

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2138778	<b>(X3) Date Survey Completed</b>  09/25/2019
<b>Name of Provider or Supplier</b>  Durham Women's Clinic	<b>Street Address, City, State</b>  7780 Brier Creek Parkway, Suite 330, Raleigh, NC	
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>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency records and interview with laboratory director (LD) 9/25/19, the laboratory failed to establish competency procedures that meet the regulations as stated in section 493.1413(b)(8) of the 42 CFR Part 493 Requirements for Laboratories. Section 493.1413(b)(8) states: "The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to... Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing of previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; Findings: Review of TP competency records revealed a form entitled "Competency Assessment for Testing Personnel - Affirm Testing". The form is a checklist of tasks that testing personnel must be able to do. The checklist fails to establish a competency policy or procedure, it does not indicate how the evaluations are conducted and documented, and does not include the criteria used for the evaluation. The checklist also fails to include the required procedures for evaluation of the competency of staff as required in section 493.1413(b)(8) of the 42 CFR Part 493 Requirements for Laboratories. During exit interview with LD at approximately 2:00 p.m. the LD stated she was unaware that there was a problem with the competency assessments and that these</p>

were used by the previous laboratory director so she assumed they were sufficient and met the regulations.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing (PT) records and interview with office manager and laboratory director (LD) 9/25/19, the laboratory failed to verify the accuracy of the testing performed on the BD MicroProbe Processor. Findings: The laboratory performs testing for *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis* using the BD Affirm VPIII microbial identification test on the BD MicroProbe Processor. Review of laboratory PT records revealed the laboratory had copies of Medical Laboratory Evaluation (MLE) PT records from their "sister" facility located at a separate address. The records failed to document PT or verification of accuracy for the testing performed at the facility surveyed. Interview with office manager and LD at approximately 12:00 p.m. confirmed the PT records were copies of PT performed at their "sister" facility. The office manager stated they were told by MLE that they would not have to enroll for this site if they were already enrolled at another site for the same testing.

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure manual and interview with testing personnel (TP) 9/25/19, the laboratory procedure manual failed to include current quality control (QC) procedures for the BD Affirm VPIII testing. Findings: The laboratory performs testing for *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis* using the BD Affirm VPIII microbial identification test on the BD MicroProbe Processor.

Review of laboratory procedure, "Affirm VPIII Procedure", revealed "PROCEDURE"... "Automated Processing... Refer to Procedural Chart Illustrations that came with the BD MicroProbe Processor... 12) Check for positive and negative internal controls." The "Procedural Chart Illustrations" and the "Affirm VPIII Procedure" fail to include what type of QC is performed externally, how often external QC is performed, the criteria used to determine if QC passed, the course of action to take if QC fails and how external QC is documented. During interview with TP #1 at approximately 11:30 a.m., the TP stated she was unsure exactly how she needed to document or perform the QC for the Affirm VP III testing. She stated she was documenting the internal controls for each patient, performing the external controls weekly and was unsure how to document each new lot number of reagent. She stated she had contacted the manufacturer's service representative, but was still unsure of what was required.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, interview with testing personnel (TP) and review of laboratory quality control (QC) records the laboratory failed to perform and/or document QC as required by the manufacturer and established by the laboratory for the BD Affirm VPIII testing performed. Findings: The laboratory performs testing for *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis* using the BD Affirm VPIII microbial identification test on the BD MicroProbe Processor. Review of manufacturer's instructions for the BD Affirm VPIII microbial identification test revealed "Quality Control... Test includes two internal controls on each PAC... these control beads are tested simultaneously with each patient specimen... Each reagent lot must be tested for adequate sample lysis and release of target nucleic acid using a swab streak of fresh indicator culture... or commercially prepared swab of *Candida albicans*... To further verify test performance, quality control testing with *C. albicans*..., *T. vaginalis*..., and *G. vaginalis* may be conducted...". 1. During interview with TP #1 at approximately 11:30 a.m., TP #1 stated external (QC) was performed weekly using commercially prepared swabs. Review of laboratory quality control records "Affirm VPIII Lab Testing Log" revealed the laboratory failed to perform weekly quality control as required per interview with TP #1 on the following dates: 1. QC due 8/27/18 was performed 8/30/18; 3 patients tested. 2. QC due 9/24/18 was performed 10/3/18; 14 patients tested. 3. QC due 10/22/18 was performed 11/1/18; 12 patients tested. 4. QC due 11/8/18 was performed 11/13/18; 3 patients tested. 5. QC due 11/28/18 was performed 12/4/18; 5 patients tested. 6. QC due 12/11/18 was performed 12/21/18; 11 patients tested. 7. QC due 12/28/18 was performed 1/17/19; 13 patients tested. 8. QC due 1/24/19 was performed 2/8/19; 17 patients tested. 9. QC due 2/21/19 was performed 2/25/19; 1 patient tested. 10. QC due 3/4/19 was performed 3/11/19; 6 patients tested. 11. QC

