

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2083937	(X3) Date Survey Completed 10/25/2019
Name of Provider or Supplier 2nd Chance Treatment Center	Street Address, City, State 16620 N 40th Street, Ste E-1, Phoenix, AZ	
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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) documentation, analytic test records, laboratory policies and procedures and interview with the technical supervisor, (A) the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified with lot to lot verification and (B) the laboratory failed to identify problems associated with the matrix type assigned to Quality Control and calibration materials. Findings include: 1. The laboratory performs toxicology testing on urine specimens on the Diatron Pictus 400, with an approximate annual test volume of 100,000. A1. No documentation was presented for review to indicate the laboratory had established a written policy for the acceptable criteria when establishing a new mean of control reagents. A2. The laboratory's Quality Control policy #3005 states, "When at least 20 points of the new control material have been accumulated and values entered on the New Lot QC/Cal verification worksheet, determine the new mean and SD for each parameter and enter the verified mean and SD into the Pictus system", but the policy lacked the laboratory's criteria for acceptability for the new mean and SD. A3. The technical supervisor confirmed that the laboratory failed to have the laboratory's criteria for acceptability as stated above in written policy. B1. Review of the laboratory's Quality Control and Calibration data indicated serum as the specimen type. B2. The laboratory personnel confirmed that "serum" was entered into the Diatron analyzer as the specimen type instead of "urine".</p>

D5801

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the laboratory's information system (LIS). Findings include: 1. The laboratory performs toxicology testing on urine specimens on the Diatron Pictus 400, with an approximate annual test volume of 100,000. 2. The laboratory performs testing on the Diatron Pictus 400 analyzer, and the test results do not automatically interface into the Laboratory Information System (LIS), Stratus DX. The patient test results are maintained in the LIS. The laboratory developed an interface to transfer the test results to an Excel spreadsheet which then automatically interface into the LIS. 3. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are interfaced from the analyzer, to the Excel spreadsheet, and then to the LIS. 4. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are electronically sent from the analyzer to the LIS.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

The Condition of Laboratory Director was found to be not met based on the failure to have a director who meets the qualification requirements of 493.1443 of this subpart. See D6078 for findings.

D6078

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 review of the CMS-209, Laboratory Personnel Report presented for review during the survey and interview with the Technical Supervisor, the laboratory failed to have a qualified Laboratory Director at the time of the survey. Findings include: 1. The laboratory performs high complexity testing on the Diatron Pictus 400 analyzer, with an approximate annual test volume of 100,000. 2. During the survey conducted on October 25, 2019 it was discovered that the Laboratory Director listed in the CMS database at the time of the survey for CLIA# 03D2083937 was no longer affiliated with the facility as of May 2019. The State Agency received no notification of a Laboratory Director change for this CLIA certification. 3. The CMS-209, Laboratory Personnel Report presented for review during the survey listed a physician as the Laboratory Director, but there was no evidence presented for review at the time of the survey of the individual's experience directing or supervising high complexity testing for at least 2 years. 4. The Technical Supervisor acknowledged that the laboratory failed to provide evidence of a qualified Laboratory Director. 5. The individual assumed the responsibilities of the Laboratory Director of a high complexity testing lab in May 2019.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the technical supervisor, the laboratory failed to indicate the correct dates on the competency evaluation documentation for one out of one testing personnel. Findings include: 1. The 6 month competency evaluation presented for review for one testing personnel hired on 1/16 /2018 indicated the competency evaluation was completed on 06/10/2018, however the form was signed and dated by the technical supervisor and employee on 06/10/19. 2. The technical supervisor confirmed that the signature dates were incorrect on the competency evaluation form referenced above.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the technical supervisor, the laboratory failed to indicate the correct dates on the competency evaluation documentation for one out of one testing personnel. Findings include: 1. The annual competency evaluation presented for review for one testing personnel hired on 1/16 /2018 indicated the annual competency evaluation was completed on 01/25/2019, however the form was signed and dated by the laboratory director, technical supervisor and employee on 1/25/18. 2. The annual competency form referenced above listed the 'Period of Evaluation' as a "6 month evaluation" instead of an annual evaluation. 3. The technical supervisor confirmed that the signature dates and the Period of Evaluation were incorrect on the competency evaluation form referenced above.