

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0506774	<b>(X3) Date Survey Completed</b> 05/22/2023
<b>Name of Provider or Supplier</b> Regence Health Network, Inc	<b>Street Address, City, State</b> 410 Canyon Street, Plainview, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of calibration records and interview, the laboratory failed to retain all calibration records on the Horiba ABX Micros 60 for Complete Blood Counts (CBCs) for one of two calibrations performed from 01/01/2022 - 05/09/2023. Findings follow. A. Attempted review of the calibration performed on 05/04/2023 showed no records for review. B. Interview with the Regional Director of Operations on May 10, 2023 at 1415 hours in the office acknowledged the printer on the Horiba was not working and confirmed it was no longer printing calibration reports.</p>
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p>

This STANDARD is not met as evidenced by:  
Based on review of proficiency testing records and interview, the laboratory failed to verify the accuracy of analytes not graded by the proficiency testing agency for one of one exception reviewed. Findings follow. A. Review of the laboratory's American Proficiency Institute's (API) Microscopy/Urine Sediment proficiency testing reports from the 1st event of 2023, and the 1st, 2nd, and 3rd events from 2022 showed the laboratory failed to evaluate the results for Vaginal Wet Preparation for one of one exception reviewed. In the 2nd event of 2022, the proficiency testing agency failed to grade 1 of 1 specimen for Vaginal Wet Preparation. Review of the results on the 2022 2nd Event Comparative Evaluation found that VA-02 was "Not Graded" with Exception Code 2 (No Consensus). B. Interview of Testing personnel #1, as listed on the CMS Form 209, on May 10, 2023 at 1150 hours in the office acknowledged he thought the specimen was not up to par and did not self-grade.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
I. Based on review of a textbook procedure, the laboratory's policy and procedure, query, and interview, the laboratory failed to follow textbook procedure for performing Wet Preps used for the identification of yeast when they failed to examine a drop of the vaginal secretions with 10% KOH (potassium hydroxide) for 85 of 85 patients tested from 01/01/2023 - 05/09/2023. Findings follow. A. Review of the laboratory's textbook procedure from Clinical Methods: The History, Physical, and Laboratory Examinations, 3rd Edition, 1990, Chapter 179, Tests on Vaginal Discharge, under Technique stated, "Place the sample in 1 ml of saline and agitate to mix. Take a drop of this mixture and place it on a slide... cover with a cover slip.... The slide may be warmed briefly (to increase motility of trichomonas) and should be looked at promptly. A careful search of several fields should be made at both medium and high power for trichomonas, clue cells, and yeast. Trichomonas are motile flagellated organisms about the size of a white blood cell (WBC). They are best recognized by their characteristic twisting motion. Clue cells are vaginal epithelial cells with adherent coccobacilli. Yeast may be seen as budding or hyphal forms, and may be seen best with the addition of potassium hydroxide. Lastly, the presence or absence of a large number of leukocytes should be noted. A few may be normal, but more than 10 per high-power field is abnormal. An additional [drop] should be ... placed on a slide. Add a drop of 10% potassium hydroxide (KOH) and cover with a cover slip... The slide should then be examined carefully for the presence of budding yeast or hyphae." B. Review of the laboratory's policy and procedure titled Wet Prep/Hanging Drop, reviewed 10/06/2022, stated, "Procedure for Wet Mounts ...The provider performs the collection of vaginal secretions. The swab is collected from the vaginal walls, or any area that appears to be inflamed. The swab is placed in a tube containing sterile physiologic saline. The tube should be thoroughly mixed. Preparation of the slide: 1. Place a clean microscope slide on a flat, level surface. Use the tip of a dripping swab to transfer a drop of the saline suspension to the surface of the slide. 2. Immediately lay a cover slip over the material. 3. The slide is ready for direct examination under a microscope. Microscopic examination of the slide: 1. The

