

Standard Operating Procedure for the use of Amnisure

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Target Audience:

People who need to know about this document in detail	All midwifery and obstetric staff working within CTM UHB
People who need to have a broad understanding of this document	As above
People who need to know that this document exists	As above

Integrated Impact Assessment:

Equality Impact Assessment Date & Outcome	Date: December 2024 Outcome: no negative impact
Welsh Language Standard	Choose an item.
Date of approval by Equality Team:	(00/00/0000)
Aligns to the following Wellbeing of Future Generation Act Objective	Choose an item.



Disclaimer:

If the review date of this document has passed please ensure that the version you are using is the most up to date version either by contacting the author or CTM_Corporate_Governance@wales.nhs.uk

Definition of a Standard Operating Procedure

A procedure is a set of detailed step-by-step instructions that describe the appropriate method for carrying out tasks or activities to achieve a stated outcome to the highest standards possible and to ensure efficiency, consistency and safety. A Standard Operating Procedure is defined as;

'Detailed, written instructions to achieve uniformity of the performance of a specific function'

1.3 The aim of SOPs is to ensure that any procedure performed as part of a trial is done to a consistently high standard, thus enhancing the quality of the data produced. SOPs are of particular importance when a trial is being run over several sites. SOPs set out the way practice and procedures must (i.e. mandatory) or should (i.e. advisory) be performed. SOPs should be: clear; concise; of common style; format and content; available where and when needed; and be subject to a system of document control.

Minor Amendments

If a minor change is required to the document, which does not require a full review please identify the change below and update the version number.

Type of change	Why change made	Page number	Date of change	Version 1 to 1.1	Name of responsible person
Version 2	Update/revision of existing guideline		December 2024		Liza mukhopadhyay

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AmniSure

AmniSure is a simple and quick bed-side qualitative test for rupture of membrane that can be used to aid the diagnosis with high sensitivity and specificity. 20% to 25% pregnant women will present with signs and symptoms of rupture of membrane. Among them 47% of cases will not have an obvious diagnosis with clinical examination.

A negative test can be safely relied on to rule out rupture of membrane and reduce unnecessary intervention and admission to the hospital.

A positive test can also be safely relied upon to confirm the diagnosis of PROM or PPRM and avoid delay in management.

The test strip for Amnisure contains highly sensitive antibodies to detect the presence of PAMG-1 protein in vaginal discharge.

Indication for AmniSure Test

- AmniSure should only be used when there is uncertainty of the diagnosis of ruptured membranes. i.e. History of ruptured membranes with no evidence on speculum examination. Please refer to the CTM UHB Rupture of Membranes Guideline for the assessment for rupture of membranes and should be consulted prior to the use of Amnisure. If the clinical assessment confirms the diagnosis of ruptured membranes (strong history, pooling of liquor on speculum, evidence of liquor on pad), AmniSure is not needed.
- It can be used at any gestational age.
- Amnisure can be used in the presence of urine, vaginal infection, semen after intercourse, minimal amounts of blood and in the presence of minimal amount of water-based lubricants.

Contraindication for AmniSure Test

- When the woman is in established term or preterm labour.
- During the Induction of Labour process.
- When there is clear evidence of liquor on clinical examination.
- Heavy vaginal bleeding, all blood loss should be measured if evidence on admission and women should be encouraged to quantify any blood loss seen at home. The volume of blood loss should be discussed with the Obstetrician for clinical significance.
- Amnisure whilst recommended for pre-term pregnancies (NICE NG25 2015) can be used to support diagnosis of ruptured membranes in any gestation.

AmniSure Test

1. Take full history and clinical examination including speculum examination to determine whether there was evidence of ruptured membranes or not (the woman should be encouraged to lay on the bed for 30 minutes prior to speculum examination when there is no clear evidence of rupture of membranes).
2. If uncertain, inform the woman that you are going to perform a diagnostic test. Explain the procedure and obtain verbal consent.
3. The test package contains a sterile swab, solvent vial and test strip.

Preparation

1. Complete the test before any digital examination or use of any disinfectants
2. Wear gloves
3. Set up a clock or timer
4. Remove test kit from packaging.

Step 1 – Vaginal swab

1. The polyester tip of the swab should not touch anything before insertion.
2. Insert the polyester tip of the swab 2-3 inches inside the vagina.
3. Withdraw the swab after 1 minute.
4. Do not leave the woman exposed during this time.

Step – 2 Dilute sample

1. Place the polyester tip of the swab into the solvent vial.
2. Rinse the swab in the solvent by rotating for one minute.
3. Remove and dispose of swab. Do not break swab off and leave it in the vial.

