

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2083457	(X3) Date Survey Completed 09/13/2023
Name of Provider or Supplier Crossroads Treatment Center Of Greensboro, Pc	Street Address, City, State 2706 North Church Street, Greensboro, NC	
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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based upon review of 2022 and 2023 Alternate (PT) Proficiency Testing records and interview with the Compliance Specialist on 9/13/2023, the laboratory failed to investigate discrepancies within a 2022 Alternate PT Event. Review of Alternate PT Event "SLP-UR-A-2022" revealed the following discrepancies: 1. Sample UR22-01 contained naloxone and 6-acetylmorphine; however, the laboratory did not report these analytes were detected. 2. Sample UR22-02 contained hydromorphone and ritalinic acid; however, the laboratory did not report these analytes were detected. 3. Sample UR22-05 contained oxycodone; however, the laboratory did not report this analyte was detected. During interview at approximately 12:45 p.m., the Compliance Specialist stated the discrepancies were overlooked during her review of the Alternate PT event.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based upon review of the laboratory's verification records and interview with the Compliance Specialist, the laboratory failed to assess the precision of ph when the analyte was added onto the Synermed IR 500 instrument in September 2021. Review of the laboratory's verification records for ph revealed the absence of an assessment for precision. During interview at approximately 12:00 p.m., the Compliance Specialist confirmed the absence of documentation for the assessment of precision. The Compliance Specialist stated there was a problem with the worksheet calculating statistical data for precision.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based upon review of the laboratory's policies and procedures and interview with the Compliance Specialist on 9/13/2023, the Laboratory Director failed to sign the laboratory's revised "Alternate Proficiency Assessment Method" policy prior to its implementation in November 2022. A review of the laboratory's policies and procedures revealed no signature (physical or electronic) of the Laboratory Director to document his review and approval of the revised Alternate Proficiency Assessment Method policy. During interview at approximately 1:25 p.m., the Compliance Specialist stated the policy updated in November 2022 and the Lab Director has not signed the revised policy.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 upon review of the Technical Supervisor's job description and review of 2021, 2022 and 2023 competency records, the Technical Supervisor failed to evaluate the competency of 4 of 6 Testing Personnel. Review of the Technical Supervisor's job description revealed "Duties in Above and Related Areas: ...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..." Review of the testing personnel's competency records revealed that 4 testing personnel who float between different facilities did not have their competency assessed or signed by the laboratory's Technical Supervisor. The competencies of these floating testing personnel were assessed at other facilities and signed by the staff of the other facilities.