



Bwrdd Iechyd Prifysgol
Cwm Taf Morgannwg
University Health Board

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Standard Operating Procedure for the use of Amnisure

Introduction

The purpose of this standard operating procedure is to provide clear guidance on the use of amnisure.

Objectives

There are a number of objectives, including:

- Safety of women in respect of amnisure usage
- Provide governance for the use of amnisure

Operational Date 14.04.2021

Expiry Date April 2024

Formal – three years

Informal – one year

Scope

This procedure applies to all staff on all locations across the UHB.

Equality Impact Assessment

An Equality Impact Assessment has been completed

Distribution

All staff via internet and team briefings.

To be read by

All staff involved in the administration of medicines in secondary care

Documents to be read in conjunction with this SOP:

- **CTM UHB Spontaneous Rupture of Membranes Guideline**
- **Pre-labour Premature Rupture of Membranes Guideline**

Approved by

Antenatal Forum

Accountable Executive / Lead Director

(responsible for formal review every three years)

CTM UHB Maternity Clinical Director

Author / Management Lead

(carries out informal review annually)

CTM UHB Maternity Antenatal Forum

Freedom of Information Status

Open (most will be open, seek advice from the Head of Corporate Services if unsure)

If the review date of this policy has passed, please ensure that the version you are using is the most up to date either by contacting the document author or the Corporate Services Department.

To avoid use of out of date policies please do not print and then store hard copy of this document.

Out of date policies cannot be relied upon.

Amendment Record

If a change has been made to the document, the changes must be noted and circulated to the appropriate colleagues.

Detail of change	Why change made?	Page number	Date of change	Version	Name of Policy Author
New to CTM UHB Maternity Services				1	Ihab Abbasi

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

Contents

Definition of a Standard Operating Procedure	2
Minor Amendments	2
1. AmniSure	4
2. Indication for AmniSure Test	4
3. Contraindication for AmniSure Test	4
4. How to carry out the AmniSure Test	4
5. Rupture of Membranes – test result positive	5
6. Rupture of Membranes – test result negative	5
7. References	5

1. AmniSure

AmniSure is a simple and quick bed-side test that can be used to aid the diagnosis with high sensitivity and specificity.

A negative test can be safely relied upon to rule out rupture of membranes and therefore 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.

2. 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 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.

3. 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 can be used with history of mild bleed or recent sexual intercourse or vaginal examination within any time frame.

4. How to carry out the 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 a verbal consent.
3. Insert the swab in the vagina (without speculum) and leave for 60 seconds.
4. Do not leave the woman exposed during this time.
5. Remove the swab and insert it in the test tube mixing it thoroughly in the liquid provided for 60 seconds. The swab should not be covered in blood or lubricating gel therefore when performing speculum avoid using too much lubricating gel.
6. Remove the swab from the tube and insert the test strip and leave for 5 minutes.
7. Read the results after 5 minutes and document clearly in the notes.

Notes;

- Do not read the test strip after 10 minutes as it could have a faint second line.
- 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

5. 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.

6. 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.

7. References

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