

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1079153	(X3) Date Survey Completed 10/17/2019
Name of Provider or Supplier Oswego Immediate Care	Street Address, City, State 6701 Us Highway 34, Oswego, IL	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (CMS 209), proficiency testing (PT) records and interview with Technical Consultant (TC) #1; the laboratory director failed to attest to the routine integration of Proficiency Testing samples into the patient workload. Findings: 1. The laboratory listed a total of 4 TCs on the CMS 209. 2. Review of PT records revealed that there is a space for the signature of the laboratory director or his designee to attest to the integration of PT samples into the patient workload. 3. There was no documentation to show that the current laboratory director and 4 of 4 TCs attested to the integration of PT samples in to the patient workload for of 3 of 3 PT events in 2018 and 3 of 3 PT events in 2019. 4. During survey date 10/17/19 at 11:30 AM, the TC #1 confirmed the surveyor's findings.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p>

This STANDARD is not met as evidenced by:
 Based on review of the laboratories testing menu, personnel records, patients' test report, verification records and interview with Technical Consultant #1; the laboratory director failed to ensure verification procedures to determine the accuracy, precision, and other pertinent performance characteristics of its iStat analyzer are adequate to test for Troponin and DDimer. Findings: 1. Review of the laboratories testing menu revealed that the laboratory performs testing for the following: a. Complete Blood Counts (CBC) using a Sysmex XP 300. b. Troponin using an iStat. c. Ddimer using an iStat. 2. Review of personnel records, revealed that initial training of testing personnel for the performance of Ddimer was November 2017 and Troponin February 2018. 2. During survey date October 17, 2019 at 1:00 PM, the surveyor reviewed 7 patients' test reports. 3. Troponin and Ddimer results were reported for 2 of 7 patients' test reports reviewed. 4. There was no documentation to show that the laboratory demonstrated that it can obtain performance specifications of its iStat for the following: a. Accuracy. b. Precision. c. Reportable range of test results. d. Reference intervals (normal values) appropriate for the laboratory's patient population. 5. During survey date October 17, 2019 at 1:00 PM, Technical Consultant #1 confirmed the surveyor's findings.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
 Based on review of Laboratory Personnel Report (CMS 209), proficiency testing (PT) records and interview with Technical Consultant (TC) #1; the laboratory director failed to ensure that all PT reports are reviewed by the appropriate staff to evaluate the laboratory's PT performance. Findings: 1. The laboratory listed a total of 4 TCs on the CMS 209. 2. Review of PT records revealed that current laboratory director and 4 of 4 TCs failed to review the results of PT performance. 3. During survey date 10/17/19 at 11:30 AM, the TC #1 confirmed the surveyor's findings.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's testing menu, verification records and interview with Technical Consultant #1; verification procedures did not include the accuracy of its iStat when it performed Troponin and Ddimer testing. Findings: 1. Review of the

laboratory's testing menu revealed that Troponin and Ddimer analytes were added to the laboratory's testing menu. 2. On October 17, 2019 at 11:30 AM, the surveyor requested the laboratory's documentation of the verification of performance characteristics of its iStat for Troponin and Ddimer tests. 3. There was no documentation to show that accuracy of Troponin and Ddimer were included when verification procedures of the lab's iStat were performed. 4. During survey date October 17, 2019 at 1:30 PM, Technical Consultant #1 confirmed the surveyor's findings.