

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2083937	(X3) Date Survey Completed 09/15/2022
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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test requisitions and interview with the facility personnel, the laboratory's test requisition failed to include the test(s) to be performed. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Toxicology, with an approximate annual test volume of 300,000. The laboratory utilizes the Diatron Pictus 700 to perform a urine drug screen. 2. The test requisitions (CM495117, DD77000, FM608987 and BL380499) reviewed during the survey conducted on September 15, 2022 indicated the test to be performed as "Toxicology Screen". 3. The laboratory failed to produce documentation, whether on the test requisition or in laboratory policy, to indicate the specific analytes that are tested by the laboratory on the Diatron Pictus 700 analyzer for a 'Toxicology Screen'. 4. The urine drug screen performed by the laboratory on the Diatron Pictus 700 analyzer tests for the following analytes: AMPH-FI, BENZ-FI, BUPR-FI, COCA-FI, FENT-FI,</p>

METH-FI, OPIA-FI, OXY-FI, SPG, THC-FI, U CREAT, and pH DRI. 5. The facility personnel interviewed on 9/15/22 at 10:55am confirmed that the test requisitions reviewed during the survey failed to include the specific analytes tested in a Toxicology Screen.

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 lack of post-analytic comparison documentation and interview with the facility personnel, the laboratory failed to follow established policies 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 700 with an approximate annual test volume of 300,000. 2. The test results from the Diatron analyzer are electronically interfaced into the Laboratory Information System (LIS). 3. The laboratory's established post-analytic Quality Assessment (QA) policy (SOP# SCTCL-QAU102) states, "Periodic evaluation of results is compared throughout the entire process LIS to instrument, instrument to LIS, and LIS to portal to confirm results match across all parameters." 4. No documentation from 2020 through the date of the survey on September 15, 2022 was presented for review to indicate the laboratory periodically verified the accuracy of test results which are electronically interfaced from the analyzer to LIS. 5. The facility personnel interviewed on 9/15/22 at approximately 11:50am confirmed that the laboratory did not follow the established policy referenced above to periodically verify the accuracy of the patient test results that are electronically sent from the Diatron analyzer to the LIS.

D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:
Based on review of corrected test reports and interview with the facility personnel, the laboratory failed to maintain duplicates of the original report, as well as the corrected report. Findings include: 1. Review of corrected test reports generated from the Laboratory Information System (LIS) for sample ID# 71138 collected on 6/16/21

included two separate corrected test reports: - All results included in the Toxicology Screen show "result corrected on 6/21/2021 at 02:21 PM from the previous result reported on 6/21/2021 at 02:11 PM." - All results included in the Toxicology Screen show "result corrected on 6/21/2021 at 05:21 PM from the previous result reported on 6/21/2021 at 05:11 PM." 2. The corrected test reports indicated above failed to include the original test result (previous result) and the corrected test result. 3. The technical consultant interviewed on 9/15/22 at 12:20 PM confirmed that the corrected test reports indicated above failed to include the original test results, as well as the corrected test results. 4. The facility personnel confirmed that 5 patient test reports were corrected during 2021.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Due to the number and severity of deficient practices identified during the survey conducted on September 15, 2022, the Condition of Laboratory Testing Personnel was found to be not met as evidenced by: D6070 - Failure of each individual performing moderate complexity testing to adhere to the laboratory's procedures for test reporting; and D6074 - Failure of each individual performing moderate complexity testing to identify problems that may adversely affect the reporting of test results and failure to immediately notify the technical consultant or director of issues related to discrepant test results.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's established Standard Operating Procedure (SOP) for specimen testing on the Diatron 700 analyzer, review of patient test results and interview with the facility personnel, the testing personnel failed to follow the laboratory's procedures for test reporting. Findings include: 1. The laboratory performs toxicology testing on urine specimens on the Diatron Pictus 700 with an approximate annual test volume of 300,000. The testing is considered semi-quantitative, meaning the instrument produces a quantitative test result that is interpreted and resulted as a qualitative final result. 2. The laboratory's SOP (SCTCL-LABOP112, version 2) states, "Positives will be reported out as "Positive" and send out for confirmation per ordering provider/organizations direction....A patient sample may be repeated on the Diatron for the following reasons: (f.) The data reviewer may use their discretion to repeat a test if there are unexpected results from a patient's medication listed by the provider. The FIRST acceptable sample result will be reported." 3. Review of test results for sample ID# 71138 collected on 6/16/21 at 4:20 PM included the following test runs: - Originally run on 6/18/2021 at 12:29:04 PM -

the BUPR-FI (Buprenorphine) result showed 61 ng/mL, with a final qualitative result of 'Positive'. - Re-ran on 6/21/2021 at 11:23:56 AM - the BUPR-FI (Buprenorphine) result showed 0 ng/mL, with a final qualitative result of 'Negative'. The test results of this sample run were listed on the final test report. 4. The testing personnel failed to follow the laboratory's established procedures for test reporting by failing to send out the sample for confirmatory testing and failing to report the first sample result obtained. 5. The testing personnel interviewed on 9/15/22 at 12:04 PM stated that samples with questionable results are re-run the next business day and the test report is corrected if necessary. The testing personnel confirmed that the SOP was not followed as indicated above.

D6074

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(5)

Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.

This STANDARD is not met as evidenced by:

Based on review of patient test results, review of the laboratory's test procedure and interview with the facility personnel, the testing personnel failed to identify problems that may adversely affect the reporting of test results and failed to immediately notify the technical consultant or director. Findings include: 1. The laboratory performs toxicology testing on urine specimens on the Diatron Pictus 700 with an approximate annual test volume of 300,000. The testing is considered semi-quantitative, meaning the instrument produces a quantitative test result that is interpreted and resulted as a qualitative final result. 2. The laboratory's SOP (SCTCL-LABOP112, version 2) states, "Positives will be reported out as "Positive" and send out for confirmation per ordering provider/organizations direction....A patient sample may be repeated on the Diatron for the following reasons: (f.) The data reviewer may use their discretion to repeat a test if there are unexpected results from a patient's medication listed by the provider. The FIRST acceptable sample result will be reported." 3. Review of test results from the analyzer for sample ID# 71138 collected on 6/16/21 at 4:20 PM included the following test runs: - Originally run on 6/18/2021 at 12:29:04 PM - the BUPR-FI (Buprenorphine) result showed 61 ng/mL, with a final qualitative result of 'Positive'. - Re-ran on 6/21/2021 at 11:23:56 AM - the BUPR-FI (Buprenorphine) result showed 0 ng/mL, with a final qualitative result of 'Negative'. The test results of this sample run were listed on the final test report. 4. Review of corrected test reports in the Laboratory Information System (LIS) for sample ID# 71138 collected on 6/16/21 at 4:20 PM indicated the sample was additionally analyzed on 6/21/21 at 2:21 PM and 6/21/21 at 5:21 PM by the same testing personnel who ran the samples on 6/18/21 at 12:29:04 PM and 6/21/21 at 11:23:56 AM. 5. The testing personnel failed to identify test result discrepancies that may adversely affect the reporting of test results and failed to immediately notify the technical consultant or director. 6. The testing personnel interviewed on 9/15/22 at 12:04 PM confirmed that the sample was continually re-analyzed until a test result for BUPR-FL was obtained that would be consistent with the patient's medical history, and the testing personnel confirmed that the technical consultant and/or laboratory director were not immediately notified of issues with the test results for the sample indicated above.