Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0715273	06/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Chesapeake Women's Care	2000 Medical Parkway Ste 306, Annapolis, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) procedure and interview with the lead testing person (TP) and office manager (OM), the laboratory did not ensure that PT samples were tested in the same manner as patient specimens. Findings: 1. The laboratory's "Proficiency Testing" procedure stated "When testing is complete, write down results on a separate piece of paper, DO NOT DISCARD PAC [Probe Analysis Card] CARDS! Remove cards from processor, lay them on a paper towel for Lab Director to review and validate results." 2. In an interview on 06/05/2024 at 1:00 PM, the TP confirmed that the laboratory director did not review the PAC for patient testing prior to reporting results. 3. During the exit interview on 06/05/2024 at 1:30 PM, the lead TP and OM confirmed that PT samples were not tested the same as patient samples as the laboratory director reviewed the PAC for PT samples but not for patient samples prior to reporting the results.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must

	attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the lead testing person (TP) and office manager (OM), the laboratory failed to attest to the routine integration of samples into the patient workload using the laboratory's routine methods for four of four PT events reviewed. Findings: 1. Records from four PT events from 2023-2024 were reviewed. 2. The laboratory did not have signed attestation forms in either a hardcopy or electronic format. 3. During the exit interview on 06/05/2024 at 1:30 PM, the lead TP and OM confirmed that the laboratory did not download the attestation forms for either hardcopy or electronic signatures.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the procedure manual and competency records and interview with the lead testing person (TP) and office manager (OM), the laboratory failed to establish a written procedure for assessing competency of the testing personnel (TP). Findings: 1. The laboratory's procedure titled "Quality Assessment Worksheet 2023" stated that "Competency Assessment" was to be performed at "2 months for new hire and Annually after first year of employment. Annually for employees >2 years." 2. The laboratory used a form titled "Laboratory Personnel Evaluation" to document competency assessments, but there was no procedure describing how competency was to be performed including the six CLIA requirements for assessing competency of TP: 1) Direct observation of routine patient test performance, 2) Monitoring the recording and reporting of test results, 3) Review of intermediate test results or worksheets, quality control records, proficiency testing (PT) results, and preventive maintenance records, 4) Direct observations of performance of instrument maintenance and function checks, 5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external PT samples, and 6) Assessment of problem solving skills. 3. During the exit interview on 06/05/2024 at 1:30 PM, the lead TP and OM confirmed that the laboratory did not have an approved procedure for performing competency of the TP.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the lead testing person (TP) and office manager (OM), the laboratory failed to document the

	review and evaluation of PT results in four of four PT events. Findings: 1. Records from four PT events from 2023-2024 were reviewed. 2. The laboratory did not have a hardcopy or electronic record of the PT results that was signed by the laboratory director (LD) or designee indicating review of the PT results. 3. During the exit interview on 06/05/2024 at 1:30 PM, the lead TP and OM confirmed that the laboratory did not download the PT results for either hardcopy or electronic signatures of the LD or designee indicating their review and evaluation of the PT results.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature records, review of the manufacturer's user manual, and interview with the lead testing person (TP) and office manager (OM), the laboratory failed to record the relative humidity in the laboratory where the Beckton Dickinson (BD) MicroProbe Processor was operated. Findings: 1. The laboratory tested the BD Affirm VPIII Microbial Identification Test using the BD MicroProbe Processor. 2. The instrument user's manual (document MA0106 2016-04 (08)) listed "Operating Specifications" for "Ambient Humidity" as "10-85%." 3. Temperature records for 2023 and 2024 were reviewed and there was no documentation of ambient humidity. 4. During the exit interview on 06/05/2023 at 1:45 PM, the lead TP and OM confirmed that the laboratory was not documenting ambient humidity in the room where the BD Affirm VPIII testing was performed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of patient test logs and interview with the lead testing person (TP) and office manager (OM), the laboratory failed to ensure that test kits for the Becton Dickinson (BD) Affirm VPIII assay were not used beyond their expiration dates. Findings: 1. The laboratory documented the lot number and expiration date of the BD Affirm VPIII test kits used for each patient tested on the "Affirm Test Log." 2. Each page of the Affirm Test Log documented results for 12 patients. 3. Patient logs from 04/03/2023 to 06/04/2024 were reviewed. 4. A single page listed patient results from 04/19/2024-05/02/2024 and documented that testing was performed with Affirm kit lot number 3146709 with expiration date 04/09/2024 for all 12 patients. 5. During the

