Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0715273	01/10/2023
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the testing supervisor, the laboratory did not ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory currently has 8 TP listed on the "Laboratory Personnel Report" (CMS-209) who perform microbiology testing. 2. A review of microbiology PT attestation worksheets from 2021 and 2022 showed that PT was performed by the same TP in 3 of 6 events. 3. During an interview on 01/10/2023 at 12:00 PM, the testing supervisor confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the testing supervisor, the laboratory did not ensure that State requirements were followed when performing QC on the BD Affirm VPIII Microbial Identification System. Findings: 1. The laboratory performs microbiology testing using the BD Affirm VPIII Microbial

	Identification System. 2. A review of QC records from January through December 2022 showed that QC for this analyzer was not run weekly from 01/28/2022 to 02/08 /2022; 03/16/2022 to 03/29/2022; 04/07/2022 to 04/25/2022; 05/03/2022 to 05/19 /2022; 05/24/2022 to 06/10/2022; 06/10/2022 to 06/23/2022; 07/01/2022 to 07/15 /2022; 07/15/2022 to 07/29/2022; 08/18/2022 to 08/31/2022; and 09/16/2022 to 09/29 /2022. 3. Code of Maryland Regulations- COMAR 10.10.06 Medical Laboratories- Quality Assurance, .06 Quality Control - Single-Use Test Devices, B. Standards, (6) Quality Control Tests, (b) Qualitative Test System states, "A licensee shall ensure that quality control testing for a qualitative test system is performed and documented using known positive and negative control materials before patient testing" "At least weekly for each lot of a single-use test device used for patient testing." 4. During an interview on 01/10/2023 at 12:00 PM, the testing supervisor confirmed that the laboratory was not in compliance with the State requirements to run QC at least weekly when performing patient testing.
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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 02/22/2021 for not documenting the expiration dates of control materials used for performing microbiology testing to ensure that control materials are not used when they exceed their expiration date. The plan of correction stated that this would be corrected. I. Based on procedure manual and record review and interview with the testing supervisor, the laboratory failed to ensure that the lot numbers and expiration dates of reagents used for microbiology testing were documented. Findings: 1. The laboratory director performs direct wet mount preparations using 10% potassium hydroxide (KOH) and normal saline. 2. The procedure, "Wet Mount/Prep Supplies" states, "Each exam room contains a tray with slides, cover slips, and a bottle of KOH and normal saline. Once a year, the bottles need to be refilled with fresh solution. The KOH has an expiration date." 3. Record review showed that the laboratory had no written documentation of lot numbers and expiration dates of the KOH and normal saline used for performing direct wet mounts. 4. During an interview on 01/10/2023 at 10:35 AM, the testing supervisor stated that the expiration dates for the KOH and normal saline are typically longer than one year so they had not written it down. They confirmed that documentation of lot numbers and expiration dates of reagents used for microbiology testing was incomplete. II. Based on record review, surveyor observation, and interview with the testing supervisor, the laboratory failed to ensure that the new expiration dates of opened reagents used for microbiology testing were documented. Findings: 1. The laboratory performs microbiology testing on a BD Affirm VPIII Microbial Identification System. 2. The manufacturer's package insert, under the subtitle "Storage of Reagents" states, "The Affirm VPIII test kit is stable until the expiration date indicated on the kit box when stored at 2 to 8C. Alternatively, store at room temperature (up to 30C) no more than 3 months." 3. It was observed at 9: 50 AM that the opened and in-use kit did not have the new expiration date written on it. During an interview at that time, the testing supervisor stated that the laboratory does not write the new, opened expiration date on the test kits. 4. Review of the "AFFIRM VPIII Microbial Identification Test External Quality Control Log Sheet"

	showed that the laboratory documents the lot number and expiration date (if stored at 2 to 8C) of the test kits, but does not record the updated expiration date of opened kits stored at room temperature. 5. During an interview on 01/10/2023 at 9:50 AM, the testing supervisor confirmed that documentation of lot numbers and expiration dates of reagents used for microbiology testing was incomplete.
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 record review and interview with the testing supervisor (TP#1), the laboratory director (LD) acting as the technical consultant failed to perform and document the competency reviews on all testing personnel (TP). Findings: 1. The laboratory currently has 8 TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). 2. During an interview at 11:30 AM, TP#1 stated that they perform the competency assessments on the other 7 TP. The LD and TP#1 are the only laboratory staff qualified to perform competency assessments. 3. A review of competency assessment records from 2020 to 2022 showed that there were no competency assessments documented on TP#1. 4. During an interview on 01/10/2023 at 12:00 PM, TP#1 confirmed that there were no evaluations performed on them by the LD.