Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2099992	06/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care	1404 Pomerelle Ste A1, Burley, ID	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to retain the manufacturer's assay information sheets for quality control testing on the Sysmex pocH 100 hematology analyzer and the Nano Entek Frend analyzer since the last survey on September 6, 2016. Findings: 1. A review of quality control records for the Sysmex and Frend analyzer used to test patient complete blood counts (CBC), thyroid stimulating hormone (TSH), and prostate specific antigen (PSA), revealed the laboratory failed to retain the manufacturer's quality control assay sheets for determination of the acceptable range of results. 2. An interview on June 11, 2018 at 1:45 PM, with the laboratory lead, confirmed the laboratory failed to retain the assay sheets for both the test systems.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	Based on proficiency testing (PT) record review and an interview with the laboratory lead, the laboratory failed to evaluate the thyroid stimulating hormone (TSH) and prostate specific antigen (PSA) scores for the American Association of Bioanalysts (AAB) PT program for 2018 event 1 and 2. Findings: 1. An AAB record review revealed the laboratory failed to evaluate the scores for TSH samples (1, 3, 5) that were assigned an artificial score of 100%. The TSH results were outside the range resulting in an unsatisfactory score for TSH during 2018 event 2. 2. An interview on June 11, 2018 at 9:50 AM, with the laboratory lead, confirmed the laboratory failed to evaluate the PT scores.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory lead, the laboratory failed to document the evaluation and corrective actions for leukocyte, thyroid stimulating hormone (TSH), and prostate specific antigen (PSA) for the American Association of Bioanalysts (AAB) PT program 2018 event 1. Findings: 1. An AAB record review revealed the laboratory failed to document the evaluation and corrective actions for leukocyte, TSH, and PSA scores from 2018 event 1. 2. An AAB record review revealed the laboratory failed to document corrective actions for an unsatisfactory PSA score for the 2018 event 1. 3. An interview on June 11, 2018 at 9:50 AM, with the laboratory lead, confirmed the laboratory failed to document the corrective action for the PT results from AAB.
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 a procedure manual review and an interview with laboratory lead, the laboratory failed to determine and state the calibration, control, reference range,

	corrective action, and troubleshooting requirements for testing complete blood counts (CBC) on the Sysmex pocH 100, and thyroid stimulating hormone (TSH) and prostate specific antigen (PSA) on the Nano Entek Frend analyzer since the last survey on September 6, 2016. Findings: 1. A review of the procedure manual for the Sysmex and Frend analyzer revealed the laboratory failed to determine and state the procedure for calibration and quality control testing to include troubleshooting and corrective actions for both analyzer since the last survey. 2. A review of the procedure manual, Sysmex instrument printouts, and final patient reports revealed the laboratory failed to provide the reference ranges for CBC results. 3. An interview on June 11, 2018 at 11: 30 AM, with the laboratory lead, confirmed the laboratory failed to identify the requirements for calibration, controls, refernces ranges for CBCs, and corrective actions for the Sysmex and Frend test systems.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to monitor and document the heat block temperature for the Nano Entek Frend analyzer used to test patient thyroid stimulating hormone (TSH) and prostate specific antigen (PSA) since the last survey on September 6, 2016. Findings: 1. A record review of temperature logs revealed the laboratory failed to monitor and document the heat block temperature for the Nano Entek Frend analyzer test patient TSH and PSAs. 2. An interview on June 11, 2018 at 12:30 PM, with the laboratory lead, confirmed the laboratory failed to document the heat block temperature before June 6, 2018.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on an observation of reagents in the laboratory and an interview with the laboratory lead, the laboratory failed to label the preparation and expiration dates of reagents for the Sysmex pocH-100 complete blood count (CBC) analyzer and the Nano Entek Frend analyzer. Findings: 1. An observation of the laboratory refrigerator where the CBC quality controls are stored, revealed the three Sysmex CBC control vials failed to be labeled with the preparation (open) and expiration dates, as well as the reagents bottles for the pocH-100 analyzer. 2. An interview on June 11, 2018 at 11:

