

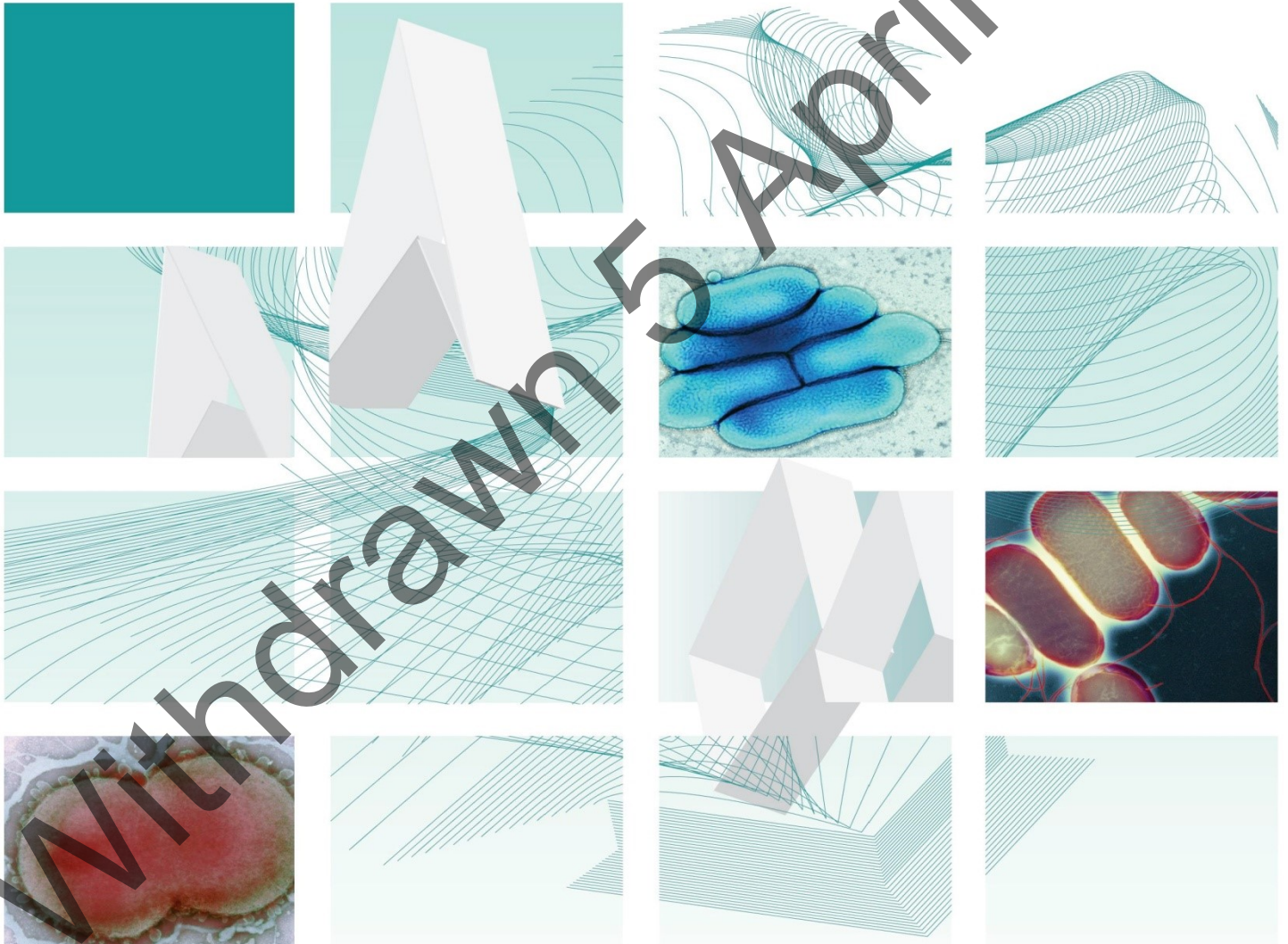


Public Health
England



UK Standards for Microbiology Investigations

Detection of Carriage of Group B Streptococci (*Streptococcus agalactiae*)



