Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	21D2037639	04/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sam's Medical Laboratory Llc	19614 Club House Road, Montgomery Village, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on review of written procedures, the lab did not include reportable ranges and patient normal ranges for analytes tested and reported using the hematology. Findings: 1. The written procedure did not include the reportable ranges and patient normal ranges for tests (complete blood count) performed on the hematology analyzer. B. Based on review of written procedures, the lab did not have written procedures and references for testing patient specimens that were collected more than 7 hours prior to the testing. Findings: 1. The manufacturer instructions require the lab to "Analyze blood samples within 7 hours of collection."; 2. The laboratory written

	procedures did not include references showing that testing on the analyzer could be delayed greater than 7 hours without risking reliability and accuracy of patient test results; and 3. Hematology testing was performed on a patient sample that was greater than twenty-four hours old, the specimen was collected and received in the lab on April 10, 2019 at 2:06 PM, and the test was performed on April 11, 2019 at 2:28 PM. During interview on the day of survey, the lab director stated that this was acceptable practice, but had not provided references or studies showing that a day old specimen would produce accurate and reliable results.
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 observation and interview with the laboratory (lab) director, the lab did not document manufacturer name, lot number and expiration dates of hematology reagents used for the analyzer (CBC testing) to ensure reagents are not used past expiration. Findings: 1. It was observed that the lab did not have a record of hematology test reagents used to perform CBC testing using the analyzer; and 2. During interview with the lab director at approximately 1:00 pm on the day of survey, the director stated that the manufacturer name, lot and expiration date of reagents used for CBC testing were not documented and the analyzer processor did not retain this information, as the information was overwritten with each new change of reagent lot.
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: A. Based on review of written procedures and interview with the laboratory (lab) director, the lab did have documentation of six month and annual preventive maintenance for the hematology analyzer (CBC testing). Findings: 1. The laboratory written procedure states that the semi-annual maintenance is performed by the manufacturer, and the annual maintenance is replacement of "new syringers" by the manufacturer; 2. The lab did not have records showing that the required preventive maintenance was performed; and 3. During interview with the lab director at approximately 1:00 pm on the day of survey, the director was unable to provide documentation showing the semi-annual and annual required maintenance was performed. B. Based on review of maintenance records for the hematology analyzer, the lab did have documentation showing that daily routine preventive maintenance was performed on days that quality control testing was conducted. Findings: 1. Quality control testing was performed on February 28, 27, 25, 23, 22, 19, 18, 17, 9, 7 and 3, 2017, and also on February 31, 23, 19, 14, 13, 12, 10, 4 and 3, 2017, but the daily preventive maintenance for these days on both months was not completed as evidenced by observation of the daily maintenance log for the hematology analyzer.

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: 5781 Based on record review and interview with the laboratory (lab) director, the lab did not document corrective actions performed for the hematology analyzer (CBC test) when the lab director stated that the analyzer was not in operation. Findings: 1. The lab director stated that the hematology analyzer was not operable March 1, 2, 5, 14 and 15, 2019, during interview at approximately 12:00 pm on the day of survey. Lab records show that patient specimens were collected on these days, but the specimens were not tested and the quality control testing was not performed. There was no documentation in the corrective action log concerning a problem with the hematology analyzer; 2. The preventive maintenance and quality control records show that the hematology analyzer was not in operation for the months of January and February 2019; 3. There was no documentation reporting the problems, corrective actions taken to troubleshoot the analyzer, actions taken to ensure lab testing was not delayed and documentation for notification of clients if delays were applicable; and 4. On October 18, 2018 and May 18, 2018, the daily maintenance was performed on the hematology analyzer, but the lab did not have the daily quality controls for each of these days and the lab did not document in the corrective action log that there was a problem with the analyzer on each of these days.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: I. Based on record review and interview with the laboratory (lab) director, the lab did not retain the manufacturer's insert for the hematology quality control reagents (low, normal and high quality control reagents). Findings: 1. The manufacturer of the hematology quality control reagents provides the laboratory with the assay values and expected ranges for each analyte measure in each of the three levels of control reagent (stated in the manufacturer's insert); 2. On the day of survey, the lab did not locate the manufacturer's inserts, but was able to obtain and FAX to the surveyor March and April 2019 (lot number KK088) and November and December 2018 (lot number KK086). Records for the other six lot numbers (two years of data) were not observed;

	3. During interview with the lab director on the day of survey, the lab director stated that he did not keep the manufacturer inserts;
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on interview with the laboratory (lab) director, the lab did not have policies and procedures notifying the authorized users of corrected lab results on patient test reports. Findings: 1. During interview with the lab director at approximately 12:00 pm on the day of survey, he stated that there was no written procedure to identify and report corrected test results to users on a corrected report.