Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0715273	02/22/2021
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on procedure manual and quality assurance (QA) record review and interview with the clinical coordinator, the laboratory did not follow written procedures for performing chart reviews to ensure that patient results from testing on the Affirm VPIII were documented and entered accurately. Findings: 1. The procedure "Quality Assurance - Affirm Testing" states, "The Clinical Coordinator (Testing Supervisor) will insure that the Affirm Test result log is reviewed for accuracy and proper charting each month." "In general, 5-7 log entries will be reviewed for entry completion, results documented in the EHR, order (by provider) documented in EHR, and the scanned copy of results is present." It also states, "Reviewed entries will be listed on a form and the clinical coordinator will insure any necessary action (procedure reminders, entering missing results, error investigation, etc.) is taken and documented as such." 2. A review of QA logs from August, 2018 to June, 2019 showed that in August, 2018 1 of 26 patients checked as part of the QA review did not have a response for "Provider Order present?" documented. 3. In January, 2019 1 of 25 patients checked had "no" marked in the box labeled "All info entered?" but no corrective action was documented. 4. In February, 2019 1 of 18 patients checked had "no" marked for "Results in OM?" and 1 of 18 was marked "no" for "Provider Order present?" but no corrective action was documented. 5. In March, 2019 1 of 20 patients checked had "no" marked for "Provider Order present?" but no corrective action was documented. 6. In April, 2019 1 of 19 patients checked had "no" marked for "Provider Order Present?" and 2 of 19 were marked "no" for "All info entered?" and "Results in

	OM?" but no corrective action was documented. 7. In June, 2019 1 of 18 patients checked had "no" marked for "Results in OM?" but no corrective action was documented. 8. During an interview on 2/22/2021 at 2:45 PM, the clinical coordinator confirmed that the laboratory did not follow the written procedure for performing QA reviews to assure the quality of laboratory services provided and to identify failures in quality as they occur.
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 quality control (QC) record review and interview with the clinical coordinator, the laboratory failed to ensure that the expiration dates of control materials for performing QC on the BD Affirm VPIII Microbial Identification System were documented to ensure that control materials were not used when they exceeded their expiration date. Findings: 1. The laboratory uses a "Tri-valent" positive control swab to perform QC on the BD Affirm VPIII Microbial Identification System. The laboratory documents the QC on an "Affirm VPIII Microbial Identification Test External Quality Control Log Sheet." 2. A review of Affirm QC log sheets from January, 2019 through December, 2020 showed that the laboratory failed to document the expiration date of the quality control material used, 64 out of 70 times recorded. 3. During an interview on 2/22/2021 at 2:45 PM, the clinical coordinator confirmed that the laboratory did not ensure that QC materials were not used past their expiration date.
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 temperature log record review and interview with the clinical coordinator, the laboratory failed to document corrective action when room and refrigerator temperatures were out of range. Findings: 1. The laboratory documents room and laboratory refrigerator temperatures daily. The acceptable range for room temperature is 71-82 degrees Fahrenheit, and the acceptable range for the laboratory refrigerator temperature is 35-46 degrees Fahrenheit. 2. A review of room temperature logs from Sept. - Dec. 2018 showed that 2 of 80 times recorded the temperature was outside of acceptable ranges, however there was no corrective action documented. 3. A review

	of room temperature logs from 2019 showed that 5 of 253 times recorded the temperature was out of range. The laboratory documented "thermostat adjusted" but no second temperature was recorded to show that the temperature came back into acceptable range. 4. In January, 2020 3 of 22 times recorded the room temperature was out of range. The laboratory documented "building service request placed and maintenance performed" but no second temperature was recorded to show that the temperature came back into acceptable range. 5. A review of laboratory refrigerator temperature logs from April - June 2020 showed that 21 of 59 times recorded the temperature was out of range. The laboratory documented "thermostat adjusted" and that from May 19-22 and June 9-25, 2020 the refrigerator was "defrosted, thermostat adjusted" and that "maintenance repair" was performed in June, 2020 but no second temperature was recorded to show that the temperature came back into acceptable range. 6. During an interview on 2/22/2021 at 2:45 PM, the clinical coordinator confirmed that the laboratory did not ensure that all corrective actions were documented when room and refrigerator temperatures were out of range.