Issued by the Standards Unit, Microbiology Services, PHE

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Acknowledgments

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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.	7/26.06.18
Issue no. discarded.	3
Insert Issue no.	3.1
Section(s) involved	Amendment
Whole document.	<p>Title amendment to add "<i>Streptococcus agalactae</i>".</p> <p>Content, references and hyperlinks updated to reflect current policy of the UK National Screening Committee and guidance from the National Institute for Health and Care Excellence and the Royal College of Obstetricians & Gynaecologists which recommends the circumstances in which the screening may be helpful in determining the risk of developing early-onset neonatal GBS (EOGBS) or in examining cases of late-onset neonatal GBS.</p> <p>Specimen updated to be more specific to maternal samples.</p>
1.1 Specimen collection, transport and storage.	Amies or Stuart medium for transport added.
4.5.1 Culture media, conditions and organisms.	Gentamicin and nalidixic acid combination added as a LIM Broth option.
4.7 Antimicrobial susceptibility testing.	Antimicrobial susceptibility testing and reporting table added.
4.9 Referral to reference laboratories.	Updated sentence to: "Refer all GBS which are associated with an infection control or cluster investigation in addition to all invasive isolates."
Appendix.	Updated.

Amendment No/Date.	6/19.06.15
Issue no. discarded.	2.3
Insert Issue no.	3
Section(s) involved	Amendment
Whole document.	Hyperlinks updated to gov.uk.
Page 2.	Updated logos added.
Whole document.	<p>Emphasis on availability of this GBS detection method for laboratories to undertake when required and does not cut across the UK National Screening Committee recommendation that antenatal screening for GBS colonisation is not recommended.</p> <p>Any mention of screening pregnant women for colonisation of GBS has been removed to minimise ambiguity.</p>
Title.	The title of the document has been changed from 'Processing swabs for Group B streptococcal carriage' to 'Detection of carriage of Group B streptococci'.
Scope.	Amended to make the scope and purpose of the document clear.
Introduction.	Re-structured to present the information clearly.
Colonisation.	Colonisation of GBS amended from up to 30% to up to 28% and referenced.
Infection.	Updated. Reference to a 1998 Working Group removed.
Method of investigation.	Updated. The use of selective agar for subculture from enrichment broth added. Collection of recto-vaginal swabs between 35 and 37 weeks gestation and USA guidelines has been removed.
Treatment.	The section is outside the scope of the document and has been removed.
Rapid methods.	Section added.
Specimen collection.	Updated for clarity. Type of manufactured swabs covered. Collection of specimens by qualified caregiver or patient added.

Culture and investigation.	Updated to provide information on culture examination.
4.5.1 Culture media, conditions and organisms.	Updated to include options for selective and chromogenic agar for subculture of enrichment broth.
Appendix.	Flowchart added.
References.	Updated.

Withdrawn 5 April 2024

UK SMI[□]: scope and purpose

Users of SMIs

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

UK 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. Quality guidance notes describe laboratory processes which underpin quality, for example assay validation.

Standardisation of the diagnostic process through the application of UK 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

UK 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 <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories> <http://www.hpa-standardmethods.org.uk/>.

Inclusion of a logo in an UK SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing UK SMIs. Nominees of professional societies are members of the Steering Committee and working groups which develop UK 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. UK SMIs are developed, reviewed and updated through a wide consultation process.

Quality assurance

NICE has accredited the process used by the UK SMI working groups to produce UK SMIs. The accreditation is applicable to all guidance produced since October 2009. The process for the development of UK SMIs is certified to ISO 9001:2008. UK SMIs represent a good standard of practice to which all clinical and public health microbiology laboratories in the UK are expected to work. UK SMIs are NICE accredited and represent neither minimum standards of practice nor the highest level

[□] 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.

of complex laboratory investigation possible. In using UK SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. UK SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. UK SMIs also provide a reference point for method development. The performance of UK 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 UK SMI working groups are committed to patient and public involvement in the development of UK SMIs. By involving the public, health professionals, scientists and voluntary organisations the resulting UK 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 <https://www.gov.uk/government/organisations/public-health-england/about/equality-and-diversity>.

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

While every care has been taken in the preparation of UK SMIs, PHE and the partner organisations, 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 UK SMI or any information contained therein. If alterations are made by an end user to an UK SMI for local use, it must be made clear where in the document the alterations have been made and by whom such alterations have been made and also acknowledged that PHE and the partner organisations shall bear no liability for such alterations. For the further avoidance of doubt, as UK SMIs have been developed for application within the UK, any application outside the UK shall be at the user's risk.