Step 3 – Testing the sample

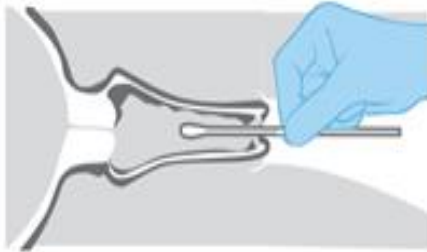
1. Dip the white end of the test strip into the vial with solvent.
 2. Remove the test strip if two stripes are visible in the vial or after 5 minutes
 3. Place on dry flat surface to read. Avoid reading results after 10 minutes after dipping the test strip into the vial.
- If you find any difficulty reading the results after 5 minutes, obtain a second opinion and if both are unable to determine if there is one or two lines,
 - Disregard the test and use clinical judgement
 - Escalate to a senior obstetrician / Band 7 MW
 - Complete a Datix incident form

Please follow the link below to watch a training video

<https://www.youtube.com/watch?v=Qt1n-2TS0nk&t=2s>

AmniSure 4-Step Testing Procedure*

1



Collect sample

1 minute - collection.

Collect sample of vaginal discharge with sterile collection swab (no speculum required).

2



Transfer to solvent

1 minute - dilution.

Rinse specimen swab in solvent vial. **Discard swab.**

3

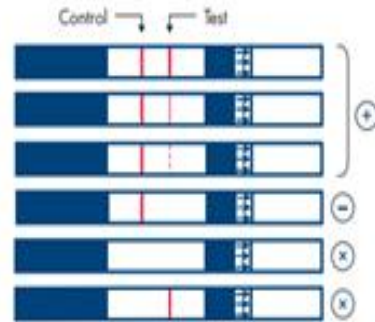


Insert test strip

10 minutes - removal of test strip.

Insert test strip into vial to initiate PAMG-1 detection. Remove the test strip after 10 minutes and then read the test results within 5 minutes.

4



Read results

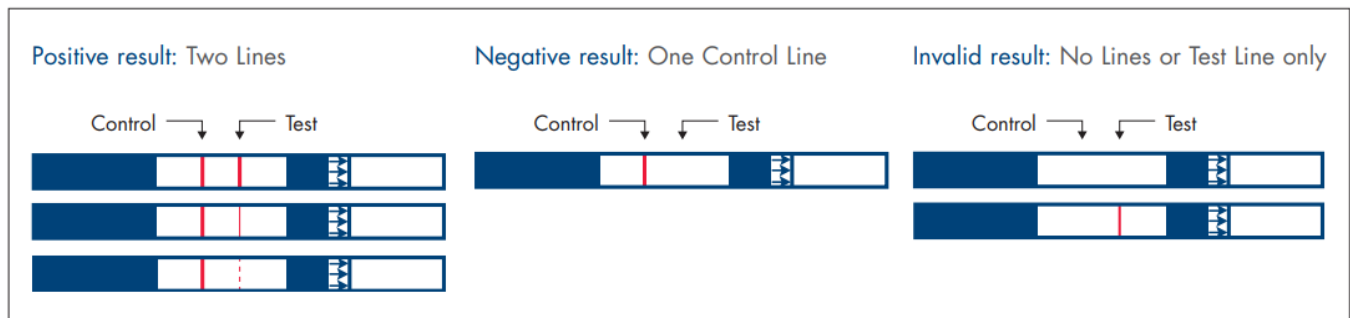
Remove test strip from vial, observe and record results. Do not read after 15 minutes have passed since inserting the strip into the vial. **Note: Faint or broken lines should always be read as positive.**

Rupture of Membranes – test result positive

Following clinical assessment and or diagnostic confirmation of rupture of membranes an Obstetric clinical review is required for the management and plan of care. Please refer to the CTM UHB Guidelines for The Management of Spontaneous Rupture of Membranes and or the CTM UHB Guidelines for the Management of Pre-labour Premature Rupture of Membranes.

Rupture of Membranes – test result negative

Women should be advised to continue to report any further losses or concerns and the importance of monitoring fetal movements and to report concerns to their community midwife or the Obstetric Unit out of hours.



If anyone has any query regarding the product, please contact AG Health on info@aghealth.co.uk

References

NICE NG 25 2019 Preterm labour and birth. NICE guideline [NG25] Published date: 20 November 2015

[Pre Labour Rupture of Membranes \(PPROM\) Guideline](#)

wisdom.nhs.wales/health-board-guidelines/cwm-taf-maternity-file/management-of-pre-labour-spontaneous-rupture-of-membranes-srom-at-term-37-0-gestation/