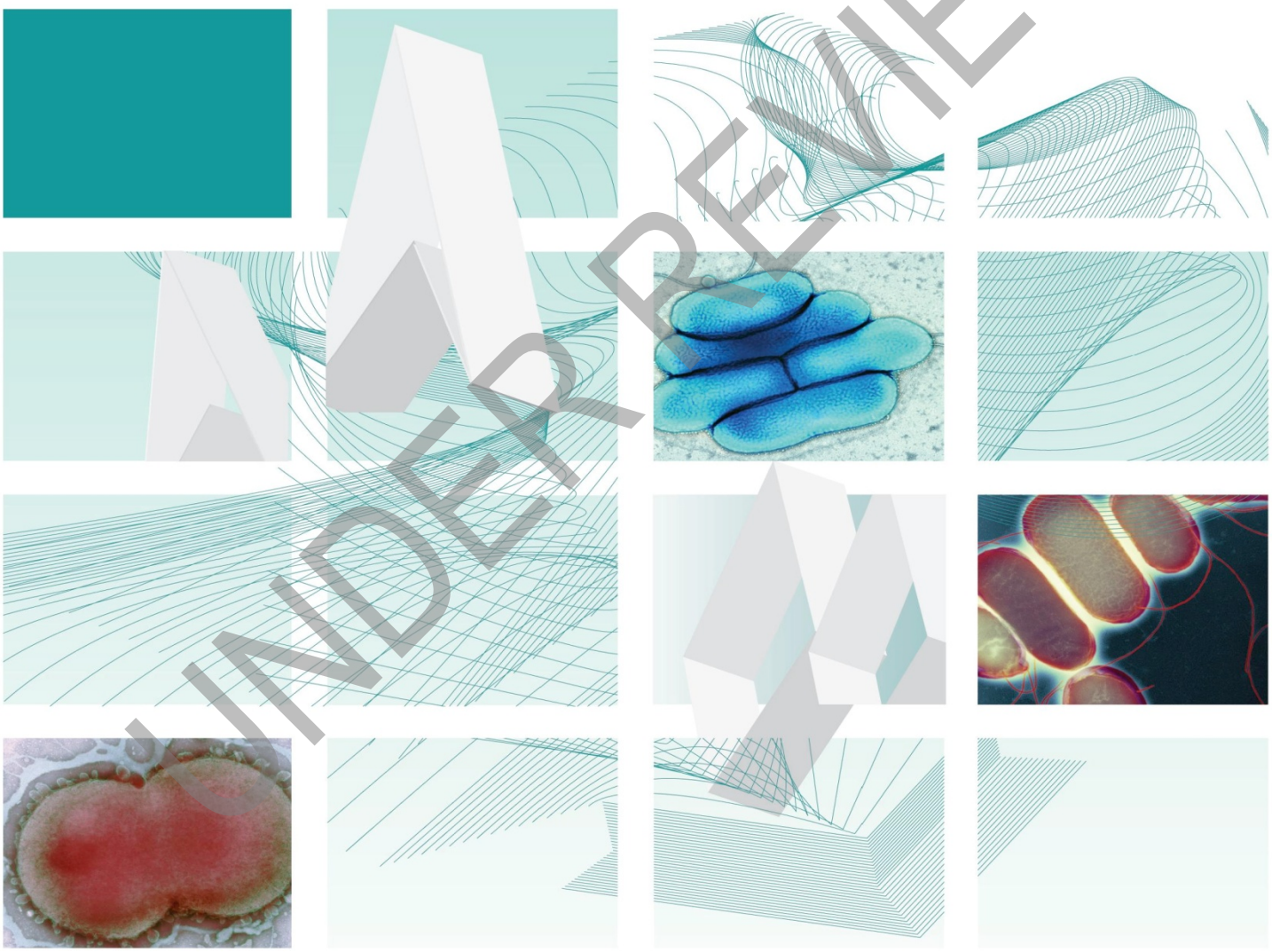
Public Health England

NHS

UK Standards for Microbiology Investigations

Processing Swabs for Group B Streptococcal Carriage



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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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UK Standards for Microbiology Investigations are produced in association with:

Contents

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.	5/04.06.14
Issue no. discarded.	2.2
Insert Issue no.	2.3
Section(s) involved	**Amendment**
Whole document.	Document has been transferred to a new template to reflect the Health Protection Agency's transition to Public Health England. Front page has been redesigned. Status page has been renamed as Scope and Purpose and updated as appropriate. Professional body logos have been reviewed and updated. Standard safety and notification references have been reviewed and updated. Scientific content remains unchanged.

