Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0692410	03/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Eden Springs Healthcare Center	401 North Broadway Street, Green Springs, OH	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and an interview, the laboratory failed to rotate proficiency testing specimens among the personnel who routinely perform testing from 2016 through 2017. All patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of proficiency testing documentation found that Testing Personnel #1 had participated in every proficiency testing event from 2016 through 2017. 2. An interview with the Performance Improvement Coordinator, on 3/12/18 at 9:32 am, confirmed that Testing Personnel #1 routinely performed proficiency testing activities from 2016 through 2017.
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 record review and interviews, the laboratory failed to retain quality control test records documenting analytic systems activities for at least two years. All patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of quality control data, on 3/12/18 at 1:30 pm, found it was printed from the

	instrument on thermal paper. 2. An interview with the Performance Improvement Coordinator and Testing Personnel #1 , on 3/12/18 at 1:30 pm, confirmed that neither electronic, nor hard copies were made from quality control instrument printouts, on thermal paper that fades over time, to ensure that they are retrievable and legible for at least two years.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review the laboratory failed to establish and follow written policies and procedures to assess and document the competency of the Technical Consultant based on the responsibilities of the position. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of the laboratory's competency documentation, on 3/12/18 at 10:40 am, found no completed competency assessment for the Technical Consultant based on responsibilities of that position. 2. Review of policies and procedures, on 3/12/18 at 10:40 am, found that the laboratory failed to establish a policy and procedure to determine Technical Consultant competency based on responsibilities of that position.
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 record review and an interview, the laboratory failed to include a procedure for calibration and calibration verification, when applicable to the test systems, in the procedure manual. All patients tested at this laboratory have the potential to be affected. Findings include: 1. A review of the procedure manual, on 3/12/18 at 11:25 am, failed to find a policy and procedure regarding calibration and calibration

	verification. 2. An interview with the Performance Improvement Coordinator, on 3/12 /18 at 11:25 am, confirmed that the laboratory did not have a policy and procedure for calibration and calibration verification.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and an interview, the laboratory failed to verify performance specifications of the test system before reporting patient test results. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of policies and procedures, on 3/12/18 at 11:38 am, failed to locate a policy stating that performance specifications, including accuracy, precision, reportable rage and verification that the manufacturer's were appropriate for the patient population, were established. 2. An interview with the Performance Improvement Coordinator, on 3/12 /18 at 11:38 am, confirmed that laboratory did not have a policy regarding performance specifications. 3. An interview with the Performance Improvement Coordinator, on 3/12/18 at 11:38 am, confirmed that laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, reportable range of test results, and reference intervals for the laboratory's test systems.
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 record review, the Technical Consultant failed to evaluate the competency of all testing personnel and assure the staff maintained their competency to perform test procedures and report rest results promptly accurately, and proficiently. All patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of competency assessment documentation found that Testing Personnel #1 performed thirty one out of forty four competency assessments from 2016 and 2017. 2. Review of competency assessment documentation found the signature of Testing Personnel #1 as the assessor under the column labeled "Date and assessors initial when deemed competent."