

ST. JAMES'S HOSPITAL LABMED DIRECTORATE			
Edition No.:	02	Microbiology Department	Doc No: LP-MICRO-0210
Author: Sinead Saab		Date: 23/04/2019	Date of issue: 23/04/2019
Authorised By: Dr Brendan Crowley		Date: 23/04/2019	



GONOCOCCAL REFERENCE LABORATORY USER MANUAL

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1. LOCATION

The Gonococcal Reference Laboratory is located within the Department of Clinical Microbiology, St. James's Hospital, Dublin. This facility is an INAB accredited Medical Testing Laboratory, Registration Number 327MT in compliance with the international standard ISO/IEC 15189:2012 edition "*Medical laboratories- particular requirements for quality & competence*".

2. CONTACT DETAILS/ ADDRESS

Gonococcal Reference Laboratory,

Central Pathology Laboratory,

Microbiology Department,

St. James's Hospital,

James's St.

Dublin 8.

Telephone: +353 1 416 2968

Fax: +353 1 428 4351

3. CONTACT NAMES

Role	Name	Telephone	Email
Medical Director	Dr. Brendan Crowley	01 416 2968	bcrowley@stjames.ie
Deputy Medical Director	Dr. Breida Boyle	01 416 2971	Bboyle@stjames.ie
Chief Medical Scientist	Ms. Antoinette Power	01 416 2986	ampower@stjames.ie
Surveillance Scientist	Dr. Aoife Colgan	01 876 5353	aoife.colgan@hpsc.ie
Senior Medical Scientist	Ms. Sinéad Saab	01 416 2917	ssaab@stjames.ie

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4. CONTACT DETAILS FOR ADVICE

Patient treatment / management	Dr. Brendan Crowley	01 416 2968
	Dr. Breida Boyle (Deputy)	01 416 2971
Laboratory aspects	Ms. Sinead Saab	01 416 2917
Surveillance aspects	Dr. Aoife Colgan	01 876 5353

5. OPENING HOURS

Monday to Friday 9.00 am to 5.00 pm

6. USERS OF THE LABORATORY SERVICE

The Gonococcal Reference laboratory service is available to all hospital microbiology laboratories in Ireland. Users of the service, at their own expense, are responsible for the packaging and transportation of samples in accordance with the ADR (European Agreement concerning the international carriage of dangerous Goods by Road, 2017) regulations (see section 11)

7. DATA PROTECTION

The Gonococcal Reference laboratory will ensure that its obligations as a Data Processors under the Data protection Act and other relevant EU Directives are fulfilled.

8. SERVICES AVAILABLE

Gonococcal Reference Laboratory provides the following services:

8.1. Reference diagnostics

- Antimicrobial susceptibility testing – provision of extended antimicrobial susceptibility testing for *Neisseria gonorrhoeae* (*N. gonorrhoeae*) to identify and monitor current resistance profiles in Ireland.

8.2. Scientific Advice

8.2.1. Technical advice

- Development and dissemination of guidance on appropriate diagnostic methods, including storage and transport of isolates.
- Proactive and reactive provision of advice and information to other laboratories that carry out *N. gonorrhoeae* identification and antimicrobial susceptibility testing.

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- Support and advice to other laboratories that carry out *N. gonorrhoeae* nucleic acid amplification testing.
- Molecular characterisation by whole genome sequencing of all NG isolates with reduced susceptibility to extended-spectrum cephalosporins and/or high-level azithromycin resistance will be performed in collaboration with the WHO Gonococcal Reference Laboratory in Orebro, Sweden

8.2.2. Clinical advice

- A point of contact of clinical queries from clinicians and other clinical microbiologists.
- Proactive dissemination of information to clinicians and other clinical microbiologists in relation to gonococcal diagnostics.

8.3. Collaboration and research

- International research collaboration
- Clinical/ laboratory research collaboration
- Supporting clinical and laboratory based research, at both both Msc and PhD level

8.4. Monitoring, alert and response

- In collaboration with the Health Protection Surveillance Centre (HPSC), determining what is representative gonococcal sentinel sampling
 - Contribution to and participation in gonococcal surveillance including the European - Gonococcal Antimicrobial Surveillance Programme (Euro-GASP)
 - Provision of early warning occurrences to national surveillance body (HPSC) and relevant Public Health Departments
 - Participation and provision of technical advice/expertise in the context of an outbreak.
 - Provision of an annual report on activity and future objective to the Sexual Health and Crisis Pregnancy programme (SHCPP).
- Data protection

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9. ISOLATES

Isolates should be submitted as fresh subcultures on chocolate agar slopes from 18-hr pure subcultures grown on chocolate agar or Gonorrhoea selective agar. Isolates should be submitted as soon as possible after isolation. Isolates must be submitted as pure cultures and all isolates must be accompanied by a Gonococcal Reference Laboratory request form (LF-MICRO-0504). Request forms are available to download from the St. James's website <http://www.stjames.ie/GPsHealthcareProfessionals/GPEExternalRequestForms>

The Gonococcal Reference laboratory **does not test primary samples** e.g. swabs / first void urines.