	exit interview on 06/05/2024 at 1:45 PM, the lead TP and OM confirmed that 12 patients listed on a single page of the Affirm Test Log were tested with expired BD Affirm VPIII test kits.
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 the manufacturer's instructions for use (IFU), the laboratory's procedure, the patient test log, and the quality control (QC) log and interview with the lead testing person (TP) and office manager (OM), the laboratory failed to perform external QC testing on new test kit lot numbers prior to testing patient specimens for five of eight test kit lot numbers reviewed. Findings: 1. The manufacturer's IFU (document 670160JAA(06) 2023-11) stated that "each reagent lot must be tested for adequate sample lysis and release of target nucleic acid." The laboratory used a tri-valent swab that included all three test organisms included in the assay. The manufacturer's IFU also stated that "If quality control (QC) testing with all three organisms, ensure that the results for the internal controls are both acceptable (i.e. , blue Positive Control bead and colorless Negative Control bead) and interpret results as follows: 1. If all three organism beads turn blue, all patient results can be reported." 2. The laboratory's "Quality Control Testing" procedure stated that the "External Control" should be performed "with a new box of Affirm BD VPIII is opened. Before patient testing or monthly." 3. The laboratory recorded each test kit lot number used for each patient specimen on the "Affirm Test Log" and each external QC result for each test kit lot number on the "External Quality Control Log Sheet." Both logs were reviewed for patient testing performed from 04/03/2023-06/05/2024. 4. Five of eight test kit lot numbers reviewed were tested with external QC after patient testing had begun with that test kit lot number: a. Lot number 3051325: QC was first performed on 09/22/2023 and patient testing began on 09/07/2023 b. Lot number 3135433: QC was first performed on 11/06/2023 and patient testing began on 10/10/2023 c. Lot number 3115101: QC was first performed in 12/2023 (the day was not recorded) and patient testing began on 11/16/2023 d. Lot number 3146709: QC was first performed on 01/05/2024 and patient testing began on 01/04/2023 e. Lot number 3262038: QC was first performed on 05/13/2024 and patient testing began on 04/19/2024 5. During the exit interview on 06/05/2024 at 1:45 PM, the lead TC and OM confirmed that external QC was not consistently performed on new test kit lot numbers prior to patient testing with those lot numbers.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or

both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions for use (IFU), the quality control (QC) procedure, the patient test log, and the QC log and interview with the lead testing person (TP) and office manager (OM), the laboratory failed to document corrective actions when results of internal and external QC did not meet acceptability criteria. Findings: 1. The manufacturer's IFU (document 670160JAA(06) 2023-11) stated that the test "includes two internal controls on each PAC [Probe Analysis Card]: a Positive Control bead and a Negative Control bead. These control beads are tested simultaneously with each patient specimen, ensuring the proper performance of PAC, Reagent Cassette (RC) and Processor. The Positive Control also ensures the absence of specimen interference. The Negative Control also ensures the absence of non-specific binding from the specimen. In a properly functioning test, the Positive Control bead will be blue and the Negative Control bead remains colorless (i.e., absence of blue color) after processing. If the Positive Control does not turn blue, and /or the Negative Control does not stay colorless, the test results are invalid and patient results should not be reported." The IFU also stated that when testing external QC, "ensure that the results for the internal controls are both acceptable (i.e., blue Positive Control bead and colorless Negative Control bead)." 2. The laboratory's "Quality Control Testing" procedure stated that the results from the external positive QC should be "All positive or blue with exception of negative control" and for the external negative QC should be "All negative or clear with an exception of positive control." Then stated that "If there are any results other then listed above, or any other concerns about the accuracy of testing, please notify the lab Director and contact the company responsible for Tri-Valent." 3. The laboratory documented all patient results on the "Affirm Test Log" (patient log) which included results from the negative and positive internal controls. The patient log stated to record the results of each internal control and to "Use + or pos for 'positive' and - or neg for 'negative.'" 4. The positive internal control for the first patient tested on 05/15/2024 was documented as "-" indicating that the result was negative. Patient results were reported and there was no documentation of corrective actions taken for the invalid result. 5. The laboratory documented all results for external QC on the "External Quality Control Log Sheet" (QC log) which included results from the negative and positive internal controls as well as results from the three organisms tested (Trichomonas vaginalis, Gardnerella vaginalis, and Candida species). The QC log stated "Record the reactions of the Affirm Test external control. Verify that the internal controls are Positive and Negative. Blue = Positive, POS, or (+) Colorless = Negative, NEG, or (-)." 6. Results for 23 external positive and negative QC tested from 02/21/2023 - 06/04/2024 were reviewed. A total of 19 of the 23 results were recorded as having unacceptable results. Of the 19 results recorded as having unacceptable results, 3 documented that the negative external QC tested positive for the 3 organisms (T. vaginalis, G. vaginalis, and Candida sp.) and 16 documented that the external positive QC had positive results for the negative internal control (which is expected to be negative). There was no documentation of corrective actions taken for the invalid results. 7. During the exit interview on 06/05/2024 at 1:45 PM, the lead TP and OM confirmed that the positive internal control result for the first patient tested on 05/15/2024 and 19 of 23 results for the external positive and negative QC were recorded on the log as having

