Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2002111	02/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lifestream Health Center	4000 Mitchellville Road #A306, Bowie, 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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of the CASPER Report 0096D CLIA Application and Survey Summary report and interview with the laboratory director, the laboratory did not authorize the American Proficiency Testing (API) agency to release the proficiency testing (PT) results to Center for Medicare & Medicaid Services (CMS) to determine successful participation. Findings: 1. The laboratory is required to authorize API to submit the PT results to CMS. The results are entered into the federal data base. These results are available to the state agency (SA) for periodic review. 2. Prior to the survey the CASPER Report 0096D CLIA Application and Survey Summary (individual laboratory profile for PT results) was pulled for review. The CASPER Report 0096D report lists the year, event number, each analyte tested in the laboratory and score for three consecutive years. The report that was pulled indicated that "No routine scores found for this provider" had been received. 3. During the survey at 12:00 PM on 02/20 /2018 the laboratory director confirmed that the PT results did not show up on the CASPER Report 0096D for review by the SA staff.
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: Based on review of the procedure manual and interview with the laboratory director, the laboratory did not have written policies and procedures for all required activities performed by the testing personnel. Findings: 1. Review of the procedure manual showed that there were no written procedures for batching urine specimens to be tested periodically each month and a limit as to how long the specimens can be saved prior to testing. 2. Review of the procedure manual showed that there were no written policies and procedures for maintaining post analytical paperwork and documenting the results into the computer system. 3. During the survey on 02/20/2018 at 12:00 PM the laboratory director confirmed that the there were no policies and procedures for batching specimens, maintaining post analytical paper and documenting patient results in the computer system.
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 laboratory worksheets and interview with the testing person, the laboratory did not ensure that reagents, quality control (QC) and calibration materials for the Pictus 400 (toxicology analyzer) were not used after their expiration date. Findings: 1. The laboratory worksheets for the Pictus 400 for 2017-2016 were reviewed. The worksheets showed the lot number and expiration dates of the materials currently in use in the laboratory. 2. The testing person stated that the current boxes that the materials are stored in are labeled with the opened date. 3. Once the reagents, QC and calibration materials are used up the documentation of the open date recorded on the box is discarded. The laboratory records did not show that the reagents, QC and calibration materials were not used past the recorded expiration date. 4. During the survey on 02/20/2018 at 12:00 PM the testing person confirmed that the laboratory records did not include the lot numbers and expiration dates of the reagents, QC and calibration materials that had been used during the last two years of testing.
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) records and interview with the laboratory director (LD), the LD did not ensure that the QA plan included instructions for the testing personnel to send the documentation of the monthly QA review to the LD each month for review and how to store the QA documentation. Findings: 1. During the survey the testing personnel stated that once the monthly QA checklist is completed the worksheet is sent to the LD via e-mail or fax. The LD documents the review of the QA checklist and sends the worksheet back to the lab for storage. 2. During the survey on 02/20/18 at 12:00 PM the LD confirmed that the QA policies and procedures did not include written instructions for submitting the QA documentation to the LD and storage after there review.