Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2037639	10/24/2024
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
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 record review and interview with the laboratory director (LD), the laboratory failed to document the lot number, expiration date, and dates in use for endocrinology reagents. Findings: 1. The laboratory performed thyroid-stimulating hormone (TSH) testing. 2. Lot numbers, expiration dates, and in use dates for the TSH reagents used for patient testing were not documented. 3. During the survey on 10/24 /2024 at 11:40 AM, the LD confirmed that the lot numbers, expiration dates, and in use dates for the TSH reagents were not documented.
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 record review and interview, the laboratory did not document preventive maintenance on the chemistry analyzer when patient testing was performed. Findings: 1. The laboratory performed thyroid-stimulating hormone (TSH) testing on November 22, 2023 on patient C's specimen. The laboratory did not document daily and monthly preventive maintenance for this test. The last day the laboratory documented

	preventive maintenance for the chemistry analyzer was April 25, 2023. This was one of one test events reviewed for TSH testing. 2. This finding was confirmed during interview with the laboratory director on October 24, 2024 at 12:00 pm.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of urinalysis patient test records and interview with the laboratory director (LD), the laboratory testing records for two of eight test records reviewed did not ensure reliable and accurate recording of patient test results. Findings: 1. The laboratory performs waived testing for urine chemistry using a multi test strip analyzer. The laboratory also performs non-waived urine microscopic analysis. 2. Patient A was tested on June 1, 2024. The urine sample was recorded as being red and cloudy. The 3+ result for leukocyte and the positive nitrite result, from the urine chemistry analyzer printout were crossed out. The nitrite result for Patient A was reported as negative and the leukocyte was reported as few. The laboratory did not document why the results were changed or if the red color caused interference with the readings. 3. Patient B urine for testing was collected August 5, 2024. The patient identification number on the final report and the analyzer printout was 8726, this did not agree with the patient identification number 6601 that was recorded on the intermediate test record. The analyzer printout for the sample from Patient B showed that the protein was 1+ and the pH was 6.0, but the protein was reported as trace and the pH was reported as 8.0 on the patient final report.