	50 AM, with the laboratory lead, confirmed the laboratory failed to label the CBC quality control vials and reagents for the analyzer.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to establish and document a maintenance program for scheduled and unscheduled maintenance activities and corrective actions for the Nano Entek Frend and the Sysmex pocH 100 analyzer since the last survey on September 6, 2016. Findings: 1. A record review of the laboratory procedures revealed the laboratory failed to establish a maintenance protocol for documenting when maintenance activities are performed on the analyzers since the last survey. 2. An interview on June 11, 2018 at 2:50 PM, with the laboratory lead, confirmed the laboratory failed to establish and document maintenance activities on the analyzers.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to establish the number, type and frequency of external quality controls for thyroid stimulating hormone (TSH) and prostate specific antigen (PSA) test performed on the Nano Entek Frend since the last survey on September 6, 2016. Findings: 1. A review of the laboratory's Individualized Quality Control Plan (IQCP) revealed the quality control plan failed to include the number, type, and frequency of external quality control reagents for TSH and PSA testing since the last survey. 2. An interview on June 11, 2018 at 11:50 AM, with the laboratory lead, confirmed the IQCP for quality controls for TSH and PSA failed to identify the number, type, and frequency of control reagents to detect immediate errors in the test system since the last survey.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to meet the manufacturer's quality control criteria for thyroid stimulating hormone (TSH) and prostate specific antigen (PSA) test results performed on the Nano Entek Frend prior to reporting patient test result from December 2017 through March 2018. Findings: 1. A review of quality control records for PSA revealed the laboratory failed to evaluate failed quality control level 1 results from 12/13/2017, 12 /14/2017, 12/20/2017, 12/26/2017, 1/10/2018, and 2/6/2018 prior to reporting 5 patient samples. 2. A review of quality control records for TSH revealed the laboratory failed to evaluate failed quality control level 2 results from 03/01/2018 and 3/23/2018 prior to reporting 6 patient TSH samples. 3. An interview on June 11, 2018 at 1:00 PM, with the laboratory lead, confirmed the laboratory failed to evaluate patient PSA results when 1 out of 2 levels of quality control results for the PSA and TSH failed to meet the manufacturer's quality control criteria.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to evaluate and document corrective actions of patient thyroid stimulating hormone (TSH) and prostate specific antigen (PSA) test results, performed on the Nano Entek Frend, when 1 out of 2 levels of quality control failed to meet the manufacturer's criteria for acceptance from December 2017 through March 2018. Findings: 1. A review of quality control records and documentation of corrective actions for PSA revealed the laboratory failed to evaluate patient test results when quality control level 1 results from 12/13/2017, 12/14/2017, 12/20/2017, 12/26/2017, 1 /10/2018, and 2/6/2018 were not within the manufacturer's acceptable range. 2. A review of quality control records and documentation of corrective actions for TSH revealed the laboratory failed to evaluate patient test results when quality control level 2 results from 03/01/2018 and 3/23/2018 were not within the manufacturer's acceptable range. 3. An interview on June 11, 2018 at 1:00 PM, with the laboratory lead, confirmed the laboratory failed to evaluate patient test results for TSH and PSA results when 1 out of 2 levels of quality control for the PSA and TSH failed to meet the manufacturer's reference range.

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 a record review of final patient reports and an interview with the laboratory lead, the laboratory failed to indicate the name and the address of the reference laboratory performing laboratory tests since the last survey on September 6, 2016. Findings: 1. A review of final patient laboratory test reports, revealed the name and address of the reference laboratory for tests performed failed to be included on the patient's final test reports. 2. An interview on June 11, 2018 at 2:15 PM, with the laboratory lead, confirmed the name and address of the reference laboratory failed to be indicated on patient laboratory test reports.
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 a record review and an interview with the laboratory lead, the laboratory director failed to ensure that a quality assessment program is established for the Sysmex pocH-100 used to test complete blood counts (CBC) and the Frend used to test thyroid stimulating hormone (TSH) and prostate specific antigen (PSA) for the analytical and post-analytical phases of testing since the last survey on September 6, 2016. Refer to D5403, D5441, D5481, D5805, and D5783. Findings: 1. A procedure review revealed the laboratory director failed to establish a quality assessment procedure to identify and correct problems in the analytic and post-analytic test systems since the last survey. 2. An interview on June 11, 2018 at 1:45 PM, with the laboratory lead, confirmed the laboratory failed to establish quality assessment activities for the analytic and post-analytic phases of CBC, TSH, and PSA patient testing.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in

	accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to provide a technical consultant who meets the qualifications and provide technical oversight for the laboratory. Refer to D6035, D6042, D6046, and D6053.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to provide a qualified technical consultant for the position based on education, training, and experience requirements since the last survey on September 6, 2016. Findings: 1. A review of the CMS 209 Personnel Report form for the laboratory revealed the position for a qualified technical consultant was not met. 2. An interview on June 11, 2018 at 8:45 AM, with the laboratory lead, revealed the laboratory failed to have a technical consultant that met all qualifying requirements.

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 a record review and an interview with the laboratory lead, the laboratory failed to provide a technical consultant to meet the responsibility for establishing a quality control program for testing complete blood counts (CBC), thyroid stimulating hormone (TSH), and prostate specific antigen (PSA) since the last survey on September 6, 2016. Findings: 1. A review of the laboratory's procedure manual for CBC testing performed on the Sysmex pocH-100 and for TSH and PSA testing performed on the Frend analyzer revealed the laboratory failed to establish a quality control program for the performance, troubleshooting, corrective actions, and reporting of CBC, TSH, and PSA on patient samples. 2. An interview on June 11, 2018 at 10:45 AM, with the laboratory lead, confirmed the laboratory failed to have a program for quality control.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the laboratory lead, the laboratory failed to provide a technical consultant to perform and document the competency of 5 testing personnel who perform complete blood counts (CBC), thyroid stimulating hormone (TSH), and prostate specific antigen (PSA) since the last survey on September 6, 2016. Findings: 1. A review of personnel records revealed 5 out of 5 testing personnel listed on the CMS-209 Personnel Report form failed to have competency assessments performed and documented. 2. An interview on June 11, 2018 at 9:15 AM, with the laboratory lead, confirmed competency assessments were not performed on the testing personnel performing testing on patient samples.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the

	laboratory lead, the laboratory failed to evaluate and document the competency of testing personnel at least semiannually during the first year of patient testing for complete blood counts (CBC) on the Sysmex pocH-100 and for thyroid stimulating hormone (TSH) and prostate specific antigen (PSA) on the Frend analyzer since the last survey September 6, 2016. Findings: 1. A record review of personnel documents revealed 3 out of 5 testing personnel listed on the CMS-209 Personnel Report form failed to have competency assessments performed and documented at least semiannually during their first year of patient testing. 2. An interview on June 11, 2018 at 9:20 AM, with the laboratory lead, confirmed the laboratory failed to perform competency at least semiannually on 3 testing personnel.