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Applicability	All Beaumont Hospitals

pHizatest

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform pH testing with the pHizatest strips and to provide quality monitoring and troubleshooting directions for non-laboratory testing personnel.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

A. The pHizatest phenaphthazine paper utilizes nitrazine indicator paper that is intended for *in vitro* semi-quantitative determination of body fluid pH. When pHizatest is exposed to body fluids, the paper changes color and is compared to the color chart on the dispenser to determine the pH. pHizatest evaluates pH in the range of 4.5-7.5.

B. pHizatest is used as an aid to practitioners at the point of care (POC) for the diagnosis of premature rupture of amniotic membranes and bacterial vaginitis.

1. Rupture of the amniotic membrane can result in small amounts of amniotic fluid leaking into the upper vagina. The presence of amniotic fluid tends to elevate the pH of the upper vagina. A combination of history, Fern testing, and pH testing should provide the highest sensitivity.
2. The diagnosis of the cause of vaginitis symptoms generally requires the assessment of clinical symptoms (vaginal discharge, odor, appearance, discomfort, etc.) in conjunction with laboratory tests (pH, microscopic, whiff test, and possibly cultures). The normal pH of vaginal secretions is 3.8 to 4.5 and with bacterial vaginosis the pH rises to >4.5. The determination of vaginal pH using pH paper is an aid in the diagnosis of bacterial vaginosis.

C. Users must have a record of successful color discrimination or functional assessment of test interpretation on file in order to perform testing.

III. SPECIMEN COLLECTION AND HANDLING:

A. Follow Standard Precautions/Hand Hygiene in addition to any ordered Isolation Transmission Precautions when performing patient testing. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used. Gloves must be worn when performing patient testing and be changed between patients.

B. Patient Preparation

1. The patient should avoid contamination of vaginal fluid with alkaline fluids such as semen, soaps, or urine. Contamination with blood will interfere with reading.

C. Patient Identification

1. Patients must be identified at the bedside with at least two independent identifiers. Name and identification (ID) number from the wristband must be primary identifiers. If the sample is taken from the collection area to be interpreted, the sample must be labeled with the patient name and ID number. Use a hand written or computer-generated patient information label.

D. Specimen Labeling

1. Testing should be performed at the patient's bedside. If the specimen is taken to another location for patient testing, the specimen must be labeled with patient name and ID number, per Joint Commission.

E. Specimen Collection, Processing, and Disposal

1. Vaginal fluid is collected by an Advanced Practice Provider (APP) or Physician.
    a. Using a vaginal speculum, part the labia exposing the cervix.
    b. Insert the pHizatest strip into the vagina. Do not allow the strip to come into contact with vaginal tissue during entry (posterior vaginal fornix and external cervical os).
        i. Alternately, collect fluid using a sterile and clean disposable pipette and place the sample in a clean, labeled urine cup. The specimen should be kept at room temperature and tested immediately.
    c. All collection supplies and used pHizatest strips should be discarded in a biohazard container.

F. Specimen Acceptability Criteria

1. Specimens should be free of contamination and tested immediately after collection.

G. Specimen Rejection Criteria

1. Pooled vaginal fluid is the only acceptable sample type.
2. Specimens contaminated with alkaline fluids or blood should not be tested.

3. pHizatest strips that have touched vaginal tissue or other surfaces should not be interpreted.

IV. REAGENTS:

A. pHizatest Paper and Color Chart

1. Availability: Each case contains 10 dispensers enclosed in a protective box. The product is obtained by each testing area from the PeopleSoft ordering system.
2. Storage: Store paper at room temperature (64-77°F / 18-25°C). Protect against exposure to acid or alkaline fumes. Avoid exposure to air and excessive moisture. Once opened, the foil does not need to be replaced on the roll. The foil may be discarded. The color of the base stock may vary from lot to lot, from tan to olive green. This will not affect the accuracy of the results.
3. Handling: Use paper immediately after tearing off a strip. Do not leave the dispenser open and exposed to air and moisture.
4. Expiration: When stored properly, unopened paper is stable until the manufacturer's expiration date. Once the foil has been removed from the paper roll, the manufacturer recommends a 6-month expiration date. Document the 6-month expiration date on the container or the manufacturer expiration date if it precedes the 6-month shelf life date from opening.
5. Warnings: For *in-vitro* diagnostic use only. Do not use if the roll has been stored outside the dispenser and exposed to air. Adhere to standard precautions policy when handling reagents.

