

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2144369	(X3) Date Survey Completed 01/28/2020
Name of Provider or Supplier Synchronized Lab Service	Street Address, City, State 26154 Woodward Avenue Suite 6, Royal Oak, MI	
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
D2000	<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, the Synchronized Lab Services, LLC laboratory referred proficiency testing samples to 23D2119597 Clinical Connect Laboratories, LLC (CCL) for toxicology testing. The laboratory reported CCL proficiency testing results to the College of American Pathologist proficiency testing program as their own. Refer to D2013. The laboratory engaged in inter-laboratory communication with other laboratories prior to the proficiency testing submission date. Refer to D2011.</p>
D2011	<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 or discussions across sites/locations concerning proficiency testing sample results</p>

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 and the Laboratory Consultant, the laboratory engaged in inter-laboratory communication with other laboratories prior to the proficiency testing submission date for 2 (UT-B and UT-C 2019) of 3 testing events. Findings include: 1. A review of the laboratory's procedure "Proficiency Testing," with no effective date, revealed a section stating, "Results are not allowed to be discussed with other labs prior to sending the results to CAP (College of American Pathologists)." 2. A record review of the proficiency testing documents for each laboratory revealed Testing Personnel #1 (TP1) was listed on the proficiency testing attestation sheets and ran all the specimens for 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 2019 3. An interview on 1/27/2020 at approximately 3:37 pm, the Laboratory Manager and the Laboratory Consultant confirmed TP1, listed on the CMS 209 form for all laboratories listed above, was performing proficiency testing for all laboratories.

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, and interview with the Laboratory Manager and the Laboratory Consultant, the laboratory referred proficiency testing samples to 23D2119597 Clinical Connect Laboratory, LLC (CCL) and returned the CCL results to the College of American Pathologists' proficiency testing program for 1 (UT-B 2018) of 5 urine toxicology testing events reviewed. Findings include: 1. A record review of the laboratory's "Proficiency Testing" procedure, with no effective date, revealed the following section stating, "CAP specimens are not to be sent to outside labs for results." 2. A review of the timeline of when each laboratory was referring patient specimens to Clinical Connect Laboratory, LLC, provided by the Laboratory Manager on 1/28/2020 at approximately 12:49 pm, revealed the following information

about the Synchronized Lab Services laboratory: a. 4/18/2018- 7/9/2018 testing was performed in Royal Oak at Synchronized Lab Services b. 7/10/2018- 11/4/2018 testing was performed in Troy and referenced to CCL c. 11/5/2018- 12/3/2018 testing was performed in Royal Oak and referenced to CCL d. 12/4/2018- 12/20/2018 testing was performed in Royal Oak at Synchronized Lab Services e. 12/21/2018- 6/30/2019 testing was performed in Royal Oak and referenced to CCL f. 7/1/2019- current testing was performed in Royal Oak at Synchronized Lab Services 3. An interview on 1/28/2020 at 12:33 pm with the Laboratory Consultant revealed the laboratory did not retain any proficiency testing records for UT-A, UT-B, and UT-C testing events in 2018, but was able to provide the surveyor with the final reports from the CAP website. 4. A record review of the CAP proficiency testing final reports for testing events UT-B and UT-C in 2018 revealed results had been submitted to CAP when the laboratory was not testing patient samples between 7/10/2018 and 12/20/2018 and referring them to CCL. 5. A 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 (Neuro Pain Consultants), 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." 6. An interview on 1/28/2020 at approximately 1:05 pm with the Laboratory Manager and the Laboratory Consultant confirmed proficiency testing results were submitted to CAP during the time when the laboratory was referring specimens to CCL between 7/10/2018 and 12/20/2018.

D3037

RETENTION REQUIREMENTS
 CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the Laboratory Consultant, the laboratory failed to retain proficiency testing records for 1 (2018) of 2 years reviewed. Findings include: 1. A record review of the timeline of when each laboratory had been operating and referring specimens to another laboratory, provided by the Laboratory Manager on 1/28/2020 at approximately 12:49 pm, revealed Synchronized Laboratory Services was testing patient specimens as of 4/18/2018. 2. A record review of the laboratory's College of American Pathologists' (CAP) proficiency testing records revealed a lack of documentation for 2018. 3. When requested on 1/28/2020 at 12:05 pm, the Laboratory Consultant was not able to provide the following documents from 2018: a. signed attestation sheets by the testing personnel and the Laboratory Director or designee b. instrument data used in the submission of results c. final CAP reports reviewed by testing personnel and the Laboratory Director or designee 4. An interview on 1/28/2020 at 12:33 pm with the Laboratory Consultant confirmed the laboratory did not retain proficiency testing data for 2018.