Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D1015809	**(X3) Date Survey Completed** 05/03/2022
Name of Provider or Supplier Ashcake Family Physicians, Inc	**Street Address, City, State** 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 unannounced CLIA off-site proficiency testing desk review of Ashcake Family Physicians was conducted on 04/29-05/03/22 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition- Successful Participation. D2017- 42 C.F.R 493.807 (a)(b) Condition- Reinstatement of Nonwaived Laboratories. The laboratory must achieve satisfactory performance of at least 80% for two consecutive events for the White Blood Cell Differential (WBC DIFF) analyte. Citations issued and notice sent to Northeastern and Midwestern Operations Branch Philadelphia Office on 05/03/22.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor

	compliance history. This CONDITION is not met as evidenced by: A. Based on off-site proficiency testing (PT) desk review and interview with the testing personnel and laboratory director on 04/29/2022, the laboratory failed to achieve satisfactory performance of at least 80% for three consecutive events for the White Blood Cell Differential (WBC Diff) analyte for the second and third events in 2021 and the first event in 2022, resulting in a repeat unsuccessful performance. Refer to D2130. B. Based on off-site proficiency testing (PT) desk review and interview with the testing personnel and laboratory director on 04/29/2022, the laboratory failed to participate in one of one Complete Blood Count (CBC) events reviewed. Refer to D2123.
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on the off-site review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, the CASPER 155D Individual Laboratory Profile report, and interview with the testing personnel and laboratory director, the laboratory has not participated in reinstatement testing for the White Blood Cell Differential (WBC Diff) analyte. Findings include: 1. As of the date of the desk review, the laboratory had not submitted evidence of satisfactory performance on two consecutive PT events for the analyte of WBC Diff. 2. As of the date of the desk review, the laboratory had not submitted evidence that is has voluntarily withdrawn its certification for the analyte of WBC Diff. 3. A phone interview with the testing personnel and laboratory director on 04/29/22 at 11:50 AM revealed the "lab ceased patient testing with the older hematology analzyer on 10/19/21. The new hematology analzyer was installed and verification completed on 01/13/22 and patient testing began on 01/14/22. We encountered issues with the PT samples from AAB for the first event in 2022 and did not submit the results within the required timeframe."
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories

	failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and an interview, the laboratory failed to participate in one of one Complete Blood Count (CBC) PT event reviewed. Findings include: 1. Review of the CASPER 0155D Individual Laboratory Profile Report and the American Association of Bioanalysts (AAB) PT records for the first event in 2022 revealed the laboratory received a score of 0%. 2022 Event A- 0%- for the CBC module (Notation by API-"NR" not reported). 2. A phone interview with the testing personnel and laboratory director on 04/29/22 at 11:50 AM revealed the "lab ceased patient testing with the older hematology analzyer on 10/19/21. The new hematology analzyer was installed and verification completed on 01/13/22 and patient testing began on 01/14/22. We encountered issues with the PT samples from AAB for the first event in 2022 and did not submit the results within the required timeframe."
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the off-site review of the proficiency testing (PT) scores for the second and third events in 2021 and the first event in 2022, the CASPER 0155D Individual Laboratory Profile report, and an interview with the laboratory director, the laboratory failed to achieve satisfactory performance of at least 80% for three consecutive events for the White Blood Cell Differential (WBC Diff) analyte. Findings include: 1. Review of the American Association of Bioanalysts (AAB) hematology PT records and the CASPER 0155D Individual Laboratory PT report revealed the following scores: 2021 2nd event WBC Diff- 26% 2021 3rd event WBC Diff- 67 2022 1st event WBC Diff- 0% The laboratory received a repeat unsuccessful AAB PT score for the above listed analyte. 2. A phone conference with the testing personnel and laboratory director on 04/29/22 at 11:50 AM confirmed the findings.