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Owner	Jeanna Begay
Area	Administrative - Waived Testing
Applicability	Hopi Health Center
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Hydrion (Nitrazine) pH Paper

PRINCIPLE

Hydrion pH Paper is a wide range pH indicator in the pH 1.0 to 12.0 range. The color changes as pH changes giving a broad range of colors from yellow through blue.

PURPOSE

Hydrion Paper is used in the obstetric area of Short Stay/ER to assist in the diagnosis of preterm premature rupture of membranes (PROM), or rupture of membranes (ROM), by testing the vaginal pH of expectant mothers. Normal vaginal and urinary secretions are acidic while amniotic fluid is alkaline. In most cases, a fern test will also be performed as part of the evaluation.

STORAGE

Hydrion test papers should be stored at room temperature (15-30°C) in dry conditions protected from sunlight. When handled in this manner, Hydrion papers have a shelf life of three years from the date of manufacture.

SPECIMEN

Vaginal secretions from the posterior vaginal pool.

- Do not touch swab or pH paper to the mucus plug in the cervix.
- Test sample **immediately** after collection.

Criteria for Unacceptable Specimens

- Amniotic fluid specimens are estimated to be stable for 2-5 minutes at room temperature (15-30°C).
- Contamination with vaginal-cervical mucus, blood or urine may lead to false positives.

PROCEDURE

Standard Precautions must be adhered to by testing personnel.

1. Tear off a strip of Hydrion paper from the dispenser.
2. Place a drop of suspected amniotic fluid on the Hydrion paper.
3. Compare the resulting color to the paper dispenser's pH scale.
4. Record results in the patient electronic health record and on the Nitrazine pH Strip Patient Result Log.

INTERPRETATION OF RESULTS

Positive result: A pH of 7.1 – 7.3 would indicate that amniotic fluid is present. A pH reading of 7 would indicate positive.

Negative result: A pH of 6.0 and below indicates that amniotic fluid is not present.

Reference Range: Normal vaginal pH is acidic between 4.0 and 4.7 in pregnancy.

DOCUMENTATION OF RESULTS

- All patient testing must be documented on the Nitrazine pH Strip Patient Result Log.
- Results must be entered into E.H.R. using the POC Lab Entry button. See the "Electronic Health Record POC Lab Entry Button for Entering Point of Care Test Results Procedure" for detailed instructions.

QUALITY CONTROL

1. **Supplies:** pH calibrating buffers, pH 2.0 and pH 7.0. Store buffers at room temperature (15-30°C). Buffers are stable until the expiration date on the bottles.
2. Each new roll of Hydrion Paper must be tested with both levels of pH buffers before using and bi-weekly thereafter.
    a. Add one drop of buffer to Hydrion test paper.
    b. Compare color to the paper dispenser's pH scale. The pH must be within 1.0 pH units of the designated pH to be acceptable.
    c. Document all results on the Hydrion pH Paper Quality Control Log.

    If controls are out of range, do not report any patient results until corrective action has been taken.

a. Repeat the procedure.
b. Repeat using a different Hydrion test roll.
c. If controls are still out of range, call the Laboratory for assistance.

SPECIFIC PERFORMANCE CHARACTERISTICS

The Hydrion paper measures pH values generally to within 1 pH unit in the range of 1.0-12.0 visually.

INTERFERENCES

1. The Hydrion test is highly sensitive but not very specific. Most studies report a 5% false-positive rate and a 1% false-negative rate.
2. False-positive results may occur from specimen contamination due to heavy vaginal discharge, blood, cervical mucus, semen, alkaline urine, bacterial vaginosis, trichomoniasis, and soap.
3. False-negative results can be produced by prolonged rupture of membranes (longer than 24 hours) or when only a small quantity of fluid has leaked.

REFERENCES

1. https://www.microessentiallab.com/product/hydrion-d-r-dispenser-1-0-12-0

2. Gibbs RS. Premature rupture of membranes. In: Scott JR, Gibbs RS, Karlan BY, Haney AF, Danforth DN, editors. Danforth's Obstetrics and Gynaecology. 9th ed. Philadelphia, PA: Lippincott Williams and Wilkins; 2003. pp. 188.

Approval Signatures

Step Description	Approver	Date
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