Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468584	(X3) Date Survey Completed 04/01/2021
Name of Provider or Supplier Fayetteville Diagnostic Clinic	**Street Address, City, State** 3344 North Futrall Drive, Fayetteville, AR	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Through a review of the Maintenance Logs for the ACL Elite coagulation analyzer, lack of documentation, and interviews with lab staff, it was determined the laboratory failed to perform monthly maintenance on the ACL Elite in June 2020. Survey findings follow: A. The laboratory uses the ACL Elite for moderate complexity coagulation tests (Protime and PTT). The manufacturer's maintenance logs include the following required monthly maintenance: Clean the air filter; back up/archive data; and hard drive maint disk. B. A review of ACL Elite Maintenance Logs for January 2020 through March 2021 revealed the monthly maintenance was not documented in one of fifteen months reviewed. There was no documentation of monthly maintenance in June 2020. C. In an interview, at 9:35 on 4/1/2021, laboratory employee #3 (as listed on the form CMS-209) confirmed the monthly maintenance for June 2020 was not documented.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Through a review of laboratory policies and procedures, a review of the quality control reports for the MedTox Profile-V drug screens, and interviews with laboratory staff, it was determined the laboratory failed to perform quality control each day for the moderate complexity MedTox Profile-V drug screens. Survey findings include: A. Laboratory policies and procedures were reviewed and it was determined the quality control policy for the MedTox Profile-V drug screens stated that positive and negative quality controls are run weekly and if starting a new lot of test kits. B. Documentation of MedTox Profile-V drug screen quality control was reviewed for July 2020, November 2020, and February 2021. In July 2020, quality control was tested 7/6,7/13, 7/20, 7/27, and 7/31. In November 2020, quality control was documented on 11/2, 11 /9, 11/16, 11/23, and 11/30. In February 2021 drug screen quality control was documented 2/1, 2/8, 2/16, and 2/22. C. In an interview, at 12:48 on 4/1/2021, laboratory employee #3 stated that the laboratory started using the MedTox Profile-V (MedTox Scan) in February 2020 and that the quality control is performed weekly. She further stated that the laboratory had not developed and IQCP for this test.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through a review of the Laboratory Policies and Procedures, a review of blood gas quality control documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform blood gas quality control each day of testing using a combination of control materials that include both low and high values and cover normal, alkalosis, and acidosis. Survey findings include: A. The policy for quality control of blood gas testing on the iSTAT states, "Run 2 levels of QC rotating between 3 levels (1 and 2, 2 and 3, 3 and 1) each day of testing and after calibration. B. Through a review of blood gas quality control results for July 2020, it was determined that each day of patient testing, the following quality control was documented: On 7/1 levels #1 and #3, on 7/2 levels #1 and #2, on 7/6 levels #2 and #3, on 7/7 levels #1 and #3, on 7/8 levels #1 and #2, on 7/17 levels #2 and #3, on 7/20 levels #1 and #3, on 7/27 levels #1 and #2, and on 7/31 levels #2 and #3. C. Through a review of blood gas quality control results for November 2020, it was determined that each day of patient testing, the following quality control was documented: on 11/2 Level #1 only, on 11/4 levels #2 and #3, on 11/5 levels #2 and #3, on 11/9 levels #2 and #3, on 11/11 levels #1 and #2, 11/13 levels #2 and #3, 11/16 levels #1 and #3, 11 /17 levels #1 and #2, 11/18 levels #2 and #3, 11/20 level #2 only, 11/23 levels #2 and #3, 11/25 levels #1 and #3, 11/30 levels #1 and #2. D. Through a review of blood gas quality control results for February 2021, it was determined that each day of patient testing, the following quality control was documented: on 2/3 levels #2 and #3, on 2 /16 levels #1 and #3, and on 2/25 levels #1 and #2. E. Both low and high were documented on 3 of 9 days of testing in July 2020, 3 of 13 days in November 2020, and 1 of 3 days of testing in February 2021. All three levels of control were documented 0 of 25 days in the three months reviewed. F. In an interview, at 3:39 on 4 /1/2021, laboratory personnel #3 (as listed on the form CMS-209) confirmed the

	laboratory failed to test three levels of quality control covering normal, alkalosis, and acidosis each day of testing.