B. Quantimetrix Dropper Plus Urine Dipstick Controls

1. Availability: Quantimetrix Dropper Plus controls are supplied in 2 levels (1-normal and 2-abnormal) in 5 mL bottles. Obtain the controls to perform QC testing as follows:
    a. Dearborn: The testing area orders the quality control (QC) and sends to the laboratory for storage.
    b. Farmington Hills: POC orders and stores the QC.
    c. Grosse Pointe: The testing area orders and stores the QC.
    d. Royal Oak: Ancillary Testing orders and stores the QC.
    e. Trenton: The testing area orders and stores the QC.
    f. Troy: The testing area orders and stores the QC.
    g. Wayne: The testing area orders and stores the QC.
2. Storage: Quantimetrix controls are stored in a refrigerator, designated for biohazard storage, between 2-8°C (36-46°F) before placed into use. Do not freeze.
3. Ingredients: Quantimetrix controls are prepared from human urine fortified to target levels with compounds that produce the desired reaction when tested. Preservatives including sodium azide have been added to inhibit microbial growth.

4. Handling: Prior to use, remove the controls from the refrigerator and allow to warm to room temperature for 15-30 minutes. Mix by gentle inversion and avoid foaming.
5. Expiration: Controls are stable until the manufacturer's expiration date when stored refrigerated between uses. After the initial use, the opened bottles can be stored at room temperature (18-25°C). Do not store above 30°C (86°F). When stored at room temperature, the controls are stable for one month. The room temperature expiration date must be written on the bottle. Discard the controls if turbid or any evidence of microbial contamination is present.
6. Warnings: Controls contain human urine. Sodium azide (preservative) has explosive properties. Do not dispose of control solutions in a sink. Discard in a properly-labeled biohazard container.

V. SUPPLIES:

A. Gauze

B. Gloves

C. Sample Collection Supplies

VI. QUALITY CONTROL (QC):

A. Each lot of pHizatest paper has been verified for accuracy using National Institute of Standards and Technology (NIST) traceable standards prior to product shipment. The manufacturer recommends QC checks only if the product is kept open for greater than 30 days. QC must be performed, at a minimum, every 30 days. Additional QC testing is indicated whenever the pHizatest dispenser has been left open and exposed to light and moisture and if the test results are questionable and/or do not correlate with clinical symptoms.
    1. Remove the controls from refrigerator and allow the bottles to warm to room temperature (appoximately 15-30 minutes) prior to testing.
    2. Confirm that the controls are not expired and examine for any signs of microbial contamination. If past the expiration date or cloudy/turbid due to contamination, discard and obtain new QC bottles.
    3. Tear off a strip of pHizatest paper and place the paper on a piece of gauze.
    4. Gently mix the control solutions by inversion.
    5. Remove the cap from one level of QC and invert. Gently squeeze the sides of the dropper bottle to place a drop of solution on the paper.
        a. To prevent contamination of the QC solution, wipe the tip of the dropper with clean gauze after each use and recap the bottle.
    6. Immediately compare the color of the pHizatest paper with the color chart provided on the dispenser by holding the test strip close to the color blocks on the chart and matching to the closest color block.
        a. Performing the color comparison and interpretation is recommended under a combination of florescent light and natural daylight.

7. Compare the result to the established QC ranges provided on the pHizatest Quality Control form and document the results on the form.
8. Repeat procedure with remaining level of QC.
9. Dispose of testing supplies in a biohazard container.
10. If both levels of QC are within the expected ranges, proceed with patient testing. If either or both levels of QC is unacceptable, follow the troubleshooting steps below.
    a. QC Failure Procedure
        i. If QC values are unacceptable, cease patient testing until the issue is resolved.
        ii. Verify that the lot number on the QC bottle matches the lot number posted on the pHizatest Quality Control form.
        iii. Confirm that both the pHizatest paper and QC are not expired.
        iv. Repeat testing using a new strip of pHizatest paper.
        v. If QC continues to remain unacceptable, open a new paper dispenser and obtain new bottles of QC and repeat testing.
        vi. Record the QC failure on the pHizatest Quality Control form along with the corrective action.
        vii. If problems persist, contact the site-specific POC department.
            a. Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
            b. Farmington Hills: Call the POC/Quality Lead MT at 947-521-7167
            c. Grosse Pointe: Call POC at 313-473-1831.
            d. Royal Oak: Call Ancillary Testing at 248-898-8012.
            e. Trenton: Call the Trenton Lab Manager at 734-671-3859.
            f. Troy: Call Decentralized Testing at 248-964-8009.
            g. Wayne: Call the Wayne Lab Manager at 734-467-4233.

VII. PROCEDURE:

A. Verify that the pHizatest paper is not expired and tear the length needed from the dispenser.
B. Touch the pHizatest paper to the vaginal fluid and allow the fluid to soak into the paper. Lightly tap off excess fluid, if necessary.
C. Immediately compare the color of pHizatest paper to the color chart located on the same lot number of the dispensing roll.
    1. Performing the color comparison and interpretation is recommended under a combination of florescent light and natural daylight.
D. Dispose of collection supplies and pHizatest paper in a biohazard container.

VIII. RESULT REPORTING:

A. Dearborn: pHizatest results are documented in the OB/GYN admission tab and must include the date, time, and testing personnel.