Amendment No/Date.	4/02.08.12
Issue no. discarded.	2.1
Insert Issue no.	2.2
Section(s) involved	**Amendment**
Whole document.	Document presented in a new format. The term "CE marked leak proof container" is referenced to specific text in the EU in vitro Diagnostic Medical Devices Directive (98/79/EC Annex 1 B 2.1) and to the Directive itself EC[1,2]. Edited for clarity. Reorganisation of [some] text. Minor textual changes.
Sections on specimen	Reorganised. Previous numbering changed.

collection, transport, storage and processing.	
References.	Some references updated.

UK SMI[#]: Scope and Purpose

Users of SMIs

Primarily, SMIs are intended as a general resource for practising professionals operating in the field of laboratory medicine and infection specialties in the UK. SMIs also 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. The documents also 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.

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

[#] 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.

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. (2014). Processing Swabs for Group B Streptococcal Carriage. UK Standards for Microbiology Investigations. B 58 Issue 2.3. http://www.hpa.org.uk/SMI/pdf

Scope of Document

Type of Specimen

Vaginal swabs, rectal swabs

Scope

This SMI describes the processing of specimens from pregnant women for carriage of Group B streptococci (GBS). Recognising that it is not recommended in the UK to screen routinely for GBS (Royal College of Obstetricians and Gynaecologiosts 2003, National Institute for Clinical Excellence 2008), this SMI provides a standardised method for culture where clinicians decide to investigate specific patients with conditions considered to confer a high risk of infection[3,4]. Commercial tests detecting the GBS group antigen extracted from vaginal swabs based upon latex agglutination, ELISA, immunofiltration, immunochromatography, optical immunoassay and other methods are available. However, the evidence accumulated has shown that the sensitivity and specificity of direct antigen tests is inferior to that of culture methods[5].

This SMI should be used in conjunction with other SMIs.

Introduction

Lancefield Group B Streptococci

Lancefield Group B streptococci, or *Streptococcus agalactiae*, are oxidase negative, catalase negative, Gram positive cocci occurring in chains. GBS are facultative anaerobes that are serologically classified on the basis of cell wall polysaccharide antigens. On blood agar, the species exhibit β-haemolysis. This can be used as an early step in identifying clinical isolates. After 18-24hr incubation at 35-37°C colonies tend to be slightly larger than other streptococci (approximately 1mm) and have a less distinct zone of β-haemolysis.

GBS normally colonises the vagina in many women and the intestines of men and women. Up to 30% of women carry GBS in the vagina or rectum without it causing problems or symptoms[6,7]. The gastrointestinal tract is the likely human reservoir of GBS, with the genitourinary tract the most common site of secondary spread[8].

Infection

GBS may cause potentially devastating early onset disease, primarily in newborns, pregnant women, and adults with underlying medical conditions (eg diabetes mellitus). In pregnancy, this organism can infect the amniotic fluid (see B 26 – Investigation of Fluids from Normally Sterile Sites), which can lead to neonatal sepsis, pneumonia and meningitis[8].

In pregnant women, GBS infection causes urinary tract infection, amnionitis, endometritis, wound infection; stillbirths and premature delivery have also been attributed to GBS[8]. In non-pregnant adults, skin or soft tissue infection, bacteraemia, genitourinary infection, and pneumonia are the most common manifestations of disease[9].

Neonatal infection

Neonatal infection refers to infection occurring during the first four weeks of life. Infection may be superficial and localised (eg conjunctivitis, pustules, skin infection), deep and localised (pneumonia, septic arthritis) or systemic (septicaemia, meningitis). Presentation differs according to age at onset: early onset disease is more likely than late onset to present with sepsis[8].