	unacceptable results with no documented corrective actions.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and staff interview, the laboratory director failed to ensure that the PT results were reviewed to evaluate the laboratory's performance and to identify any problems that may have required corrective action. Cross-refer to tag D5211 for details.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) procedures, monthly QA checklists, proficiency testing (PT) records, patient test log, and quality control (QC) log and interview with the lead testing person (TP) and office manager (OM), the laboratory director (LD) failed to ensure that the QA program was maintained to be able to monitor, assess, and when indicated, correct identified problems. Findings: 1. The "Quality Assessment Checklist" procedure stated to "Review patient result log weekly but daily if needed for any missing information or incorrect test results" and "Review internal QC logs monthly to ensure appropriate action(s) were taken for unacceptable values/ or incorrect results." 2. The "Quality Assessment Worksheet 2023" included a table that stated that the activity "Supervisor reviews QC logs, result logs and temperature logs" was to be performed with the frequency of "Result logs and temperature logs are monitored daily; QC/proficiency logs are monitored monthly" and that the activity "Laboratory Director review and signs QC logs" was to be performed with the frequency of "Monthly." There was no documentation of LD review on the QC logs. 3. The laboratory completed a "Monthly Quality Assurance Checklist" which included the following checklist items and a column to document "Yes/No Not Applicable." The monthly QA checklists were reviewed from 04/2023-04/2024. All checklists were signed as reviewed by the LD. a. "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." All checklists documented "N/A" when there was no PT that month or "Y" when there was. b. "All reagents, controls, kits, etc. that exceeded their expiration date were

	discarded." All checklists documented "Y." c. "All quality control/calibrations were performed and accepted before patient test results were reported." All checklists left this blank. d. "Quality control results were examined for possible problems." All checklists documented "Y." 4. The laboratory did not download the PT results from the PT provider's portal to enable review and evaluation of the laboratory's PT performance. Cross-refer to tag D5211 for more details. 5. The patient log included one page with 12 patient results documented as performed with an expired test kit. Cross-refer to tag D5417 for more details. 6. Patient and QC logs showed that external QC was not consistently performed on new test kit lot numbers prior to testing patient specimens. Cross-refer to tag D5445 for more details. 7. No corrective actions were documented when QC results were recorded as having unacceptable results. Cross-refer to tag D5783 for more details. 8. The QA program and monthly QA checklists did not ensure that PT results were reviewed, that testing was not performed on expired test kits, that QC was performed on new test kit lot numbers prior to patient testing, and that corrective actions were taken for QC results documented as unacceptable. 9. During the exit interview on 06/05/2024 at 1:45 PM, the lead TP and OM confirmed that the monthly QA checklists should document the results from the QA activities that were performed.
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 personnel report and personnel records and interview with the lead testing person (TP) and office manager (OM), the competency evaluations for eight of eight TP performed in 2023 and 2024 were not performed by the technical consultant (TC). Findings: 1. The laboratory personnel report (CMS-209) listed eight TP and documented that the TC was the laboratory director. 2. Records showed that in 2023 and 2024, the competency evaluations for TP #2-TP #8 were performed by TP #1 who was not qualified as a TC. The competency evaluation for TP #1 did not include the initials of the reviewer. 3. During the exit interview on 06 /05/2024 at 1:30 PM, the lead TP and OM confirmed that the competency evaluations from 2023 and 2024 were not performed by the LD in their role as TC or by an individual qualified as a TC.