

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0451122	<b>(X3) Date Survey Completed</b>  08/22/2023
<b>Name of Provider or Supplier</b>  Mercy Hospital	<b>Street Address, City, State</b>  218 E Pack, Moundridge, KS	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's non-waived test list, lack of approved procedure for the Affirm VPIII testing, patient test reports for 2023, and interview with General Supervisor (GS) #1, the laboratory failed to have a written procedure available to and followed by, laboratory personnel for the operation of the Affirm VP III test system used for the detection of Trichomonas vaginalis, Gardnerella vaginalis and Candida species before reporting patient results. Findings: 1. Review of the non-waived test list included a "Vaginitis Panel" performed on the Affirm VPIII. a. The panel consists of three organisms reported as positive or negative: Trichomonas vaginalis, Gardnerella vaginalis, and Candida species. 2. Request was made for the procedure for the vaginitis panel performed on the Affirm VPIII. No approved procedure was made available at the time of survey. 3. Review of patient results reported from 1/1/23 to 8/22/23 revealed 42 patient reports were released. 4. Interview with GS #1 on 8/22/23 at 2:25 p.m. confirmed, the laboratory failed to have a written procedure available to and followed by, laboratory personnel for the operation of the Affirm VP III test system used for the detection of Trichomonas vaginalis, Gardnerella vaginalis and Candida species before reporting patient results.</p>
<b>D5425</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)</p> <p>The laboratory must determine the test system's calibration procedures and control</p>

procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:  
Based on the review of the Individualized Quality Control Plan (IQCP) for the BD Affirm VPIII test system for Trichomonas vaginalis, Gardnerella vaginalis and Candida species detection and interview with GS #1, the laboratory failed to describe what quality control (QC) was to be used and failed to include the history of the QC frequency (stability study) for the defined QC interval. Findings: 1. Review of the IQCP for the BD Affirm VPIII, signed by the laboratory director 3/20/23 revealed: a. Under "QC plan:", item #4: "QC should be run every new shipment, new lot and every month of the current lot. b. Further review finds the QC material is not defined with any information as to the type of control, manufacturer or expected results (positive control or negative control). c. Item #4 continues with the following: "Past QC data collected and proficiency testing show that QC testing can be run once a month without clinically significant error." d. No QC history to support the defined QC interval was included in the IQCP. The laboratory was not able to provide this documentation at the time of survey. 2. Interview with GS#1 on 8/22/23 at 2:25 p.m. confirmed, the laboratory failed to describe what quality control (QC) was to be used and failed to include the history of the QC frequency (stability study) for the defined QC interval.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on the review of the CMS116 test list, QC and patient testing performed from 1/1/23 to date of survey, package insert for the BD Affirm VPIII test system for Trichomonas vaginalis, Gardnerella vaginalis and Candida species and interview with GS #1, the laboratory failed to perform both a positive and negative control as required before reporting patient results for Trichomonas vaginalis, Gardnerella vaginalis and Candida species. Findings: 1. Review of the 116 test list included a "Vaginitis Panel" performed on the BD Affirm VPIII. a. The panel consists of three organisms reported as positive or negative: Trichomonas vaginalis, Gardnerella vaginalis, and Candida species. It is classified by FDA as moderate complexity. 2. Review of the QC and patient test logs from 1/1/23 to date of survey revealed no external negative control had been performed and a total of 42 patient results have been reported. 3. Review of test system package insert, under Quality Control states: "Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures." 4. Interview with GS #1 on 8/22/23 at 2:25 p. m. confirmed, the laboratory failed to perform both a positive and negative control as required before reporting patient results for Trichomonas vaginalis, Gardnerella vaginalis and Candida species.