

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 50D0661583	(X3) Date Survey Completed 06/06/2023
Name of Provider or Supplier Odessa Memorial Hospital	Street Address, City, State 502 E Amende Dr, Odessa, WA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC), the laboratory failed to have competency assessment for 1 of 1 TC. Findings include: 1. Record review revealed that the laboratory failed to have competency assessment for 1 of 1 TC for year(s) 2021 and 2022. 2. Interview of the TC on 06/06/2023 at 03:15 PM confirmed that competency assessment was not performed for year(s) 2021 and 2022.</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> <p>This STANDARD is not met as evidenced by: Based on patient record review, and interview with the Technical Consultant (TC), the laboratory failed to include reportable range in the verification of performance</p>

specifications for the i-STAT CG4+ and i-STAT Troponin-I. findings include: 1. Record review of i-STAT Troponin-I start date of 02/2023 failed to include reportable range in verification of performance. 2. Record review of i-STAT CG4+ failed to include reportable range in verification of performance. 3. Interview with the TC on 06/06/2023 at 03:15 PM confirmed that reportable range was not included in the verification of performance for i-STAT CG4+ and i-STAT Triage-I. 4. The laboratory performs approximately 372 chemistry tests annually.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on record review and interview with the Technical Consultant (TC), the laboratory failed to record the reference intervals (normal values) for the analytes Troponin-I and Blood Urea Nitrogen (BUN) on the test report. Findings include: 1. Record review of patient report #5234 revealed that Troponin-I did not have a reference range (normal values) for 3 of 3 tests performed on 2/14/2022. 2. Record review of patient report #521 revealed that BUN reference range (normal values) units of measure was incomplete and reported as "8-26 mg." 3. Interview with the TC on 06/06/2023 at 03:15 PM confirmed that the laboratory failed to have Troponin-I reference ranges (normal values) and BUN POCT reference range (normal values) was incomplete. 4. The laboratory performs approximately 372 chemistry tests annually.