



PROCEDURE # 945.8007
AMNIOTIC FLUID TESTING USING AMNIOTEST SWABS

PREPARED BY	DATE ADOPTED	SUPERSEDES PROCEDURE #
Dorothy Wojtylak	June, 2002	N/A

REVIEW DATE	REVISION DATE	SIGNATURE

DISTRIBUTED TO	# COPIES	DISTRIBUTED TO	# COPIES
Torresdale Campus Laboratory	1		
Hospital Intranet	1		



PRINCIPLE:

A swab impregnated with Nitrazine yellow dye is brought into contact with the upper vagina. The swab absorbs fluid associated with the tissue and the dye develops a color which correlates with the pH of the absorbed fluid over the range pH 5.5 to pH 7.5.

Amniotic fluid has a neutral pH while the pH of the upper vagina is normally acidic. A pH of 6.5 or higher in the upper vagina is consistent with leakage of amniotic fluid.

REAGENTS:

Pro-Lab Amniotest consists of disposable swabs impregnated with Nitrazine yellow dye. The swabs are packaged in individual sleeves. Swabs are sterilized by gamma radiation and are sterile until opened.

OPERATORS:

Physicians who are properly trained in vaginal exams/speculum exams with the assistance of registered nurses.

SPECIMEN:

Amniotic fluid collected from the patient via Amniotest swab either during digital or speculum exam.

COLLECTION:

Patient Identification:

- Patient is asked to state their name and date of birth. This information is verified using their identification band.
- If a patient without known identity is tested, the results are kept with the chart and identifying information is recorded once information is obtained.

MATERIALS REQUIRED:

Vaginal speculum.
Amniotest swab.

QUALITY CONTROL TESTING MUST BE PERFORMED ACCORDING TO THE CRITERIA LISTED BELOW:

Quality control is performed monthly and whenever a new lot is put into use. The personnel in the Urinalysis Department are responsible for testing. The records are maintained in the Urinalysis department at each campus.

PROCEDURE:

1. Check QC log to verify that QC has been performed.
2. Remove swab from the protective sleeve. Do not allow swab to come in contact with any liquid or substance that may affect pH.
3. Do not allow swab contact with vaginal tissue during entry and insert swab into the vagina.
4. Allow the tip to remain in contact with the upper vaginal tissue for about 15 seconds.



- Remove the swab and immediately examine the color of the tip. An olive green color pH 6.5 or higher is considered positive (See Amniotest color card).

COLOR	APPROXIMATE pH	INDICATION
Yellow orange	5.0	Intact amniotic membrane
Yellow gold	5.5	Intact amniotic membrane
Yellow olive	6.0	Intact amniotic membrane
Olive green	6.5	Ruptured amniotic membrane
Blue green	7.0	Ruptured amniotic membrane
Blue black	7.5	Ruptured amniotic membrane

- Record patient results in Wellsoft computer program.

REAGENT STORAGE:

Amniotest swabs are kept at room temperature (15° C and 30° C) in the original container.

QUALITY CONTROL PROCEDURE:

Performance and Remedial Action:

- pH Buffers 5.0 and 7.0. QC material must have the date received, the date opened and expiration on all bottles.
- QC is performed monthly and when a new lot is put into use.
- Remove swab from sleeve.
- Add 3-4 drops of each buffer solution to individual swabs.
- Immediately compare colors to Amniotest color card.

COLOR	APPROXIMATE pH	INDICATION
Yellow orange	5.0	Intact amniotic membrane
Yellow gold	5.5	Intact amniotic membrane
Yellow olive	6.0	Intact amniotic membrane
Olive green	6.5	Ruptured amniotic membrane
Blue green	7.0	Ruptured amniotic membrane
Blue black	7.5	Ruptured amniotic membrane

- pH of 5.0 will be yellow orange and pH of 7.0 will be blue green.
- Document pH results on the Amniotest Swabs QC Log. Verify that the lot numbers of the buffers recorded on the top of the form are still in use. If a new lot of buffers is started, begin using a new form. Include the following on the form:
 - Date of test/QC.
 - Signature of personnel performing test
 - Lot # and expiration date of swabs.
 - Actual reading/result of control.
- If the pH does not agree with the color card, repeat using a fresh swab.
- If pH still does not match, check the expiration date of pH material and the Amniotest swabs.
- If quality control is still not in range, contact manufacturer for replacement swabs.
- Actual patient testing cannot be performed unless QC reactions are appropriate.

QUALITY CONTROL PROGRAM:

The Amniotest swabs QC log is reviewed on a monthly basis.



REFERENCES:

Pro Lab Diagnostics, Canada Amniotest Package Insert, Product Code PL.901.