

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2119597	<b>(X3) Date Survey Completed</b>  01/28/2020
<b>Name of Provider or Supplier</b>  Clinical Connect Laboratories, Llc	<b>Street Address, City, State</b>  30675 Stephenson Highway Suite L 1, Madison Heights, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, 23D2119597 Clinical Connect Laboratories, LLC received proficiency testing samples from other laboratories for the College of American Pathology proficiency testing event UT-B in 2018 and failed to notify CMS of receipt of those samples. The laboratory engaged in inter-laboratory communication with 3 other laboratories prior to the proficiency testing (PT) submission date for 3 (UT- A, UT-B, and UT-C 2019) of 3 testing events. Refer to D2011 and D2013.</p>
<b>D2011</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications</p>

or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Manager (LM) and the Laboratory Consultant (LC), the laboratory engaged in inter-laboratory communication with 3 other laboratories prior to the proficiency testing (PT) submission date for 3 (UT- A, UT-B, and UT-C 2019) of 3 testing events. Findings include: 1. Review of the laboratory's procedure "Proficiency Testing" signed by the Laboratory Director on 4/4/2018 states, "Results are not allowed to be discussed with other labs prior to sending the results to CAP (College of American Pathologists)." 2. Record review of the PT documents revealed for each laboratory Testing Personnel #1 (TP1) was listed on the proficiency testing attestation sheets and ran all the specimens for each the testing events for each laboratory listed below: a. 23D2113189 RPPC Labs, LLC -UT-A and UT-C in 2019 b. 23D1057542 Neuro Pain Consultants - UT-A and UT-C in 2019 c. 23D2119597 Clinical Connect Laboratory, LLC - UT-A, UT-B, and UT-C in 2019 d. 23D2144369 Synchronized Lab Services, LLC - UT-B and UT-C in 2019 3. During the interview on 1/28/2020 at approximately 12:30 p.m., LM and LC confirmed that TP1 performed the same proficiency testing at multiple labs in 2019.

**D2013**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

. Based on record review, procedure review, and interview with the Laboratory Manager (LM) and the Laboratory Consultant (LC), the laboratory received proficiency testing (PT) samples for 1 (UT-B 2018) of 5 testing events from 4 (23D2144369 Synchronized Lab Services, 23D2113189 RPPC Labs LLC , and 23D1057542 Neuro Pain Consultants PC, and LabTox {no longer testing}) laboratories. Clinical Connect Laboratories, LLC (CCL) tested and returned PT results for urine toxicology testing for 1 (UT-B 2018) of 5 events reviewed. The laboratory did not notify CMS of the receipt of those samples. Findings include: 1. Record review of a timeline presented to the surveyors on 1/28/20 at approximately 12:35 pm,

revealed the following information about 23D2144369 Synchronized Lab Services {SYN}, 23D2113189 RPPC Labs LLC {RPPC}, and 23D1057542 Neuro Pain Consultants PC {NPC} as follows: Synchronized Lab Services a. 4/18/2018-7/9/2018 testing was performed in Royal Oak at SYN b. 7/10/2018-11/4/2018 testing was performed in Troy and was referenced to CCL c. 11/5/2018-12/3/2018 testing was performed in Royal Oak and was referenced to CCL d. 12/4/2018-12/20/2018 testing was performed in Royal Oak at SYN e. 12/21/2018-6/30/2019 testing was performed in Royal Oak and was referenced to CCL f. 7/1/2019-current testing was performed in Royal Oak at SYN RPPC a. 1/1/2018-7/8/2018 testing was performed in Royal Oak at RPPC b. 7/9/2018-11/4/2018 testing was performed in Troy and was referenced to CCL c. 11/5/2018-6/30/2019 testing was performed in Royal Oak at RPPC d. 7/1/2019-10/2/2019 testing was performed in Royal Oak at CCL e. 10/3/2019-current testing was performed in Royal Oak at RPPC Neuro Pain Consultants PC a. 1/1/2018-7/1/2018 testing was performed in Royal Oak at NPC b. 7/2/2018-11/5/2018 testing was performed in Troy and referenced to CCL c. 11/5/2018-6/30/2019 testing was performed in Royal Oak at NPC d. 7/1/2019-10/2/2019 testing was performed Royal Oak and referenced to CCL e. 10/3/2019-current testing was performed in Royal Oak at NPC 2. Reports generated with the "Clinical Connect Laboratory" logo at the top left, "1307- A100 Allen Drive, Troy, MI 48083" and "CLIA# 23D2119597" in the top right of the reports. Reports included the name of other laboratories under the "Physician" area of the report for the following proficiency testing samples reported: i. UT-06 CAP ii. UT- 07 CAP iii. UT-08 CAP iv. UT-09 CAP v. UT-10 CAP 3. Record review of an email sent on 3/29/2019 by the Laboratory Consultant to the Laboratory Manager, the previously employed testing personnel, and other laboratory staff from the six laboratories, revealed the following statement "Clinical Connect Lab- UT-B PT was run at the CCL lab as it should be, and results were reported to CAP. At this time, CCL was located in Troy in the B3 complex. CLIA was notified of the change of address and it is documented. Therefore, CCL did not violate any PT policy. NPC, RPPC, Synchronized, LabTox- At this time These, four labs were not running any specimens. All of their work was being referenced to CCL per agreement. CAP should have been notified that no results will be sent in for the UT-B because patients were not being run. However, what happened was that (previously employed testing personnel) took the CAP samples, ran them at CCL and reported out the results." 4. During the interview on 1/28/20 at 1:05 pm, the LM and LC confirmed the toxicology proficiency testing samples were received from 4 (23D2141469 Synchronized Lab Services, 23D2113189 RPPC Labs LLC, and 23D1057542 Neuro Pain Consultants PC, and LabTox {no longer testing}) laboratories, proficiency testing was performed and results returned to the sending laboratory for 1 (CAP UT-B) of 5 events reviewed and CMS was not notified of the receipt of those referred specimens.