



GROUP B STREP COLLECTION KIT

VAGINAL & RECTAL SWAB



Group B Streptococcus is the most common cause of life-threatening infection in newborn babies in the UK.

This kit contains everything required to collect a sample and return it to the designated laboratory for testing GBS carriage.

What is Group B Streptococcus (GBS)?

Group B Streptococcus is the UK's most common cause of life-threatening sepsis in newborn babies, and of meningitis in babies up to age 3 months.

Most GBS infections can be prevented by giving antibiotics intravenously (through a vein) at the onset of labour to all women with risk factors for GBS. UK guidelines recommend offering these antibiotics in labour if GBS has been detected during the current or previous pregnancy, if a previous baby had GBS infection, if she is in preterm labour (before 37 completed weeks of pregnancy) or if she has a fever in labour. Another risk factor is waters breaking more than 18 hours before birth.

Intravenous antibiotics in labour are highly effective at preventing GBS infection in newborn babies, reducing the risk for a newborn baby born to a woman carrying GBS from around 1 in 400 to around 1 in 5000. Oral antibiotics should not be given during pregnancy for GBS carriage as they have not been shown to reduce GBS infection in babies.

There are always small but potentially serious risks associated with taking antibiotics, and this needs to be fully discussed with your doctor or midwife.

Detecting a GBS carrier

Screening for GBS is not routinely offered in the NHS. Laboratory testing for GBS is carried out at The Doctors Laboratory (www.tdlpathology.com) following the method described in the UK Standards for Microbiological Investigations, using enriched culture medium (ECM). Two swabs (lower vaginal and rectal) need to be cultured, ideally in the last five weeks of pregnancy, to best predict GBS carriage around the time of delivery.

When the ECM test is properly performed within 5 weeks of giving birth, a negative result was shown to be 96% predictive of not carrying GBS at delivery (4% of women acquired carriage between the test and birth) and a positive result 87% predictive of carrying GBS at delivery (13% of women lost carriage in that time). The test can be performed earlier, but isn't as reliable at predicting carriage status over longer periods. It can be performed later, although the chance of the baby arriving before the result increases.

Testing for GBS needs to be included in the pregnancy and birth plan and discussed with the midwife, obstetrician or GP including the treatment plan if GBS is detected. UK guidelines recommend that, when GBS is detected during the current pregnancy, the woman should be offered intravenous antibiotics in labour. This will stop most GBS infections from developing in newborn babies.

Antibiotics may affect the GBS test result. If you are taking antibiotics, or have recently, discuss this with your midwife or doctor.

Procedure for testing

GBS carriage can come and go, though tests are very predictive for a period of 5 weeks or so. Testing is usually undertaken after 35 weeks of pregnancy. **Two swabs need to be taken** and sent to the designated testing laboratory the same day by Royal Mail Tracked 24 postage; **delays in sending can affect the result**. The swabs should be **accompanied by a completed request form** showing:

- Patient's name, address, date of birth and date sample taken. Please provide the address to where results are to be sent.
- Mobile phone number if you would like also to receive results by text message.
- Name, full address, phone and email address of the healthcare professional to whom results will be sent.

The result of the test will normally be available within 3–5 working days of receipt of swabs by TDL. Results will be sent to the patient and if required to the named healthcare professional indicating whether GBS has been isolated (positive) or not isolated (negative).

References

- UK Standards for Microbial Investigations (SMI) B 28: investigation of genital tract and associated specimens.
- UK Standards for Microbial Investigations (SMI) B 58: detection of carriage of group B streptococci.
- Prevention of Early-onset Neonatal Group B Streptococcal Disease. Hughes RG, Brocklehurst P, Steer PJ, Heath P, Stenson BM on behalf of the Royal College of Obstetricians and Gynaecologists. Prevention of early-onset neonatal group B streptococcal disease. Green-top Guideline No. 36. BJOG 2017;124:e280–e305.
- www.gbss.org.uk

GROUP B STREP COLLECTION KIT

A vaginal and rectal sample collection kit used for the collection and transportation of samples for laboratory analysis of Group B Streptococcus (GBS) by enrichment culture

This kit contains the materials required for either sample self-collection or collection by a health/social care professional.