In 1998, a Working Group was established by the then Public Health Laboratory Service (now Public Health England), with a remit to assess the burden of GBS disease and to produce evidence based national guidelines for the control and prevention of invasive neonatal GBS disease. As part of this programme, enhanced surveillance was undertaken in conjunction with the British Paediatric Surveillance Unit (London)[8]. The surveillance showed an incidence of 0.74 cases per 1000 live births and a mortality rate of 9.7%. The predominant GBS serotypes were III, Ia and V[10].

The incidence of infection also increases with low birth weight or prematurity and may be divided into:

- **Early onset (0-6 days)** - this occurs in the first six days (usually within 48 hours) of life and is caused by infection ascending from the maternal genital tract or, less commonly, via the placenta. Only a small percentage of infants colonised with this organism develop early onset disease. Early infections tend to be associated with pneumonia and septicaemia and may be confused with respiratory distress syndrome
- **Late onset (7-90 days)** - this occurs after the first six days (7-90 days) and is associated with acquisition of the organism through vertical or nosocomial transmission or from the external (eg hospital) environment. GBS initially colonise the superficial sites and upper respiratory tract, and progress to cause widespread sepsis. Late infection is more likely to be associated with meningitis

Method of Investigation

In the UK, the advantages of screening pregnant women for colonisation with GBS routinely have not been demonstrated[3,4]. However, according to local protocols, patients judged clinically to be at high risk for the development of Group B streptococcal infection may be investigated for carriage. The isolation rate of GBS from clinical specimens depends on several factors. Studies have shown that the accuracy of prenatal screening cultures for identification of GBS colonisation can be enhanced by attention to the timing of cultures, the sites swabbed and the microbiological method used for culture of organisms. Collection of swabs at 35-37 weeks gestation is recommended to improve the sensitivity and specificity of detection of colonisation at the time of delivery[11]. Optimum yield will be achieved by selective/enrichment procedures applied to swabs obtained from the vagina and the anorectum which increases the likelihood of GBS isolation by up to 30% compared with vaginal or cervical culture alone[12-17]. Vaginal and rectal swabs are likely to isolate a diverse array of normal flora, and the use of selective enrichment broth is recommended to avoid overgrowth of other organisms[11].

Treatment

Any neonate showing symptoms of early onset GBS disease should be treated with broad-spectrum antibiotics to cover GBS, as well as other common pathogens, as neonatal sepsis can be rapidly fatal[3].

The treatment of pregnant women colonised with GBS is not recommended[3,4]. However, intrapartum (ie during labour and delivery) antibiotics given to high risk mothers with GBS may prevent ascending infection and subsequent early-onset streptococcal disease[16,18]. The Royal College of Obstetricians and Gynaecologists has developed more detailed guidance in liaison with the PHE Working Group, for obstetricians, midwives and neonatologists on the prevention of early onset neonatal group B streptococcal infection[3].

In contrast to the UK, current USA guidelines advise that all women colonised with GBS at 35-37 weeks gestation should be offered intrapartum antibiotic prophylaxis in the form of high dose penicillin or ampicillin[11].

Technical Information/Limitations

Limitations of UK SMIs

The recommendations made in UK SMIs are based on evidence (eg sensitivity and specificity) where available, expert opinion and pragmatism, with consideration also being given to available resources. Laboratories should take account of local requirements and undertake additional investigations where appropriate. Prior to use, laboratories should ensure that all commercial and in-house tests have been validated and are fit for purpose.

Selective Media in Screening Procedures

Selective media which does not support the growth of all circulating strains of organisms may be recommended based on the evidence available. A balance therefore must be sought between available evidence, and available resources required if more than one media plate is used.

Specimen Containers[1,2]

SMIs use the term, “CE marked leak proof container,” to describe containers bearing the CE marking used for the collection and transport of clinical specimens. The requirements for specimen containers are given in the EU in vitro Diagnostic Medical Devices Directive (98/79/EC Annex 1 B 2.1) which states: “The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.”

1 Safety Considerations[1,2,19-33]

1.1 Specimen Collection, Transport and Storage[1,2,19-22]

Use aseptic technique.

Collect swabs into appropriate transport medium and transport in sealed plastic bags.

Compliance with postal, transport and storage regulations is essential.

1.2 Specimen Processing[1,2,19-33]

Containment Level 2.

Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet[25].

Refer to current guidance on the safe handling of all organisms documented in this SMI.

The above guidance should be supplemented with local COSHH and risk assessments.

2 Specimen Collection

2.1 Type of Specimens

Vaginal swabs, rectal swabs

2.2 Optimal Time and Method of Collection[34]

For safety considerations refer to Section 1.1.

Collect specimens before antimicrobial therapy where possible[34].

Unless otherwise stated, swabs for bacterial and fungal culture should be placed in appropriate transport medium[35-39].

Swab the lower vagina (vaginal introitus) and the rectum with the same swab or two different swabs.

Cervical swabs are not recommended.

2.3 Adequate Quantity and Appropriate Number of Specimens[34]

One combined vaginal/rectal swab or two separate swabs processed as one.

Numbers and frequency of specimen collection are dependent on clinical condition of patient.

3 Specimen Transport and Storage[1,2]

3.1 Optimal Transport and Storage Conditions

For safety considerations refer to Section 1.1.

Specimens should be transported and processed as soon as possible[34].

If processing is delayed, refrigeration is preferable to storage at ambient temperature[34].

4 Specimen Processing/Procedure[1,2]

4.1 Test Selection

N/A

4.2 Appearance

N/A

4.3 Sample Preparation

For safety considerations refer to Section 1.2.

4.4 Microscopy

N/A

4.5 Culture and Investigation

4.5.1 Pre-treatment

N/A

4.5.2 Specimen processing

Enrichment Culture

Remove the cap aseptically from the container and place the swab(s) in the broth, break off (or cut) the swab stick(s) and replace the cap. Caps should be kept loose during incubation.

After incubation, sub-culture with a sterile loop and inoculate appropriate media (see table 4.5.3).

For the isolation of individual colonies, spread inoculum with a sterile loop.

4.5.3 Culture media, conditions and organisms

Clinical details/ conditions	Standard media	Incubation			Cultures read	Target organism(s)
		Temp. °C	Atmos.	Time		
Enrichment Culture	LIM Broth (10mL Todd-Hewitt broth supplemented with 10µg/mL colistin and 15µg/mL nalidixic acid)	35-37	5-10% CO_2	18-24hr	N/A	Group B streptococci
	Then subculture to blood agar	35-37	5-10% CO_2	40-48hr	18-24	

4.6 Identification

Refer to individual SMIs for organism identification.

4.6.1 Minimum level of identification in the laboratory

Streptococcus agalactiae	species level

(See ID 4 - Identification of *Streptococcus* species, *Enterococcus* species and Morphologically Similar Organisms)

4.7 Antimicrobial Susceptibility Testing

Refer to British Society for Antimicrobial Chemotherapy (BSAC) and/or EUCAST guidelines.

4.8 Referral for Outbreak Investigations

N/A

4.9 Referral to Reference Laboratories

For information on the tests offered, turnaround times, transport procedure and the other requirements of the reference laboratory click here for user manuals and request forms.

Organisms with unusual or unexpected resistance, and whenever there is a laboratory or clinical problem, or anomaly that requires elucidation should, be sent to the appropriate reference laboratory.

Contact appropriate devolved national reference laboratory for information on the tests available, turnaround times, transport procedure and any other requirements for sample submission:

England and Wales
http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1158313434370?p=1158313434370

Scotland

http://www.hps.scot.nhs.uk/reflab/index.aspx

Northern Ireland

http://www.publichealth.hscni.net/directorate-public-health/health-protection

5 Reporting Procedure

5.1 Microscopy

N/A

5.2 Culture

Report:

Negatives:

“Group B streptococci not isolated.”

Positives:

"Group B streptococci isolated."

5.2.1 Culture reporting time

Clinically urgent results: to be telephoned or sent electronically.

Written report: 16-72hr, stating, if appropriate, that a further report will be issued.

5.3 Antimicrobial Susceptibility Testing

Report susceptibilities as clinically indicated. Prudent use of antimicrobials according to local and national protocols is recommended.

6 Notification to PHE[40,41] or Equivalent in the Devolved Administrations[42-45]

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 (HCAIs) 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[42,43], Wales[44] and Northern Ireland[45].

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