Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1015809	07/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ashcake Family Physicians, Inc	7493 Right Flank Road - Suite 400, Mechanicsville, VA	

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
D0000	An announced CLIA recertification survey was conducted at Ashcake Family Physicians on July 23, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Ashcake Family Physicians was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on a review of the maintenance checklists, manufacturer's Instructions for Use, lack of documentation, and interviews, the laboratory failed to perform yearly maintenance on the Beckman Coulter DxH 500 Hematology analyzer for twenty (20) of 20 months reviewed. Review timeframe November 2023 through June 2025. Findings include: 1. Review of the laboratory's Hematology maintenance checklists revealed required yearly maintenance of: lubricate pistons, and replace the rinsing head O-ring (or every 18000 cycles). 2. Review of the November 2023 through June 2025 maintenance checklists for the Beckman Coulter DxH 500 Hematology analyzer revealed a lack of yearly maintenance documented during the 20 months reviewed. 3. A review of the manufacturer's Beckman Coulter DxH 500 Instructions for Use revealed that piston lubrication should be done yearly, and replacing the Rinsing Head O-ring should be done yearly or every 18,000 cycles. 4. During an interview with the primary testing personnel (TP) at 11:45 AM, the inspector inquired about the lack of yearly maintenance and requested to review documentation of the annual maintenance if performed by the Beckman Coulter service engineer. The TP stated that the

	laboratory did not have an engineer come in to perform yearly preventative maintenance (PM). 5. An interview with the primary TP on 7/23/25 at 1:00 PM confirmed the above findings. B. Based on a review of the laboratory policies, maintenance checklists, daily start-up documentation, Beckman Coulter DxH 500 Training guide, and interview, the laboratory failed to perform daily shutdown of the Hematology analyzer for fourteen (14) days of the 20 months reviewed. Review timeframe November 2023 through June 2025. Findings include: 1. Review of the lab's CBC (Complete Blood Count) manual revealed a policy that stated, "When all specimens have been performed for the day, a daily shutdown will need to be initiated". 2. Review of the November 2023 through June 2025 maintenance checklists for the Beckman Coulter DxH 500 Hematology analyzer revealed a lack of daily shutdown documented on: 2024: 3/8, 3/18, 3/19, 6/3, 6/4, 6/28, 7/19, 8/29, 10 /14, 12/31, and 2025: 4/1, 6/2, 6/3, 6/10. A total of 14 days. 3. Review of the daily Beckman Coulter DxH 500 start up documentation revealed the instrument start up printout contains a "Date of last Shutdown". Review of the start-up documentation for the 14 days after the missed shutdowns listed above confirmed that shutdown did not occur. 4. Review of the Beckman Coulter DxH 500 Training guide revealed that the manufacturer "recommends shut down once every 24 hours". The guide explained that the shut down removes the diluent and introduces the cleaner into the system. 5. An interview with the primary Testing Personnel on 7/23/25 at 1:00 PM confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on a review of laboratory's hematology quality control (QC) records, procedures, lack of documentation, and interviews, the laboratory failed to perform an evaluation of statistical analysis to identify possible shifts and trends for Complete Blood Count (CBC) testing on the Beckman Coulter DxH 500 hematology analyzer for two (2) of 20 months reviewed. Review timeframe October 2023 through June 2025. Findings include: 1. Review of the Hematology QC Log Books for October 2023 through June 2025 revealed QC printouts for each lot and level of QC (abnormal Low, Normal, abnormal High). The printouts included a statistical Mean, SD (Standard deviation) and CV (Coefficient of Variation) for each QC level. The QC printouts for October 2023 through June 2025 lacked a director signature or initials indicating review. 2. Review of the laboratory's Quality Assessment (QA) Plan and Documentation Log Book revealed: a QA Attestation that included "the correction of any problems detected", a QC category that included "QC results were examined for possible problems", and a comment box for "Problem Resolution". 3. Review of the laboratory's Quality Assurance Implementation policy revealed that "At the end of each month, a Monthly Quality Assurance Checklist is completed." The policy indicates that the monthly review includes laboratory staff and the laboratory director, and that Quality control results are reviewed for trends and shifts. The QA checklists for October 2023 through June 2025 were reviewed.. The two (2) months of April 2024 and July 2024 lacked a director signature indicating QC evaluation and QA participation. 4. An interview with the primary testing personnel on 7/23/25 at 1:00 PM confirmed the findings above.