

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2106111	(X3) Date Survey Completed 07/11/2019
Name of Provider or Supplier Advanced Central Laboratory	Street Address, City, State 35540 W Michigan Avenue, Wayne, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of testing for urine toxicology confirmation testing at least twice annually for 2 (1 event in 2017 and 1 event in 2018) of 4 events reviewed. Findings include: 1. A review of "Split-Specimen" testing records revealed a lack of verification of accuracy testing for one testing event in 2017 and one testing event in 2018 for the following urine toxicology confirmation testing listed on the laboratory test menu: a. Gabapentin b. Hydroxybupropion c. Mitragynine d. N-DesMethylcitalopram e. Pregablin f. Secobarbital g. Tapentadol 2. A review of the "Proficiency Testing (PT) and Split-Specimen Testing" procedure showed a section titled "Mechanism of Review: Split-Specimen Testing" that states, "Split-Specimen testing is required on five specimens twice each year for all unregulated analytes not enrolled in PT." 3. An interview on 7/11/19 at 9:38 am with the GS confirmed verification of accuracy testing was not performed twice annually in 2017 and 2018.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to document corrective actions for 2 (the third event in 2017 and the</p>

third event in 2018) of 5 proficiency testing events reviewed. Findings include: 1. A review of Urine Toxicology Proficiency Testing records exposed the following testing events with a lack of corrective action documented: a. 2017 UT-C, specimen UT-12 was unacceptable b. 2018 UT-C, specimen UT-11 was unacceptable 2. A review of the "Proficiency Testing (PT) and Split-Specimen Testing" procedure revealed a section titled "Frequency of Review" stating, "Each PT event will be evaluated as the results are received. Appropriate corrective action will be taken at that time to prevent future failures and improve the the quality of patient test results." 3. An interview on 7 /11/19 at 9:21 AM with the GS confirmed corrective action had not been documented for the 2017 third event or the 2018 third event proficiency tests.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor (GS), the laboratory failed to document and retain corrective action taken on out of range temperatures for Freezer #2 and Refrigerator #2 for 2 (2017-2019) of 2 years. Findings include: 1. A review of the "Freezer Temperature Log" for Freezer #2 revealed daily recorded temperatures were out of the laboratory's specified acceptable range of equal to or less than 20 degrees C for the following months: a. August 2017, 2 days b. September 2017, 6 days out of range c. October 2017, 6 days out of range d. November 2017, 6 days out of range e. December 2017, 4 days out of range f. January 2018, 4 days out of range g. February 2018, 7 days out of range h. March 2018, 10 days out of range i. April 2018, 13 days out of range j. May 2018, 16 days out of range k. June 2018, 20 days out of range l. July 2018, 11 days out of range m. August 2018, 13 days out of range n. September 2018, 6 days out of range o. October 2018, 10 days out of range p. November 2018, 10 days out of range q. December 2018, 7 days out of range r. January 2019, 5 days out of range s. February 2019, 5 days out of range t. March 2019, 5 days out of range u. April 2019, 3 days out of range v. May 2019, 8 days out of range w. June 2019, 4 days out of range x. July 2019, 2 days out of range 2. A review of the "Refrigerator Temperature Log" for Refrigerator #2 revealed daily recorded temperatures were out of the laboratory's specified acceptable range of 2-8 degrees C for the following months: a. August 2017, 2 days out of range b. September 2017, 1 day out of range c. October 2017, 7 days out of range d. November 2017, 9 days out of range e. December 2017, 13 days out of range f. January 2018, 2 days out of range g. February 2018, 6 days out of range h. March 2018, 5 days out of range i. April 2018, 4 days out of range j. May 2018, 8 days out of range k. June 2018, 14 days out of range l. July 2018, 12 days out of range m. August 2018, 17 days out of range n. September 2018, 17 days out of range o. October 2018, 20 days out of range p. November 2018, 21 days out of range q. December 2018, 14 days out of range 3. When requested on 7/11/19 at 11:21 AM, the GS did not provide

corrective action for the dates when recorded temperatures were out of range for Freezer #2 or Refrigerator #2. 4. An interview on 7/11/19 at 11:21 AM with the GS confirmed corrective action for Freezer #2 and Refrigerator #2 had not been documented and retained by the laboratory.