The evidence base and microbial taxonomy for the UK SMI is as complete as possible at the date 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.

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Suggested citation for this document

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Withdrawn 5 April 2024

Scope of document

Type of specimen

Maternal low vaginal and rectal swabs

Scope

The method describes the examination of specimens to detect carriage of group B streptococci (GBS). This method may also be of value to support research projects investigating GBS carriage.

The recommendations within the UK SMI recognise the current policy of the UK National Screening Committee (2017) and guidance from the National Institute for Health and Care Excellence and the Royal College of Obstetricians & Gynaecologists (2017) which states that routine universal antenatal screening using bacteriological culture or near patient testing techniques should not be introduced in UK practice¹⁻³. However, current guidance recommends that in certain settings, screening may be helpful in determining the risk of developing early-onset neonatal GBS (EOGBS) or in examining cases of late-onset neonatal GBS⁴. For example, in women in whom GBS was detected in a previous pregnancy, administration of intrapartum antibiotic prophylaxis (IAP) provides a clear clinical benefit⁵. This UK SMI provides details on the test method in the event of undertaking the screening of an individual mother.

On rare occasions, clusters of invasive GBS infection occur. In such circumstances, non-invasive sampling of cases or screening of individuals at risk, contacts, or the environment may assist with outbreak management⁴.

This UK SMI does not include procedures for isolation and detection of GBS from invasive specimens such as blood and CSF; refer to the UK SMIs [B 37-Investigation of blood cultures \(for organisms other than *Mycobacterium* species\)](#) and [B 27-Investigation of cerebrospinal fluid](#). However, during investigation of a maternal or neonatal invasive GBS infection or cluster, additional carriage and screening swabs may be taken from infants, mothers and the environment as part of the investigation.

The testing of environmental samples is outside of the scope of this UK SMI.

This UK SMI should be used in conjunction with other UK SMIs.

Introduction

Lancefield group B streptococci

Lancefield group B streptococci (GBS), or *Streptococcus agalactiae*, are facultatively anaerobic, oxidase-negative, catalase-negative, Gram-positive cocci occurring in chains. GBS are serologically classified on the basis of cell wall polysaccharide antigens and exhibit β -haemolysis on blood agar, although a very small proportion of strains are non-haemolytic. These characteristics can be used as an early step in identifying clinical isolates. After 18-24 hours 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 (see [ID 4 – Identification of *Streptococcus* species, *Enterococcus* species and morphologically similar organisms](#)).

Colonisation

GBS normally colonises the vagina in many women and the intestines of men and women. Up to 28% of women in the UK carry GBS in the vagina or rectum without any associated symptoms⁶⁻⁸. The gastrointestinal tract is the human reservoir for GBS and the likely source of vaginal colonisation⁹.

Infection

Although GBS colonisation is not normally associated with disease in non-pregnant women, GBS can cause infection including bacteraemia in pregnant women⁹. GBS may cause potentially devastating early onset disease, primarily in newborns and late onset disease in newborns as well as infections in pregnant women, children and adults. 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 or meningitis¹⁰.

In pregnant women, GBS infection is known to cause urinary tract infection, amnionitis, endometritis and wound infection. In men and non-pregnant women, skin or soft tissue infection, bacteraemia, genitourinary infection, balanitis (in men) and pneumonia are the most common manifestations of disease^{11,12}.

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, meningitis) or systemic (septicaemia). Presentation differs according to age at onset: early onset disease is more likely than late onset to present with generalised sepsis¹³.

Since The British Paediatric Surveillance Unit (BPSU) study of 2000–2001 there has been a significant increase in the incidence of invasive GBS disease in all five British Isles countries. Results from a repeat of this study in 2014, showed the incidence for early-onset GBS disease was 0.54 cases per 1000 live births and a mortality rate of 4.7% compared to 0.48 cases per 1000 live births and a mortality rate of 9.7% in 2000^{13,14}. Increases in erythromycin and clindamycin resistance have also been noted over this period, leading to a change in second line agent used for intrapartum prophylaxis¹⁵.