B. All other Hospitals: pHizatest results must be documented in the patient's chart and must include the date, time, and testing personnel.

C. Results may be entered into the chart using an Epic Smart Phrase.

1. Navigate to "Epic Notes". Search for the Smart Phrase by typing ".phizatest", ".vaginal pH", ".vaginal", or ".rupturedamnioticmembranes".
2. Name, current date and time will automatically populate. Change as needed.
3. Toggle to "pH pHizatest Result" to select the pH value from the drop-down list.
4. "Sign" the note to enter it in the patient's chart.

IX. EXPECTED VALUES AND INTERPRETATION OF RESULTS:

A. pHizatest interpretations should only be performed by individuals that are not colorblind.

1. Vaginal fluid pH reference range
    a. pH 3.8-4.5 for premenopausal women
2. Bacterial vaginosis
    a. pH >4.5
3. Possible ruptured amniotic membrane
    a. pH ≥6.5

X. UNEXPECTED RESULTS:

A. Results should be scrutinized in light of a patient's specific condition. If questionable results are obtained, repeat the pHizatest assay or use a different method, such as Fern testing, if deemed appropriate by the clinician.

B. Other clinical examinations may also be employed at the clinician's discretion.

XI. REPORTABLE RANGE:

A. pH 4.5 - 7.5

XII. LIMITATIONS AND INTERFERING SUBSTANCES:

A. Inaccurate results may occur due to inadequate sampling, delay in reading the pH after applying the sample, and contamination of vaginal fluid with alkaline fluids such as semen,

soaps, or urine.

B. Contamination with blood will interfere with reading.

C. Dilution of the fluid being tested may interfere with the actual pH of the fluid.

D. Avoid color comparison in florescent light only. Misinterpretation in the degree of color may occur.

E. If the pHizatest paper is exposed to acid or alkaline fumes, a reaction may occur that changes the color of the paper. If this is suspected, discard the roll.

F. Prolonged exposure to the fluid being tested prior to reading may yield erroneous results.

XIII. TROUBLESHOOTING:

A. pHizatest results are affected by poor technique during specimen collection and test procedure. The accuracy of the test is largely dependent upon the quality of the sample collection and processing. Results may be affected by any of the following:

1. Poor collection technique
2. Contamination or dilution of the specimen
3. Prolonged exposure of the pHizatest paper to the specimen
4. Delay in color interpretation
5. Interpreting results under inadequate light

B. Any result exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional testing, at the clinician's discretion.

C. If pHizatest paper is not available or there is a question about the validity of the results, contact the site-specific POC department for assistance:

1. Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
2. Farmington Hills: Call the POC/Quality Lead MT at 947-521-7167
3. Grosse Pointe: Call POC at 313-473-1831.
4. Royal Oak: Call Ancillary Testing at 248-898-8012.
5. Trenton: Call the Trenton Lab Manager at 734-671-3859.
6. Troy: Call Decentralized Testing at 248-964-8009.
7. Wayne: Call the Wayne Lab Manager at 734-467-4233.

XIV. REFERENCES:

A. Point of Care Testing Approval Process

B. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.

C. pHizatest Phenaphthazine Paper Package Insert, MICRO ESSENTIAL LABORATORY, 4224 Avenue H Brooklyn NY 11210, Version 93408 11/15/2019 www.MicroEssentialLab.com

D. Quantimetrix Dropper Plus Urinalysis Dipstick Control Package Insert, Quantimetrix 2005

Manhattan Beach Blvd., Redondo Beach, CA 90278-1205, Version E-MO44786A 07/2020 https://quantimetrix.com

E. Normal labor. Cunningham F, & Leveno K.J., & Bloom S.L., & Dashe J.S., & Hoffman B.L., & Casey B.M., & Spong C.Y.(Eds.), (2018). Williams Obstetrics, 25e. McGraw-Hill.

F. Carolyn Gardella, Linda O. Eckert, and Gretchen M. Lentz. Genital Tract Infections: Vulva, Vagina, Cervix, Toxic Shock Syndrome, Endometritis, and Salpingitis. Chapter 23, pp. 524-565. Comprehensive Gynecology, 7th Ed. Elsevier, 2017.

Attachments

pHizatest Monthly QC and New Lot QC Validation.pdf

pHizatest Quality Control Log.pdf

pHizatest Training and Competency Assessment.pdf

pHizatest Training Guide.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	3/6/2023
CLIA Medical Directors	Muhammad Arshad: Physician	3/1/2023
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	3/1/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	2/23/2023
CLIA Medical Directors	John Pui: Chief, Pathology	2/23/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	2/23/2023
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	2/23/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	2/22/2023
	Caitlin Schein: Staff Physician	2/15/2023

Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	2/2/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	2/1/2023
	Jessica Czinder: Mgr, Division Laboratory	2/1/2023

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne