Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2037639	02/24/2023
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the chemistry and hematology proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to ensure that all PT records were being saved and the records were maintained for two years as required. Findings: 1. The PT records from 2021 through 2022 (6 events) were reviewed. 2. The hematology PT records from the second event of 2021 showed that the attestation worksheet and the instrument printouts were not available at the time of the survey. 3. The chemistry PT records from the third event of 2021 showed that the attestation worksheet, the instrument printouts, and final results were not available at the time of the survey. 4. During the survey on 02/24/23 at 12:45 PM, the LD confirmed that the PT records were not available for review and not maintained for the required two years.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

	Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the instructions for use (IFU) for the vitamin D (Vit-D) quality control (QC) materials, thyroid stimulating hormone (TSH) QC worksheets, and interview with the laboratory director (LD), the laboratory failed to follow the manufacturer's instructions and establish the reference range for QC Levels 1 and 2 used on the Tosoh (endocrinology analyzer). Findings: 1. The section labeled "Expected Values" in the IFU for AUDIT MicroControls for Vit-D states: "Variation between labs will be greater than the precision for any one instrument. Accuracy and precision depend on differences in equipment, reagents, supplies and techniques. Therefore, a lab must establish its own acceptable target values and ranges." 2. The LD could not find the IFU for the TSH BioRad QC materials but stated that the manufacturer required the user to establish their own mean and standard deviations for the materials used in the laboratory. 3. During 06/2021, the reference range for Vit-D Level 1 was 6-10.47; on 10/03/22 the range was 6.2-9.4; on 10/10/22 the range was 6.2-9.9; and on 10/28/22 the range was 6.2-10.0. 4. During 06/2021, the reference range for Vit-D Level 2 was 24.2-36.4 and then in 10/2023 the range was 21.2-31.8. 5. The LD stated that the reference ranges for Vit-D Level 1 and 2 had been established with each new lot of QC materials, but the records were not available at the time of the survey. The LD did not have an explanation for the changes in the reference ranges for level 1 from 06/2021 to 10/28/22. 6. From 06/2021 through 02 /2023 the reference range for TSH Level 1 was 1.00-2.54 and TSH Level 2 was 14-24. 7. During the survey on 02/24/23 at 12:45 PM, the LD confirmed that there was no documentation showing how and when the laboratory established the reference range values for each lot of Vit-D and TSH QC materials used per the manufacturer's instructions.
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 review of the calibration records for vitamin D (Vit-D) and thyroid stimulating hormone (TSH) and interview with the laboratory director (LD), the laboratory failed to ensure that the calibration materials used were not used after their expiration date. Findings: 1. Vit-D and TSH are performed on the Tosoh (endocrinology analyzer). The calibration records from June 2021 through February 2023 were reviewed. 2. The worksheets and instrument printouts did not include the lot numbers and expiration dates of the calibration materials. The LD confirmed that the product inserts for the calibrators were also not available to verify that the lot numbers and expiration dates were acceptable at the time of use. 3. During the survey on 02/24/23 at 12:45 PM, the LD confirmed that the calibration records that were available for Vit-D and TSH did not include the expiration dates of the reagents and calibrators used in the laboratory since June 2021.

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: Based on review of maintenance and testing records and interview with the laboratory director (LD), the laboratory failed to consistently record daily maintenance activities for the Abacus 5 hematology analyzer on days when patient specimens were tested. Findings: 1. The laboratory used an Abacus 5 hematology analyzer to test patient specimens which required daily maintenance activities to be performed. 2. The daily maintenance activities were recorded on a monthly maintenance log. 3. Monthly maintenance logs and testing records from January through June 2022 were reviewed. 4. Records showed that daily maintenance activities were not recorded on the maintenance log for one of six days patients were tested in January, two of 10 days patients were tested in March, three of 11 days patients were tested in April, and one of three days patients were tested in June. 5. During the survey on 02/24/2023 at 1:15 PM, the LD confirmed that daily maintenance activities were not consistently documented on days when patient specimens were tested.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the calibration requirements found in the Tosoh (endocrinology analyzer) procedure manual for the vitamin D (Vit-D) and thyroid stimulating hormone (TSH) quality control (QC) materials and calibration records, laboratory records and interview with the laboratory director (LD), the laboratory failed to follow the manufacturer's instructions and document calibration of each analyte every 90