The incidence of infection 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, very rarely, 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

In the UK, universal antenatal screening for GBS colonisation is currently not recommended^{1-3,5,16}. However, the Royal College of Obstetricians & Gynaecologists recommends screening in women in whom GBS was detected in a previous

pregnancy at 35-37 weeks of gestation or 3-5 weeks prior to the anticipated delivery¹. This screening would determine the carriage status close to delivery and provides information that helps to assess the risk of EOGBS. Based on the results of this screening, IAP can be offered and in the case of mothers with clinical risk factors they can choose to decline IAP if they test negative.

Method of investigation

The isolation rate of GBS from clinical specimens depends on several factors. Studies have shown that detection for GBS colonisation can be improved by attention to the timing of cultures, the sites swabbed and the microbiological method used for culture of microorganisms. The Centers for Disease Control and Prevention suggest that 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 compared with vaginal or cervical culture alone¹⁷. Recto-vaginal swabs are likely to isolate a diverse array of normal microflora and use of selective enrichment broth is recommended to avoid overgrowth of other microorganisms¹⁷.

The use of a selective enrichment broth that inhibits the growth of competing organisms such as Gram negative enteric bacilli and other normal microflora significantly increases the yield of GBS culture and is recommended since it has been found to be the most sensitive method to detect female colonisation^{17,18}. The most widely used selective enrichment broth is Todd-Hewitt broth with nalidixic acid and colistin (eg Lim broth) or nalidixic acid and gentamicin, with further subculture on blood agar plate.

Subculture from the selective enrichment broth to a selective and chromogenic agar have demonstrated equivalent or superior GBS recovery compared to subculture to blood agar¹⁸⁻²⁰.

Chromogenic media are not fully specific for GBS identification and presumptive colonies of GBS should be confirmed by a specific antigenic detection test or Matrix Assisted Laser Desorption Ionisation Time-of-Flight (MALDI-TOF)²¹⁻²⁴.

Rapid methods

A variety of rapid identification methods are available to detect GBS presence in pregnant women directly from vagino-rectal swabs, of which some are FDA approved. Assay sensitivity of some tests is reported to be higher than culture alone²⁵. However, discordant results are noted and in some cases results are variable on repeat testing. Use of broth enrichment followed by subculture on most chromogenic media and PCR assays have comparable sensitivities and allow more rapid reporting of screening for GBS than conventional culture methods²⁰.

For presumptive isolates of GBS a variety of rapid identification methods are available with high sensitivity and specificity including PCR and Matrix Assisted Laser Desorption Ionisation Time-of-Flight (MALDI-TOF)^{21,22}. Refer to [ID 4 - Identification of *Streptococcus* species, *Enterococcus* species and morphologically similar organisms](#) for the identification of GBS.

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^{26,27}

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 considerations²⁶⁻⁴²

1.1 Specimen collection, transport and storage²⁶⁻³¹

Use aseptic technique.

Collect swabs into appropriate transport medium eg Amies or Stuart, and transport in sealed plastic bags.

Compliance with postal, transport and storage regulations is essential.

1.2 Specimen processing²⁶⁻⁴²

Containment Level 2.

Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet³⁴.

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

Maternal low vaginal and anorectal swabs. Maternal high vaginal swabs should not be collected as these have a lower sensitivity.

2.2 Optimal time and method of collection⁴³

For safety considerations refer to Section 1.1.

Collect specimens before antimicrobial therapy where possible⁴³.

It is essential to specify "Detection of GBS carriage" in the specimen request.

Unless otherwise stated, swabs for GBS culture should then be placed in appropriate transport medium⁴⁴⁻⁴⁸.

Rayon or Dacron, Fibre or Flocked swabs, with non-nutritive transport media (eg Amies or Stuart's), preserve the viability of the organism by providing moisture, and buffering to maintain the pH.

Specimen(s) for culture may be collected either by the physician or other qualified caregiver (or may be self-collected by the patient, with appropriate instruction). This involves swabbing the distal vagina (vaginal introitus), followed by the rectum.

A single swab for both sites of collection is rational, but two different swabs can be used. Because lower vaginal as opposed to cervical cultures are recommended, cultures should not be collected by speculum examination.

2.3 Adequate quantity and appropriate number of specimens⁴³

One combined maternal 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 and retention^{26,27}

3.1 Optimal transport and storage conditions

For safety considerations refer to Section 1.1.

Specimens should be transported and processed as soon as possible⁴³.