10. ISOLATE IDENTIFICATION

Isolate slopes must be clearly labelled with at least **two matching identifiers** (e.g. Patient name/initials, patient's hospital number or date of birth)

Isolates slopes will be rejected if:

- Isolates are sent on agar plates
- Specimen slope is broke
- Specimen form and/or slope are unlabelled, mismatched or incomplete
- If for any other reason the specimen is not in a safe condition for processing and/or cannot be clearly identified.

When an isolate is rejected due to any of the above reasons the sender of the isolate will be contacted by telephone or email, informed and requested to send a repeat culture.

11. COMPLETING THE GONOCOCCAL REFERENCE LABORATORY REFERENCE FORMS

Forms (LF -MICRO- 0504) are available to download from the St. James's Hospital website <http://www.stjames.ie/GPsHealthcareProfessionals/GPEExternalRequestForms>

Please complete the forms as indicated below:

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- Sender: Name address and contact number and to whom the final report should be sent to. Include the service type i.e. STI clinic, GP
- Source information: Please include patients name (or initials), DOB, hospital number and all other relevant details on the request form.
- Isolate information: It is vital for surveillance that the isolate site is included. **All medico legal cases must be clear stated** on request form and accompanied with the SJH Laboratory Chain of Evidence Form (LF-MICRO-0475). LF-MICRO-0475 SJH Laboratory Chain of Evidence Form is available on the St James's Hospital LabMed User Guide at <http://www.stjames.ie/intranet/oncampus/departments/microbiology/formsbooklets/>
- Test requested: Please tick the appropriate box to request the required laboratory investigation (i.e. to confirm *N. gonorrhoeae* identification).
- Sender's laboratory results: Please include any relevant testing performed in the referring laboratory

12. DISPATCH OF GONOCOCCAL ISOLATES TO THE GONOCOCCAL REFERENCE LABORATORY

All required safety precautions for the packing and transport of gonorrhoea isolates must be observed in accordance with the European Agreement concerning the international carriage of dangerous goods by road (UNADR). It is the responsibility of the referring site to ensure compliance with these regulations.

Specimen can be referred to the Gonococcal Reference Laboratory via courier company

13. TURNAROUND TIMES

The turn-around time (TAT) is calculated from the date of receipt of an isolate in pure culture. The reference laboratory aims to report within 7 working days, the average time will be 5 working days following receipt. Where time and resources allow, we endeavour to keep the times stated, however due to workload levels some investigations must be 'batched' and TATs vary accordingly. Please see table below for approximate TATs.

Test	TAT
Confirmation of <i>N. gonorrhoeae</i> identification	7 working days
Routine <i>N. gonorrhoeae</i> full antimicrobial susceptibility testing.	7 working days
Confirmation of <i>N. gonorrhoeae</i> isolates with reduced susceptibility to	7 working days

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third generation cephalosporins and/or high level Azithromycin resistance.	
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14. REPORTING OF RESULTS

Interpretations of gradient MICs are based upon European Committee on Antimicrobial Susceptibility Testing (EUCAST) guidelines, gonorrhoea breakpoints can be found at the following link.

http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Breakpoint_tables/v_9.0_Breakpoint_Tables.pdf

Reports for isolates submitted to the Gonococcal Reference laboratory for investigation will be issued by hard copy (paper) format by post to the sender of the isolate or, where a contact name is provided to the contact person, once the report is issued. The Reference laboratory regrets that it is not in a position to routinely communicate results by telephone. However, the laboratory does appreciate in certain circumstances, telephone communication is necessary. In these cases urgent results can be phoned, please indicate this on request form when sending isolate.

For reason of confidentiality it is the policy of St. James's Hospital not to email / fax reports

15. FREEZING OF GONOCOCCAL ISOLATES

All *N. gonorrhoeae* isolates should be stored at -70°C or below. Isolates should be stored in a suitable medium such as 15-20% glycerol in nutrient broth or cryobeads (Microbank) or protect bead (follow manufacturer's instructions) ensuring both glycerol in nutrient broth and protect beads are at room temperature 20-25°C. The viability of the *N. gonorrhoeae* will be seriously affected if inoculated into a vial at 4°C and the vial/broth content may be totally lost. It is essential that the strains are stored as a pure culture. It is best store the *N. gonorrhoeae* culture from an agar plate in the morning (i.e., after approximately 18-20 h) when the culture is fresh. It is important to monitor the temperature of the freezers. When susceptibility testing is required each strain should be retrieved from cold storage (-70°C or liquid nitrogen) in a frozen cryoblock. Do not allow

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the storage media to thaw completely during retrieval if the vial is to be put back in cold storage.

16. SPECIMEN RETENTION POLICY

All chocolate agar slopes submitted to the Gonococcal Reference Laboratory will be retained for one year. All referred isolates are stored on Protect beads / glycerol broth at -80°C for one year. There are some exceptions to this policy: where isolates display a reduced susceptibility to third generation cephalosporin's and/or Azithromycin, these isolates will be kept for an extended period of time.

17. USER SATISFACTION

The Gonococcal Reference laboratory operates a service evaluation and quality improvement to meet users' needs. This process includes undertaking a user satisfaction survey every two years by the quality manager. All comments and complaints will be evaluated by laboratory management so that the service may be built and improved upon.

Should you have a complaint or feel that any part of the service is unsatisfactory or could be improved on in any way please contact the laboratory directly either Dr. Brendan Crowley, Ms Antoinette Power or Ms Sinéad Saab at the above contact details