	days. Findings: 1. The "Calibration Procedure" in the Tosoh procedure manual states: "The calibration curve for the ST AIA-PACK 25-OH Vitamin D is stable for up to 90 days." 2. The LD stated that the calibration requirements for Vit-D and TSH were identical. 3. The calibration records for 2021 and 2022 showed that Vit-D was calibrated on 05/05/21, 09/15/21, 06/06/22, and 08/18/22. The TSH was calibrated on 05/10/21, 09/13/21, 10/01/21, 05/18/22, and 09/10/22. 3. During the survey on 02/24 /23 at 12:45 PM, the LD confirmed that there was no documentation showing that the calibration had been performed every 90 days per the manufacturer's procedures for Vit-D and TSH.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of test reports and interview with the laboratory director (LD), the laboratory's final test report failed to include the name and address of the laboratory location where hematology specimens were taken to confirm results. Findings: 1. Test reports for patient accession numbers 5518 and 5519 included a note stating "CBC-PERFORMED AT WALTER REEDS MEDICAL CENTER, BETHEDA, MD." 2. The LD stated that these specimens were brought to and tested on the Walter Reed facility's hematology analyzer to confirm results. The results reported on the test report were from the Walter Reed facility. 3. The test report did not include the name and address of the laboratory where the patient specimens were tested.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) procedure and interview with the laboratory director (LD), the LD did not ensure that the QA procedure was appropriate for the testing performed and followed as written. Findings: 1. The most current QA procedure was implemented on January 1, 2021. 2. The procedure included instructions and forms to document multiple monthly, quarterly, and annual QA activities and included an annual calendar of when each activity was to be completed. 3. The laboratory did not have any records of the QA activity forms listed

	in the QA procedure for 2021 or 2022. 4. The LD stated that because the testing volume was low and the LD was performing all the testing and QA reviews, the QA procedure as written contained more activities than what was required for the current testing load. 5. During the survey on 02/24/2023 at 1:15 PM, the LD confirmed that QA activities were not performed as stated in the QA procedure.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the instructions for use (IFU) for the vitamin D (Vit-D) quality control (QC) materials, thyroid stimulating hormone (TSH) QC worksheets and interview with the laboratory director (LD), the LD acting as the technical consultant (TC) failed to establish the QC program with acceptable QC parameters for Vit-D and TSH and follow the manufacturer's instructions for establishing the reference range for Vit-D QC Level 1 and 2 used on the Tosoh (endocrinology analyzer). Findings: 1. The section labeled "Expected Values" in the IFU for AUDIT MicroControls for Vit-D states: "Variation between labs will be greater than the precision for any one instrument. Accuracy and precision depend on differences in equipment, reagents, supplies and techniques. Therefore, a lab must establish its own acceptable target values and ranges." 2. The LD could not find the IFU for the TSH BioRad QC materials but stated that the manufacturer required the user to establish their own mean and standard deviations for the materials used in the laboratory. 3. During 06/2021, the reference range for Vit-D Level 1 was 6-10.47; on 10/03/2022 the range was 6.2-9.4 (QC value = 9.3); on 10/10/2022 the range was 6.2-9.9 (QC value = 9.6); and on 10/28/2022 the range was 6.2-10.0 (QC value = 9.6). 4. During 06/2021, the reference range for Vit-D Level 2 was 24.2-36.4 and then in 10/2023 the range was 21.2-31.8. 5. The LD stated that the reference ranges for Vit-D Level 1 and 2 had been established with each new lot of QC materials, but the records were not available at the time of the survey. The LD did not have an explanation for the changes in the reference ranges for Level 1 from 06/2021 to 10/28/22. 6. From 06/2021 through 02/2023 the reference range for TSH Level 1 was 1.00-2.54. 7. From 06/2021 through 02/2023 the reference range for TSH Level 2 was 14-24. 8. The LD stated that the reference ranges for TSH Level 1 and 2 had been established with each new lot of QC materials, but the records were not available at the time of the survey. 9. During the survey on 02/24/23 at 12:45 PM, the LD acting as the TC confirmed that there was no documentation showing how and when the laboratory established the reference range values for each lot of QC materials for Vit-D and TSH used and why the reference ranges for Vit-D were changed twice during the month of October 2022.