327 6462 catherine.ison@hpa.org.uk	Laboratory Manager Mr Paul Laidler Tel: 0208 327 7798 paul.laidler@hpa.org.uk
Specialist and Reference Section Section Head Dr Sarah Alexander 0208 327 6771 sarah.alexander@hpa.org.uk	Specialist and Reference Section Team Leader Mrs Pamela Saunders 0208 327 7328 pamela.saunders@hpa.org.uk	Molecular epidemiology & Surveillance Section Head Dr Stephanie Chisholm 0208 327 6772 stephanie.chisholm@hpa.org.uk

Advice/Follow up: Please contact STBRL enquiries in the first instance regarding clinical advice and interpretation of results.
Complaints: if dissatisfied with our service please contact the Director or the Director's PA.

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SPECIALIST AND REFERENCE	Gonorrhoea	<ul style="list-style-type: none"> Confirmation of identification because of anomalous results. 	<ul style="list-style-type: none"> Gram stain Oxidase Biochemical (API-NH) Molecular : PorA pseudogene real-time PCR 	<ul style="list-style-type: none"> Isolate on chocolate slope or transwab 	3 Days	Tuesday Wednesday
		<ul style="list-style-type: none"> Confirmation of identification for medico-legal purposes 				
		<ul style="list-style-type: none"> Susceptibility testing for third generation cephalosporins and azithromycin 	<ul style="list-style-type: none"> Etest for ceftriaxone, cefixime and azithromycin 		5 Days	Monday Tuesday
		<ul style="list-style-type: none"> Molecular typing for linked isolates 	<ul style="list-style-type: none"> NG-MAST 		<ul style="list-style-type: none"> Linked isolates 	Please contact lab.

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SPECIALIST AND REFERENCE	Treponemal (Syphilis)	Serological test for syphilis	All samples <ul style="list-style-type: none"> • Enzyme immunoassay (EIA) total antibody (IgG/IgM) • Enzyme immunoassay (EIA) IgM antibody • <i>Treponema pallidum</i> particle agglutination (TPPA) • Rapid Plasma Reagin (RPR) 	<ul style="list-style-type: none"> • Serum • Plasma • CSF* 	2 Days	Any
			Discrepant samples <ul style="list-style-type: none"> • Immunoblot (IgG) : Inno-Lia 		4 Days	Monday Tuesday Wednesday

*Minimum volume required to complete all tests: 300ul
Serum or plasma are optimal specimens and should be free of lysed blood

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SPECIALIST AND REFERENCE	Genital Ulcer Disease	Molecular Test for the simultaneous detection: <ul style="list-style-type: none"> • <i>Treponema pallidum</i> • <i>Haemophilus ducreyi</i> • Herpes Simplex Virus 	In house real-time PCR test for the simultaneous detection of: <ul style="list-style-type: none"> • <i>T. pallidum</i> – 47Kd lipoprotein target • <i>H. ducreyi</i> - haemolytic cytotoxin target • HSV - Glycoprotein D target <p><i>T. pallidum</i> positive results are confirmed with the TP Pol real-time PCR</p>	<ul style="list-style-type: none"> • Fresh dry swab or swab in viral transport medium is optimal taken from genital or oral ulcer 	5 days	Any

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SPECIALIST AND REFERENCE	<i>Chlamydia trachomatis</i>	<ul style="list-style-type: none"> LGV molecular testing 	<ul style="list-style-type: none"> In House real-time PCR assay which targets cryptic plasmid to confirm CT status <i>pmpH</i> real-time PCR to confirm if LGV DNA is present in the specimen. <i>ompL</i> RFLP-PCR to determine L serovar 	<p>A clinical specimen, which has been confirmed as <i>C. trachomatis</i> positive at the local laboratory and has been sourced from (i) an appropriate site and (ii) from a symptomatic patient. Appropriate specimens include: rectal swabs, genital or urethral swabs, lymph node aspirates, ulcer swabs, and rectal and lymph node biopsies.</p> <p>Specimen type:</p> <ul style="list-style-type: none"> Residual specimen from unprocessed NAAT swab transport medium Fresh dry swab 	4 Days	Any
		<ul style="list-style-type: none"> Confirmation of <i>C. trachomatis</i> specimens sourced from non-sexual sites (eyes) and medico legal specimens. 	<ul style="list-style-type: none"> In House real-time PCR assay which targets cryptic plasmid Real Art <i>C. trachomatis</i> kit 	<ul style="list-style-type: none"> Residual specimen from unprocessed NAAT swab transport medium Fresh dry swab 	3 Days	Any

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Section	Programme	Collection Period	Isolate selection criteria	Specimen required	Outcome
MOLECULAR EPIDEMIOLOGY AND SURVEILLANCE	Gonococcal Resistance to Antimicrobials Surveillance Programme (GRASP)	<p>Annually, collaborating laboratories* to refer all isolates identified as <i>Neisseria gonorrhoeae</i> collected:</p> <ul style="list-style-type: none"> • June • July • August 	<p>If >1 isolate is collected from multiple sites in a patient, one isolate should be referred – in order of site preference:</p> <ol style="list-style-type: none"> 1. Male Rectal 2. Male Urethral 3. Female cervical 4. Any other site 	<ul style="list-style-type: none"> • Isolates stored in glycerol broth at -80°C (frozen batches collected by courier by arrangement) <p style="text-align: center;">or</p> <ul style="list-style-type: none"> • Isolate on chocolate slope or Amies charcoal transport swabs (referred to STBRL at time of isolation) 	GRASP Annual Report* Issued approx. 12 months after initial collection period.