If processing is delayed, refrigeration is preferable to storage at ambient temperature⁴³.

GBS isolates can remain viable in transport media for several days at room temperature. However, the recovery of isolates declines over 1-4 days, especially at elevated temperatures, which can lead to false-negative results. Specimens should be refrigerated before processing¹⁷.

4 Specimen processing/procedure^{26,27}

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

SELECTIVE ENRICHMENT CULTURE

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

CULTURE

After an overnight incubation at 35-37°C, 5% CO₂, subculture with a sterile loop and inoculate appropriate media (see table 4.5.1).

Optimum detection of GBS may require the use of more than one culture medium.

For the isolation of individual colonies, spread inoculum with a sterile loop onto blood agar, selective or chromogenic agar.

Incubate the plate(s) at 35 to 37°C in the appropriate atmosphere for 24-48hr.

CULTURE EXAMINATION

After an overnight incubation, observe plates for suggestive GBS colonies and identify them. If negative after overnight incubation, re-incubate an additional 24 hours before reporting a negative result.

On blood agar, suggestive colonies of GBS are grey, translucent, with a surrounding zone of beta-hemolysis (or no hemolysis: very rare).

Refer to manufacturer's instructions for GBS detection on selective and chromogenic agar.

Serotyping of isolates is available by latex agglutination or on referral to the reference laboratory if from invasive or associated to invasive cases.

4.5.1 Culture media, conditions and organisms

Clinical details/ Conditions	Specimen	Standard media	Incubation			Cultures read	Target organism(s)
			Temp °C	Atmos	Time		
Carriage of Group B streptococci	Maternal low vaginal and anorectal swabs	LIM Broth (5mL)†: Todd-Hewitt broth supplemented with 10µg/mL colistin - or 8µg/mL gentamicin and 15µg/mL nalidixic acid	35-37	5% CO ₂	18-24hr	N/A	Group B streptococci
		Then subculture to: Blood agar or	35-37	5% CO ₂	24-48hr	18-24hr and 48hr	
		Selective agar or	35-37	Ambient	24-48hr	18-24hr	
		Chromogenic agar	35-37	Ambient	24-48hr	18-24hr	

†The bottle should contain a volume of broth sufficient to cover the swabs

4.6 Identification

Refer to [ID 4 - Identification of Streptococcus species, Enterococcus species and morphologically similar organisms](#) for the identification of GBS.

4.6.1 Minimum level of identification in the laboratory

Streptococcus agalactiae	species level
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Organisms may be further identified if this is clinically or epidemiologically indicated.

4.7 Antimicrobial susceptibility testing

Refer to [EUCAST](#) guidelines. Prudent use of antimicrobials according to local and national protocols is recommended.

This UK SMI recommends selective and restrictive reporting of susceptibilities to antimicrobials. Any deviation must be subject to consultation that should include local antimicrobial stewardship groups.

4.7.1 Antimicrobial Susceptibility Testing and Reporting Table

It is recommended that the antimicrobials in bold in the table below are reported. Those antimicrobials not in bold may be reported based on local decisions.

Bacteria	Examples of agents to be included within primary test panel (recommended agents to be reported are in bold depending on clinical presentation)	Examples of agents to be considered for supplementary testing (recommended agents to be reported are in bold depending on clinical presentation)	Notes
GBS	Penicillin Clindamycin Cefotaxime Vancomycin	Clarithromycin Teicoplanin	After consultation with users, laboratories may report only Penicillin routinely and report the other agents routinely only if shown to be resistant.

4.8 Referral for outbreak investigations

See 4.9.

4.9 Referral to reference laboratories

Refer all GBS which are associated with an infection control or cluster investigation in addition to all invasive isolates.

For information on the tests offered, turn around times, transport procedure and the other requirements of the reference laboratory [click here for user manuals and request forms \(England and Wales\)](#).

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, turn around times, transport procedure and any other requirements for sample submission:

England and Wales

<https://www.gov.uk/specialist-and-reference-microbiology-laboratory-tests-and-services>

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^{49,50} or equivalent in the devolved administrations⁵¹⁻⁵⁴

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. GBS is a notifiable disease in Northern Ireland but not in England, Wales and Scotland.

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.

