

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2163989	(X3) Date Survey Completed 09/03/2019
Name of Provider or Supplier Flc Lab	Street Address, City, State 11978 S Redwood Rd, Riverton, UT	
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
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory record review, lack of documentation, and interview with staff, the laboratory lacked documentation of the time specimens are received in the laboratory. The laboratory began patient testing on 04/2019 and tests approximately 50 samples a week. Findings include: 1. Laboratory records failed to include the time samples were received by the laboratory. 2. Staff stated during the survey they did not realize documentation of the specimen receipt time was required and they did not document it.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on test method verification record review, FDA test complexity database review, and interview with the director, the laboratory failed to establish the analytical specificity for 1 of 1 tests performed not subject to FDA clearance--Ethyl Glucuronide (ETG). The laboratory performs approximately 4 ETG tests each day of testing. Findings include: 1. Laboratory verification records for ETG lacked documentation of the establishment of analytical specificity. 2. The FDA test complexity database failed to include ETG as a classified test. Unclassified tests default to laboratory developed high complexity assays requiring the establishment of analytical specificity. 3. The laboratory director stated during survey staff was under the impression the test was classified as moderately complex by the FDA.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on quality control record (QC) review, lack of documentation, and interview with staff, the laboratory failed to document corrective actions taken when quality control was outside acceptable limits for 1 of 9 drugs tested on 08/28/2019 (Buprenorphine). The laboratory reported 24 Buprenorphine test results on 08/28/2019. Finding include: 1. Laboratory QC records document 4 runs of the negative and positive Buprenorphine controls on 08/28/2019. All 4 of the positive controls were outside the acceptable range of 21-29. The positive control was 20.7 on run 1, 30 on run 2, 30.4 on run 3 and 30.2 on run 4. 2. The laboratory lacked documentation of corrective action taken when the laboratory was unable to get Buprenorphine positive control results within the acceptable range. 3. The director confirmed they did not have documentation of 2 levels of acceptable QC for 08/28/2019 and stated the laboratory had reported results for 24 patients on that day.

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:

	<p>Based on laboratory test report review and interview with staff, the laboratory test report for 6 of 6 test reports reviewed failed to include the name of the laboratory where testing was performed. Finding include: 1. Test reports reviewed for patients; JL181121, ME190419, WO190319,DW180805, SC190422, and LF190820 list the laboratory name as Fidelity Lab Solutions. 2. The laboratory owner stated Fidelity Lab Solutions was a name they originally were going to use for their facility, but the name submitted in their CLIA application was Foundation for Family Life/Family Life Center.</p>
<p>D6056</p>	<p>CLINICAL CONSULTANT CFR(s): 493.1415</p> <p>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to have a qualified clinical consultant. (See D6057)</p>
<p>D6057</p>	<p>CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417</p> <p>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.</p> <p>This STANDARD is not met as evidenced by: Based on Laboratory Personnel Report (CMS-209), director qualification documentation review, and interview with staff, the person listed as the clinical consultant failed to meet the qualification requirement of a clinical consultant. Findings include: 1. The laboratory CMS-209 lists the laboratory director as their clinical consultant. 2. The director does not meet qualifications under 493.1405(b)(1), (2), or (3)(i) and is not a physician. 3. In an interview with the laboratory owner and the director on 09/03/2019 at approximately 2:00 PM, the owner stated he was not aware the director did not qualify as the clinical consultant and that they did not have anyone on staff that could qualify as the clinical consultant.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: The laboratory director failed to meet the educational requirements necessary to qualify as the director of a high complexity laboratory (Ref. 6078)</p>

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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) Be a doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on laboratory record review, FDA test complexity database review, laboratory director education records review, and interview with the director, the director failed to meet the qualifications of a high complexity laboratory director. The laboratory performs approximately 4 high complexity tests per day of testing. Findings include:

1. The laboratory test menu list, patient reports, and method verification studies document Ethyl Glucuronide (ETG) testing.
2. The FDA test complexity database lacks classification of ETG testing.
3. Any test not classified by the FDA defaults to a high complexity laboratory developed test.
4. The director lacked the educational requirements to qualify as the director of a high complexity laboratory.
5. The director confirmed by email on 08/04/2019 at 1:10 PM ETG she was unable to find FDA classification of ETG.