*Annual reports including lists of collaborators available at <http://www.hpa.org.uk/cfi/stbrl/publications.htm>

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USER MANUAL



Retention Policy

Gonococcal isolates: Retrieved isolates are kept for a minimum of two years and any medico-legal isolates are kept indefinitely.

Molecular detection: Specimens for the molecular detection of *Chlamydia trachomatis* including LGV serovars, *Neisseria gonorrhoeae* and causes of Genital Ulcer Disease (*Treponema pallidum*, *Haemophilus ducreyi* and Herpes simplex) are kept for a minimum of two years.

Syphilis serology: Sera and CSFs are kept for two years and any sera or CSFs from medico-legal or infants are kept indefinitely.

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Compliance with the Human Tissue Act

Submitting tissue samples from deceased people

The Centre for Infections is licensed by the Human Tissue Authority (HTA) (Licence number 12459) to store tissues from deceased people for scheduled purposes. Post mortem samples are submitted to Cfl by coroners or pathologists for examination to help them determine the cause of death.

As part of our public health remit, we sometimes need to retain these samples for the purpose of public health monitoring which is defined as a scheduled purpose within the [Human Tissue Act 2004](#). Further analysis of these samples may help determine the cause of an outbreak due to an infectious disease or may allow identification of new strains of infectious agents at a later date.

Obtaining consent to remove, store and use human tissues for a scheduled purpose is one of the underlying principles of the Human Tissue Act. Cfl receives post-mortem samples from Coroners' post-mortems or from NHS establishments across the UK and therefore we are not in a position to either seek consent ourselves or have arrangements in place to confirm that the requirements of the Act have been complied with by the sender.

We would ask coroners and pathologists who send post mortem samples to Cfl to provide us with details of consent, and would also ask that consent includes retention of the samples for the purpose of public health monitoring.

When tissue samples from deceased people are received at the Centre for Infections they are retained securely and confidentiality is maintained in compliance with [Caldicott principles](#) as are all samples received at this centre. It is normal practice for tissue samples from the deceased to be disposed of in the same way that all other clinical samples we receive at Cfl are disposed of. However, we will adhere to any specific requirements regarding disposal or returning tissue samples if requested by the sending coroner or pathologist.

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Quality assurance in STBRL: participation in EQA and IQA schemes

Since April 2005 STBRL has participated in the UKNEQAS for Chlamydia detection (molecular) and Syphilis serology. This scheme consists of distributions of four samples three times each year for Chlamydia and six samples twice a year for Syphilis serology. Results are returned to the Quality Assurance Laboratory, Colindale and performance is rated and compared with national UK average. In 2004 STBRL also participated in the UKNEQAS General Bacteriology Scheme and Antimicrobial Susceptibility, but tested only those specimens relevant to their services.

Currently there are no accredited EQA schemes suitable for assessing Molecular Detection and Genotyping of *Chlamydia trachomatis* belonging to L serovars, Molecular Detection of causes of Genital Ulcer Diseases (*Treponema pallidum*, *Haemophilus ducreyi*, and Herpes simplex) and for Surveillance of antimicrobial resistance in *Neisseria gonorrhoeae*. In all cases we have an informal exchange of samples and strains with the Scottish Reference Laboratory for Sexually Transmitted Infections.

The quality of all our systems is constantly checked by our IQA scheme which requires selection of referred strains or samples for 'blinded' testing at a later date. After the processing, the results for IQA samples are unblinded and are assessed against the results originally reported to the sending laboratory. Any discrepancies are investigated fully and corrective actions are implemented if required. The results of our IQA and EQA performance are assessed at our Annual Management Review Meeting, where targets for improvement are set. The services included in the IQA scheme include: Serological testing for syphilis, Molecular detection of *Chlamydia trachomatis* belonging to L serovars, Molecular detection of causes of Genital Ulcer Disease and Confirmation and Susceptibility testing of *Neisseria gonorrhoeae*.

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USER MANUAL



Cfl recognition of Caldicott recommendations

The recommendations of the Caldicott report (1997) have been adopted by the Health Protection Agency as by the national Health Service as a whole. These recommendations relate to the security of patient identifying data (PID) and the uses to which they are put. The Centre for Infections (Cfl) observes Caldicott guidance in handling PID and has appointed its own Caldicott Guardian. He advises the Director, Cfl, on confidential issues and is responsible for monitoring the physical security of PID in all parts of Cfl. This also applies to the transfer of results of investigations to and from Cfl whether by mail services, telephone or fax. The value of 'safe haven' arrangements or other means of the sender and receiver information identifying themselves to each other before data is transferred is emphasised (see attached Cfl Policy on faxing and emailing reports containing patient data).

Cfl is anxious to audit the security of its PID in collaboration with its customers. Customers are invited to review our arrangements in conjunction with individual laboratory directors and/or the Caldicott Guardian. Customers are also asked to draw to the Caldicott Guardian's attention any instances where PID security has been threatened or has broken down. Uses that PID are put to outside clinical diagnostic services generally allow patient identifiers to have been removed before hand, and when PID is used for research purposes the proposals are considered first by the appropriate Ethics Committee. All enquiries about the security and use of PID should be addressed to the Caldicott Guardian, Dr Barry Evans; email: barry.evans@hpa.org.uk)

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