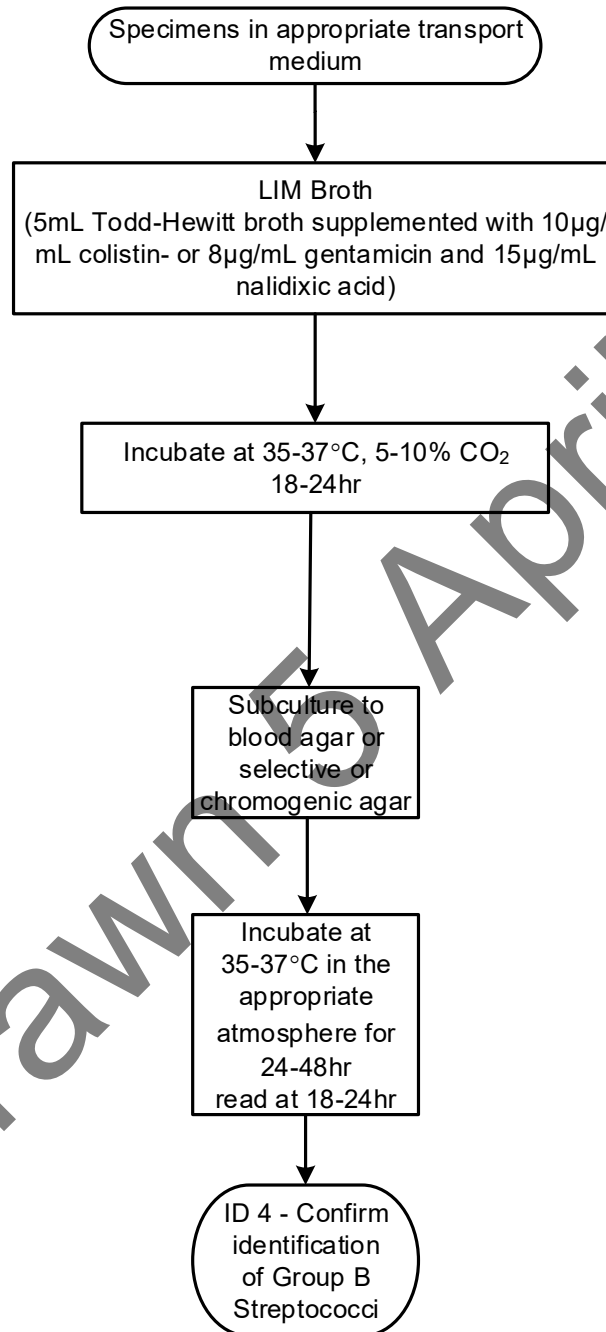
Note: The Health Protection Legislation Guidance (2010) includes reporting of Human Immunodeficiency Virus (HIV) & Sexually Transmitted Infections (STIs), Healthcare Associated Infections (HCAs) and Creutzfeldt–Jakob disease (CJD) under ‘Notification Duties of Registered Medical Practitioners’: it is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

<https://www.gov.uk/government/organisations/public-health-england/about/our-governance#health-protection-regulations-2010>

Other arrangements exist in [Scotland](#)^{51,52}, [Wales](#)⁵³ and [Northern Ireland](#)⁵⁴.

Withdrawn 5 April 2024

Appendix: Detection of carriage of group B streptococci (*Streptococcus agalactiae*)



References

1. Royal College of Obstetricians and Gynaecologists. Prevention of early onset neonatal Group B Streptococcal disease 2017.
2. UK National Screening Committee. Universal antenatal culture-based screening for maternal Group B Streptococcus (GBS) carriage to prevent early-onset GBS disease 2016.
3. National Institute for Health and Clinical Excellence. Antenatal care for uncomplicated pregnancies 2017.
4. Jauneikaite E, Kapatai G, Davies F, Gozar I, Coelho J, Bamford KB et al. Serial Clustering of Late Onset Group B Streptococcal Infections in the Neonatal Unit - a Genomic Re-Evaluation of Causality. Clin Infect Dis 2018.
5. Centers for Disease Control and Prevention. Guidelines for the prevention of Perinatal Group B Streptococcal disease 2010.
6. Hastings MJ, Easmon CS, Neill J, Bloxham B, Rivers RP. Group B streptococcal colonisation and the outcome of pregnancy. J Infect 1986;12:23-9.
7. Jones N, Oliver K, Jones Y, Haines A, Crook D. Carriage of group B streptococcus in pregnant women from Oxford, UK. J Clin Pathol 2006;59:363-6.
8. Hassan IA, Onon TS, Weston D, Isalska B, Wall K, Afshar B et al. A quantitative descriptive study of the prevalence of carriage (colonisation) of haemolytic streptococci groups A, B, C and G in pregnancy. J Obstet Gynaecol 2011;31:207-9.
9. Picard FJ, Bergeron MG. Laboratory detection of group B Streptococcus for prevention of perinatal disease. Eur J Clin Microbiol Infect Dis 2004;23:665-71.
10. Hanley J. Neonatal infections: group B streptococcus. Clin Evid (Online) 2008;2008.
11. Farley MM, Harvey RC, Stull T, Smith JD, Schuchat A, Wenger JD et al. A population-based assessment of invasive disease due to group B streptococcus in nonpregnant adults. N Engl J Med 1993;328:1807-11.
12. Lucks DA, Venezia FR, Lakin CM. Balanitis caused by group B streptococcus. JUrol 1986;135:1015.
13. Heath PT, Balfour G, Weisner AM, Efstratiou A, Lamagni TL, Tighe H et al. Group B streptococcal disease in UK and Irish infants younger than 90 days. Lancet 2004;363:292-4.
14. O'Sullivan C, Lamagni T, Efstratiou A, Boyle M, Meehan M, Reynolds A et al. Group B Streptococcal (GBS) disease in UK and Irish infants younger than 90 days, 2014–2015. Archives of Disease in Childhood 2016;101:2.
15. Lamagni TL, Keshishian C, Efstratiou A, Guy R, Henderson KL, Broughton K et al. Emerging trends in the epidemiology of invasive group B streptococcal disease in England and Wales, 1991–2010. Clin Infect Dis 2013;57:682-8.
16. Public Health England. Enriched culture medium testing for group B streptococcus is not recommended within current clinical guidance: a briefing note from PHE 2017.

17. Verani JR, McGee L, Schrag SJ. Prevention of perinatal group B streptococcal disease--revised guidelines from CDC, 2010. MMWR Recommendations and reports : Morbidity and mortality weekly report Recommendations and reports 2010;59:1-36.
18. Gupta C, Briski LE. Comparison of two culture media and three sampling techniques for sensitive and rapid screening of vaginal colonization by group B streptococcus in pregnant women. J Clin Microbiol 2004;42:3975-7.
19. El Aila NA, Tency I, Claeys G, Saerens B, Cools P, Verstraelen H et al. Comparison of different sampling techniques and of different culture methods for detection of group B streptococcus carriage in pregnant women. BMC Infect Dis 2010;10:285.
20. Church DL, Baxter H, Lloyd T, Larios O, Gregson DB. Evaluation of StrepBSelect Chromogenic Medium and the Fast-Track Diagnostics Group B Streptococcus (GBS) Real-Time PCR Assay Compared to Routine Culture for Detection of GBS during Antepartum Screening. J Clin Microbiol 2017;55:2137-42.
21. Daniels JP, Gray J, Pattison HM, Gray R, Hills RK, Khan KS et al. Intrapartum tests for group B streptococcus: accuracy and acceptability of screening. BJOG: An International Journal of Obstetrics & Gynaecology 2011;118:257-65.
22. Clark AE, Kaleta EJ, Arora A, Wolk DM. Matrix-assisted laser desorption ionization-time of flight mass spectrometry: a fundamental shift in the routine practice of clinical microbiology. Clin Microbiol Rev 2013;26:547-603.
23. Verhoeven PO, Noyel P, Bonneau J, Carricajo A, Fonsale N, Ros A et al. Evaluation of the new brilliance GBS chromogenic medium for screening of *Streptococcus agalactiae* vaginal colonization in pregnant women. J Clin Microbiol 2014;52:991-3.
24. Relich RF, Buckner RJ, Emery CL, Davis TE. Comparison of 4 commercially available group B Streptococcus molecular assays using remnant rectal-vaginal enrichment broths. Diagn Microbiol Infect Dis 2018.
25. Miller SA, Deak E, Humphries R. Comparison of the AmpliVue, BD Max System, and illumigene Molecular Assays for Detection of Group B Streptococcus in Antenatal Screening Specimens. J Clin Microbiol 2015;53:1938-41.
26. European Parliament. UK Standards for Microbiology Investigations (UK 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". 1998.
27. Official Journal of the European Communities. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices 1998. 1-37.
28. Health and Safety Executive. Safe use of pneumatic air tube transport systems for pathology specimens. 2009.
29. Department for Transport. Transport of Infectious Substances, 2011 Revision 5. 2011.
30. World Health Organization. Guidance on regulations for the Transport of Infectious Substances 2013-2014. 2012.