due 3/18/19 was performed 3/26/19; 7 patients tested. 12. QC due 4/23/19 was performed 5/6/19; 9 patients tested. 13. QC due 5/13/19 was performed 5/24/19; 6 patients tested. 14. QC due 6/12/19 was performed 6/24/19; 10 patients tested. 15. QC due 7/1/19 was performed 7/10/19; 6 patients tested. 16. QC due 8/12/19 was performed 8/16/19; 6 patients tested. 17. QC due 8/23/19 was performed 8/26/19; 2 patients tested. 18. QC due 9/2/19 was performed 9/9/19; 10 patients tested. 2. During interview with TP #1 at approximately 11:30 a.m., the TP stated she was documenting the internal controls for each patient, performing the external controls weekly and was unsure how to document each new lot number of reagent. She stated she had contacted the manufacturer's service representative, but was still unsure of what was required. Review of laboratory QC records for the manufacturer's required quality control; "Each reagent lot must be tested for adequate sample lysis and release of target nucleic acid using a swab streak of fresh indicator culture...or commercially prepared swab of *Candida albicans*." revealed the laboratory QC records failed to correctly document the QC and the surveyor was unable to determine if the requirement was met.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of manufacturer's instructions and review of laboratory temperature logs 9/25/19, the laboratory failed to document corrective action when the room temperature was not documented or failed to be within range for the BD Affirm VPIII testing performed. Findings: Review of manufacturer's instructions for the BD Affirm VPIII testing revealed "All reagents and PAC's must be at 22 to 28 degrees Celcius prior to use." Review of laboratory temperature logs revealed the laboratory failed to document corrective action on the following days in which the room temperature was not within acceptable range or was not documented before patient testing began; 9/20/19, 6/17/19 - 6/21/19, 3/18/19 -3/20/19, 3/15/19, 3/13/19, 3/6/19, 3/4/19, 2/28/19, 2/18/19, 2/15/19, 2/13/19, 2/12/19, 2/8/19, 2/5/19, 1/30/19, 1/28/19, 1/22/19, 1/21//19, 12/28/18, and 10/30/18. A total of approximately 43 patients were tested when temperatures were not within range.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of laboratory quality assessment records, quality control records and laboratory temperature records 9/25/19, the laboratory failed to establish and follow quality assessment polices that could identify and correct problems identified in the analytic systems found at time of survey. Findings: Review of laboratory quality assessment records revealed a form entitled "Monthly Continuous Quality Improvement Report". The report is a checklist of reviews that the laboratory director completes each month. The review includes Patient Test Management, Quality Control, Proficiency Testing and Personnel. Based on review of quality control records for the BD Affirm VPIII testing the quality assessment policies failed to identify quality control problems identified at time of survey. See D5445. Based on review of laboratory temperature records the quality assessment policies failed to identify and correct problems with the room temperature identified at time of survey. See D5781.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
Based on review of laboratory verification records and interview with laboratory director 9/25/19, the laboratory director (LD) failed to ensure the verification procedures used for the validation of the BD Affirm VPIII microbial identification test on the BD MicroProbe Processor were adequate. Review of validation records for the BD Affirm VPIII microbial identification test revealed the validation had not been signed and dated by the laboratory director to indicate their review and approval to begin patient testing. Exit interview with LD at approximately 2:00 p.m. confirmed the LD had not signed or dated her review of the validation records for the BD Affirm VPIII microbial identification test.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with office manager (OM) and laboratory director (LD) 9/25/19, the LD director failed to ensure that prior to testing patient specimens, 1 of 3 testing personnel (TP) received appropriate training and had demonstrated that they could perform testing for the BV Affirm VPIII microbial identification test on the BD MicroProbe Processor. Review of personnel records for TP #3 revealed there was no documentation available to indicate that TP #3 had been trained to perform testing for the BV Affirm VPIII microbial identification test on the BD MicroProbe Processor. During exit interview at approximately 2:00 p.m. the OM and LD stated all TP were trained but the documentation was at the other office. Documentation of training was then provided for TP #1 and TP #2, but no documentation was provided for TP #3.