For *in vitro* diagnostic use, sample self-collection



KT366



Carefully read the enclosed instruction leaflet before use



Important: Do not use kit if security seal is broken. Keep out of reach of children



Do not re-use



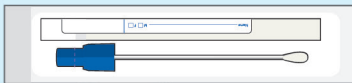
For use by persons aged 18 and over

Sample collection instructions (Steps 1–27)

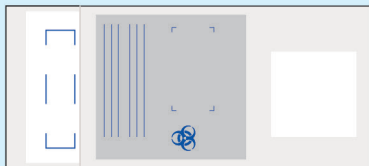
- Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.
- Use with caution if allergic to nylon fibre.
- If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the healthcare organisation who arranged the test.
- The test kit contains two swab packs, either one can be used for your vaginal or rectal sample.
- Both swabs in the pack are sterile and it is important that you do not touch the cotton end of the swab with your fingers or let it come into contact with other surfaces, for example clothing, tables or towels when taking your sample.
- Label swab tubes correctly by writing: Name, date of birth, and location of each swab (lower vaginal or rectal).

Sample collection kit contents

Please check that the kit contains all of the items outlined below. Do not proceed with sample taking if any items are missing or damaged, contact the healthcare organisation who arranged your test for assistance.



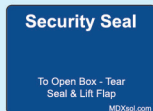
Sample collection swab x 2 STERILE R CE



Sample return bag containing absorbent pad



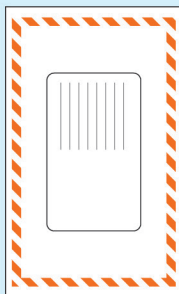
Return postal envelope



Return security label

First name:	_____
Surname:	_____
DOB:	_____
Sample type:	_____
TAP46388/02-10-21/V7 	

Sample label x 2



Collection kit outer box

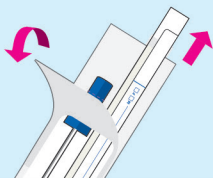
VAGINAL SWAB SAMPLE COLLECTION

- 1** If not already pre-populated please complete the test request form provided, separate to this kit. **Make sure the sample date is completed.**



Wash hands using soap and water and dry them.

- 3** Take a swab packet and peel it open from the top. Take out the collection tube.



- 4** Clearly complete a sample collection tube label using a ball point pen with:

- Your First name
- Your Surname
- Your Date of birth
- Sample type: Lower vaginal



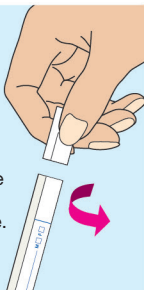
- 5** Apply the completed label along the length of the collection tube as shown.



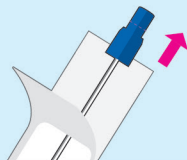
- 6** It is important to maintain a comfortable balance during the collection of both samples.

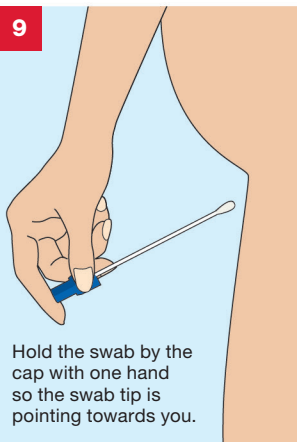


- 7** Twist and remove the white cap from the collection tube and throw it away. Keep the tube upright and put it to one side.

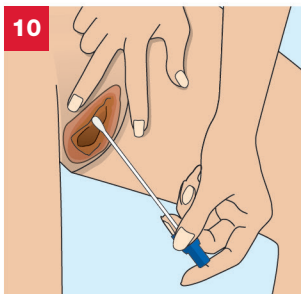


- 8** Take out the blue topped swab. Do not touch the soft swab end or let it come into contact with surfaces.

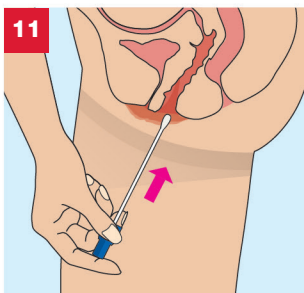


9

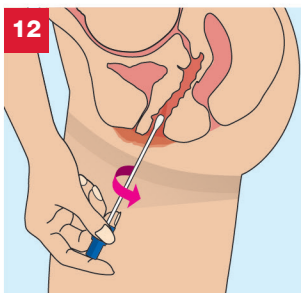
Hold the swab by the cap with one hand so the swab tip is pointing towards you.