slide should be thoroughly examined (a minimum of ten fields) for motile trophozoites of Trichomonas, budding yeast, yeast cells, pseudohyphae of yeast, and clue cells which are sloughed epithelial cells, many of which are completely covered by tiny, rods and coccobacilli." The laboratory's current procedure may inhibit testing personnel from identifying budding yeast and pseudohyphae. C. Review of the query of Wet Mounts performed from 01/01/2023 - 05/09/2023 showed 85 Wet Preps were performed. D. Interview with testing personnel #1, as listed on the CMS Form 209, on May 10, 2023 at 1500 hours in the office confirmed the laboratory does not perform the Wet Mount with KOH. II. Based on review of a textbook procedure, the laboratory's policy and procedure, query, and interview, the laboratory failed to follow textbook procedure for performing Wet Preps used for the identification of trichomonas, clue cells, and yeast when they failed to place the vaginal swab into 1 ml of saline for 85 of 85 patients tested from 01/01/2023 - 05/09/2023. Findings follow. A. Review of the laboratory's textbook procedure from Clinical Methods: The History, Physical, and Laboratory Examinations, 3rd Edition, 1990, Chapter 179, Tests on Vaginal Discharge, under Technique stated, "Place the sample in 1 ml of saline and agitate to mix. Take a drop of this mixture and place it on a slide... cover with a cover slip.... The slide may be warmed briefly (to increase motility of trichomonas) and should be looked at promptly. A careful search of several fields should be made at both medium and high power for trichomonas, clue cells, and yeast. Trichomonas are motile flagellated organisms about the size of a white blood cell (WBC). They are best recognized by their characteristic twisting motion. Clue cells are vaginal epithelial cells with adherent coccobacilli. Yeast may be seen as budding or hyphal forms, and may be seen best with the addition of potassium hydroxide. Lastly, the presence or absence of a large number of leukocytes should be noted. A few may be normal, but more than 10 per high-power field is abnormal. An additional [drop] should be ... placed on a slide. Add a drop of 10% potassium hydroxide (KOH) and cover with a cover slip... The slide should then be examined carefully for the presence of budding yeast or hyphae." B. Review of the laboratory's policy and procedure titled, Wet Prep/ Hanging Drop, reviewed 10/06/2022, stated, "Procedure for Wet Mounts ...The provider performs the collection of vaginal secretions. The swab is collected form the vaginal walls, or any area that appears to be inflamed. The swab is placed in a tube containing sterile physiologic saline. The tube should be thoroughly mixed." The laboratory's current procedure does not specify the amount of saline in the tube. C. Review of the query of Wet Mounts performed from 01/01/2023 - 05/09/2023 showed 85 Wet Preps were performed. D. Interview with testing personnel #1, as listed on the CMS Form 209, on May 10, 2023 at 1515 hours in the office acknowledged it depends on how much saline they send to us, and confirmed the amount is not specified.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
 CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
 Based on review of manufacturer's instructions, observation, and interview, the laboratory failed to label their Complete Blood Count (CBC) reagents with the open

date and open expiration date using the Horiba ABX Micros 60 analyzer for three of three reagents reviewed. Findings follow. A. Manufacturer's Instructions: 1. Review of the package insert for the ABX Minidil LMG, 04/26/2022, under Storage and Stability stated, "Open Stability: 6 months maximum at 18-25 degrees Celsius after opening and within the expiration limit." 2. Review of the package insert for the ABX Alphalyse, 02/23/2022, under Storage and Stability stated, "Open Stability: 3 months maximum at 18-25 degrees Celsius after opening and within the expiration limit." 3. Review of the package insert for the ABX Miniclean, 04/27/2022, under Storage and Stability stated, "Open Stability: 3 months maximum at 18-25 degrees Celsius after opening and within the expiration limit." B. During a tour of the laboratory on May 10, 2023 at 1205 hours, the surveyor observed the reagents on the Horiba AB Micros 60 did not have open dates or open expirations noted on them: 1. ABX Minidil LMG, Lot 220503F1, (closed date) expiration 11/03/2023 2. ABX Alphalyse, Lot 22071853, (closed date) expiration 07/18/2023 3. ABX Miniclean, Lot 220727T1, (closed date) expiration 07/27/2023. C. Interview with testing personnel #1, as listed on the CMS Form 209, on May 10, 2023 at 1205 hours in the laboratory confirmed the findings.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of the patient test report, and interview, the laboratory failed to provide the reference range for clue cells, trichomonas, and yeast on three of three Wet Prep reports reviewed. Findings follow. A. Review of three of three Wet Prep patient test reports showed no reference range for clue cells, trichomonas, and yeast on the test report as listed by collection date and MRN: Collection Date MRN 1. 03/02/2023 214397 2. 02/14/2023 342186 3. 01/09/2023 177113 B. Interview with the Regional Director of Operations on May 10, 2023 at 1545 hours in the office confirmed there were no reference ranges for clue cells, trichomonas, and yeast. KEY: MRN: Medical Record Number

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of the Laboratory Technical Consulting Agreement, competency evaluations and interview, the technical consultant failed to evaluate the competency of all testing personnel performing Complete Blood Counts (CBCs), wet mounts, and

serum hCG (human chorionic gonadotropin) for 5 of 5 testing personnel. Findings follow. A. Review of the Laboratory Technical Consulting Agreement, reviewed on 11/10/2021, stated under Duties and Responsibilities, "Consults with RHN's Lab Director to evaluate the required competencies of testing personnel." B. Review of competency evaluations for testing personnel #1-5, as listed on the CMS Form 209, showed it was unclear to determine who performed the competency evaluations. C. Interview with testing personnel #1 on May 10, 2023 at 1100 hours in the office confirmed he performed all competency evaluations [testing personnel #2-5], and the Lab Director performed the competency evaluation for himself.