31. Home Office. Anti-terrorism, Crime and Security Act. 2001.
32. Advisory Committee on Dangerous Pathogens. The Approved List of Biological Agents. Health and Safety Executive 2013. 1-35.
33. Advisory Committee on Dangerous Pathogens. Infections at work: Controlling the risks. Her Majesty's Stationery Office 2003.
34. Advisory Committee on Dangerous Pathogens. Biological agents: Managing the risks in laboratories and healthcare premises. Health and Safety Executive 2005.
35. Advisory Committee on Dangerous Pathogens. Biological Agents: Managing the Risks in Laboratories and Healthcare Premises. Appendix 1.2 Transport of Infectious Substances - Revision. Health and Safety Executive 2008.
36. Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. MMWR Surveill Summ 2012;61:1-102.
37. Health and Safety Executive. Control of Substances Hazardous to Health Regulations. The Control of Substances Hazardous to Health Regulations 2002. 5th ed.: HSE Books; 2002.
38. Health and Safety Executive. Five Steps to Risk Assessment: A Step by Step Guide to a Safer and Healthier Workplace. HSE Books, 2002.
39. Health Services Advisory Committee. Safe Working and the Prevention of Infection in Clinical Laboratories and Similar Facilities. HSE Books 2003.
40. British Standards Institution (BSI). BS EN12469 - Biotechnology - performance criteria for microbiological safety cabinets 2000.
41. British Standards Institution (BSI). BS 5726:2005 - Microbiological safety cabinets. Information to be supplied by the purchaser and to the vendor and to the installer, and siting and use of cabinets. Recommendations and guidance. 2005. 1-14.
42. Health and Safety Executive. A Guide to Risk Assessment Requirements: Common Provisions in Health and Safety Law. HSE Books, 2002.
43. Baron EJ, Miller JM, Weinstein MP, Richter SS, Gilligan PH, Thomson RB, Jr. et al. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2013 Recommendations by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM). ClinInfectDis 2013;57:e22-e121.
44. Rishmawi N, Ghneim R, Kattan R, Ghneim R, Zoughbi M, Abu-Diab A et al. Survival of fastidious and nonfastidious aerobic bacteria in three bacterial transport swab systems. JClinMicrobiol 2007;45:1278-83.
45. Barber S, Lawson PJ, Grove DI. Evaluation of bacteriological transport swabs. Pathology 1998;30:179-82.
46. Van Horn KG, Audette CD, Sebeck D, Tucker KA. Comparison of the Copan ESwab system with two Amies agar swab transport systems for maintenance of microorganism viability. JClinMicrobiol 2008;46:1655-8.
47. Nys S, Vijgen S, Magerman K, Cartuyvels R. Comparison of Copan eSwab with the Copan Venturi Transystem for the quantitative survival of *Escherichia coli*, *Streptococcus agalactiae* and *Candida albicans*. EurJClinMicrobiolInfectDis 2010;29:453-6.

48. Tano E, Melhus A. Evaluation of three swab transport systems for the maintenance of clinically important bacteria in simulated mono- and polymicrobial samples. *APMIS* 2011;119:198-203.
49. Public Health England. Laboratory Reporting to Public Health England: A Guide for Diagnostic Laboratories 2013. 1-37.
50. Department of Health. Health Protection Legislation (England) Guidance. 1-112. 2010.
51. Scottish Government. Public Health (Scotland) Act. 2008.
52. Scottish Government. Public Health etc. (Scotland) Act 2008. Implementation of Part 2: Notifiable Diseases, Organisms and Health Risk States. 2009.
53. The Welsh Assembly Government. Health Protection Legislation (Wales) Guidance. 2010.
54. Home Office. Public Health Act (Northern Ireland) 1967 Chapter 36. 1967.