10

With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vagina opening. Point the tip towards your lower back and relax your muscles.

11

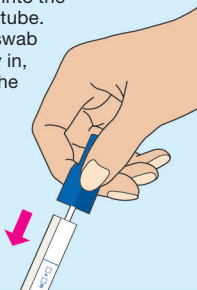
Gently slide the swab **no more than 2-4 cm** into the vagina. If the swab does not slide easily, gently rotate it as you push. **If it is too difficult, do not attempt to continue.**

12

Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Rotate the swab for 10-15 seconds.

13

Withdraw the swab and place into the collection tube. Push the swab all the way in, ensuring the blue cap is sealed securely.



RECTAL SWAB SAMPLE COLLECTION

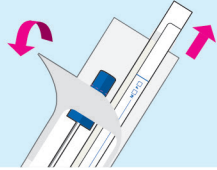
14



Please wash your hands before taking a sample.

15

Take a swab packet and peel it open from the top. Take out the collection tube.



16

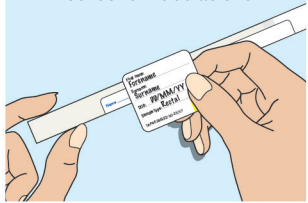
Clearly complete a sample collection tube label using a ball point pen with:

- Your First name
- Your Surname
- Your Date of birth
- Sample type: Rectal



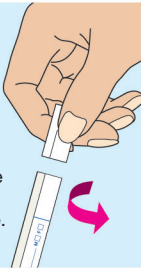
17

Apply the completed label along the length of the collection tube as shown.



18

Twist and remove the white cap from the collection tube and throw it away. Keep the tube upright and put it to one side.



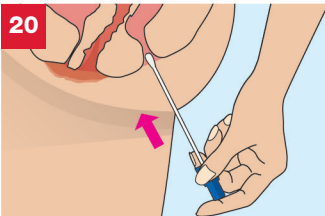
19

Take out the blue topped swab. Do not touch the soft swab end or let it come into contact with surfaces.



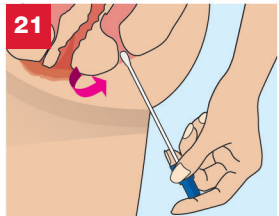
20

Holding the swab tightly, slowly insert the swab gently into the anus so that **not more than 1-2cm** of the swab is in the rectum.



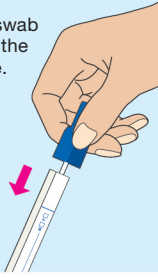
21

Gently twist the swab slightly as you slowly pull it out of your anus.



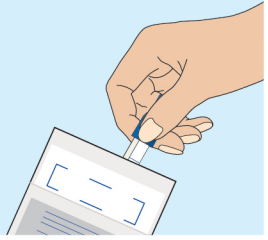
22

Withdraw the swab and place into the collection tube. Push the swab all the way in, ensuring the blue cap is sealed securely.



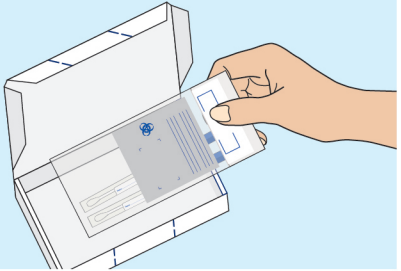
23

Place both swab tubes into the sample return bag and firmly seal.



24

Place the sample return bag into the outer collection box.



25

Samples must be sent to the laboratory on the day you collect the samples (delays can affect the results). If you are returning the sample using Royal Mail post please follow step 26, otherwise go straight to step 27.

26

Please make a note of the unique tracking number displayed under the barcode on the postal tracking label affixed to the front of the postal envelope, as shown below. Keep this in a safe place for future reference.



You can track delivery of your Royal Mail parcel by entering this number using the following link: <http://www.royalmail.com/track-your-item>

Write your tracking number here for reference – keep this safe.

