Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0715273	07/31/2026
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 proficiency testing (PT) and patient log record review and interview with testing person #1 (TP #1), the laboratory failed to ensure that the individual testing or examining the samples signed the PT attestation statements for three out of five PT events, attesting that PT specimens were run in the same manner as patient samples. Findings: 1. The laboratory performed microbiology testing using the BD Affirm VPIII Microbial Identification Test using the BD MicroProbe Processor and was subscribed to a PT provider which provided five unknown samples, three times a year. 2. A review of microbiology PT records from 2025 and 2026 showed that for two out of five PT events, it appeared that five of five TP's names entered on the attestation statements under the column "Person(s) Performing the Test" were written in the same handwriting. 3. A review of patient logs from the days of PT testing (02/11/2025 for "2025 Microbiology - 1st Event" and 06/05/2025 for "2025 Microbiology - 2nd Event") showed that five different TP tested the five PT samples during each event. 4. During an interview on 07/31/2026 at 11:00 AM, TP #1 confirmed that they had written the TP's names on the two attestation statements, not the TP who performed the testing. 5. One out of five attestation statements reviewed ("2026 Microbiology - 2nd Event") showed that four different TP signed the attestation to show that they tested PT samples "VP-07" through "VP-10." There was no signature to show which TP performed the testing on sample "VP-06." 6. During an interview on 07/31/2026 at 12:35 PM, TP #1 confirmed that not all TP who performed the PT had personally attested to the routine integration of the PT samples into the patient workload using the laboratory's routine methods.

D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with testing person #1 (TP #1), the laboratory failed to ensure that a copy of all PT documents were maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records from 2024 to 2026 showed that at the time of the survey there were no PT records available for review for the third event in 2024 for Microbiology. 2. During an interview on 07/31/2026 at 12:35 PM, TP #1 confirmed that the laboratory was not able to locate all of the records from PT performed in the last two years.
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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 06/10/2024 for failing to document the review and evaluation of proficiency testing results. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with testing person #1 (TP #1), the laboratory failed to ensure that microbiology PT results were evaluated in four out of five PT events in 2025 and 2026, and the review documented by the laboratory director (LD). Findings: 1. The laboratory performed microbiology testing using the BD Affirm VPIII Microbial Identification Test using the BD MicroProbe Processor. 2. A review of microbiology PT records from five events in 2025 and 2026 showed that in four of five events (the first, second, and third events in 2025 and the second event in 2026), the LD failed to sign the PT results report, documenting that the results had been reviewed and were acceptable. 3. During an interview on 07/31/2026 at 12:35 PM, TP #1 confirmed that there was no documentation that PT results had been evaluated and reviewed by the LD.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 06/10/2024 for the laboratory director failing to ensure that proficiency testing results were reviewed to evaluate the laboratory's performance and to identify any problems that may have required corrective action. The plan of correction stated

	that this would be corrected. Based on proficiency testing record review and interview with testing person #1, the laboratory director failed to ensure that proficiency testing results were reviewed to evaluate the laboratory's performance and to identify any problems that may have required corrective action. Cross-refer to D5211 for details.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on proficiency testing (PT) and quality assurance (QA) record review and interview with testing person #1 (TP #1), the laboratory director (LD) failed to ensure that the QA program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. The laboratory completed a "Monthly Quality Assurance Checklist" (QA form) which listed the checklist items to be performed as well as a column to document "Yes/No/Not Applicable" for each item on the checklist. The forms were signed by the LD. QA forms from July 2024 through June 2026 were reviewed. 2. The monthly QA form stated, "Our proficiency testing policies have been followed. Proficiency testing was handled in the same manner as patient specimens." The laboratory failed to ensure that each TP performing the PT signed the attestation statements, attesting that PT specimens were run in the same manner as patient samples. Cross-refer to D2009 for details. 3. The monthly QA form also stated, "Proficiency testing results were evaluated, failures were investigated and remedial action was taken." 4. A review of the "2026 API Proficiency Testing Schedule" available on the PT provider's website showed that for the discipline of Microbiology, the PT results or "evaluations" were available for printing and review online for the first PT event in March; the second PT event in July; and the third PT event in October. 5. QA record review showed that the QA forms from March, July, and October 2025 listed the task of "Proficiency testing results were evaluated" as "N/A" (not applicable). 6. A review of microbiology PT records from five events in 2025 and 2026 showed that in four of five events, the LD failed to sign the PT results report, documenting that the results had been reviewed and were acceptable. Cross-refer to D5211 for details. 7. The laboratory failed to ensure that a copy of all PT documents were maintained by the laboratory for a minimum of two years from the date of the PT testing event. Cross-refer to D3037 for details. 8. During an interview on 07/31/2026 at 12:35 PM, TP #1 confirmed that the LD failed to ensure that the QA program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.