

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0990984	(X3) Date Survey Completed 03/14/2024
Name of Provider or Supplier Integracare Ltd	Street Address, City, State 100 2nd St South, Sartell, MN	
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
D0000	The Integracare LTD laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the initial survey performed on March 14, 2024. The following standard-level deficiencies were cited: 493.1253 Establishment and verification of performance specifications 493.1254 Maintenance and function checks .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to complete the precision analysis for six of fourteen analytes included in one of three non-waived test panels implemented by the laboratory in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:05 p. m. on 03/14/24. 2. An Abaxis Piccolo analyzer was observed as present and available for use during the tour. The Piccolo Basic Metabolic Panel, the Piccolo Comprehensive Metabolic Panel (CMP), and the Piccolo Lipid Panel were approved for use on 10/10/23 as indicated in laboratory records. 3. Precision analysis documentation for six of fourteen analytes included on the CMP was not found during review of the performance verification documentation located in the Piccolo</p>

Validations manual. The laboratory was unable to provide precision analysis for the following analytes upon request: Alanine Aminotransferase Albumin Alkaline Phosphatase Aspartate Aminotransferase Total Bilirubin Total Protein 4. In an interview at 2:40 p.m. on 03/14/24, the LD confirmed the above finding. 5. The laboratory performed 195 CMP tests since implementation through date of survey as indicated by data provided by Testing Personnel 1 at 3:00 p.m. on 03/14/24. .

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document function checks (calibration) for one of one Min/Max digital thermometers in use in 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:05 p.m. on 03/14/24. 2. An Abaxis Piccolo analyzer was observed as present and available for use during the tour. The laboratory performed the Piccolo Basic Metabolic Panel, the Piccolo Comprehensive Metabolic Panel and the Piccolo Lipid Panel on this analyzer. 3. Chemistry calibrators and control materials were observed in the laboratory freezer. A digital Min/Max thermometer with serial number 22462347 and calibration expiration date 01/17/24 was in use to monitor storage temperatures on date of survey. Recalibration documentation was not found in laboratory records. The laboratory was unable to provide this documentation upon request. 4. A requirements to replace certified thermometers by the calibration due date was established in the Small Equipment Maintenance Protocol found in the Laboratory Manual. 5. In an interview at 1:15 p.m. on 03/14/24, the LD confirmed the above finding. .