27 CHECKLIST

Before you return the sample please do the following:

- Place the completed request form supplied by your doctor/clinic into the return envelope
- Make sure you have written your name, date of birth and the location of the swab on each swab tube
- Check that both swab tubes are in the return sample bag and this is sealed
- Place the return sample bag into the collection kit outer box
- Close the collection kit outer box firmly and apply the return security label to seal it
- Place the collection kit outer box into the return postal envelope

Important information if returning the sample by post:

Please ensure that you have taken note of your postal tracking number. Please post the sample to The Doctors Laboratory as soon as possible (ideally on same day or within 24 hours of sample collection)

You are now ready to seal the return envelope.



We would welcome feedback on your experience of using this self-collection kit to help us improve our services. To complete a short online survey please scan the code or visit:

<https://forms.office.com/r/nriHyUX6kj>

For more information on GBS, please contact **Group B Strep Support.**

Tel: 0330 120 0796

E-mail: info@gbss.org.uk
www.gbss.org.uk

Registered charity No 1112065



Group B Strep Support

Group B Strep Support is a UK charity providing accurate and up to date information on GBS for families and health professionals. Group B Strep Support endorses the availability of reliable prenatal testing and wants ECM testing to be available to all pregnant women through the NHS. The charity's current leaflets are available from their website at www.gbss.org.uk or by post.

If you are pregnant and want more information about Group B Strep, visit gbss.org.uk/Pregnant

Warnings and precautions

- This kit is designed for use by persons aged 18 or over and upon request of a healthcare professional or healthcare organisation.
- Please consult with a healthcare professional for guidance on sample collection processes for adolescent and younger children.
- The kit should not be used by individuals lacking the physical or mental capacity to correctly follow the self-collection instructions. If you have problems please consult with your advising healthcare professional.
- Antibiotics may affect the GBS test result. If you are taking antibiotics, or have recently, discuss this with your midwife or doctor.
- Delays in sending swabs to the laboratory may affect the GBS test result. Samples should be sent on the day of collection or within 24 hours of collection. Samples arriving at the laboratory after 7 days of sample taking may not be tested.
- Please avoid using gels or lubricants as these may contain substances which can interfere with the test.
- The accuracy of your results may be compromised if you do not read and follow the instructions in full.
- Samples arriving at the laboratory which show evidence of the below may not be tested:
 - No swab inside the collection tube
 - Two or more swabs inside the collection tube
 - Swab placed upside down in the collection tube
 - Different swab type/brand to the one supplied
 - General damage
- Use with caution if allergic to nylon fibre and ABS (Acrylonitrile butadiene styrene) material. If any problems arise during the sample collection process please contact your healthcare organisation.
- This kit is not suitable for collecting alternative sample types or for the collection and transport of viruses or other microorganisms, other than those which have been verified by the testing laboratory.

Materials required but not provided

- **Test request form.** This will be provided by TDL or your healthcare professional or healthcare organisation. **Please complete the request form with your details as instructed.**

Laboratory Tests

- The tests and procedures undertaken by The Doctors Laboratory Limited are verified and performed in line with supplier product instructions for use and supported by additional validation data for use with self-collection procedures.
- Test results are provided in line with clinically approved results pathways, agreed between The Doctors Laboratory Limited and the patients designated healthcare professional or healthcare organisation.

KEY TO SYMBOLS



For *in vitro*
diagnostic use



Catalogue number



Batch code



Sterilized using
irradiation



Biological risk.
Biological sample, treat
as potentially infectious



Do not use if package
is damaged



Use by end of year-month



Manufacturer



Distributor



UK Conformity
Assessed



EU Conformity
Assessed



Do not re-use



Temperature limits,
4°C–25°C



Consult instructions
for use



For use by persons
aged 18 and over



Caution, consult
accompanying documents



Keep away
from sunlight



Keep dry



EU Authorised
Representative



REAL Digital International Limited, 2 Queensway, Croydon, Surrey, CR0 4BD, UK
Website: www.real-digital.co.uk



Casus Europe BV, Lange Viestraat 2 B, 3511BK Utrecht, The Netherlands.



The Doctors Laboratory Limited

Distribution is restricted to regions in which the product is registered
by the manufacturer.

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RDI-IFU-064, TAP4941C/18-01-24/V29. Issue No. 2; Date 18/01/24.

Revision/Date Change summary

1	02/2023	Initial RDi product for UK Market
2	01/2024	RDi IVD product CE registration

If any serious incident occurs in relation to the use of this kit, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.