

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D2008630	<b>(X3) Date Survey Completed</b>  02/08/2023
<b>Name of Provider or Supplier</b>  Logan Health Primary Care	<b>Street Address, City, State</b>  106 Ridgewater Drive, Suite A, Polson, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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 record review, patient results reports, and interview with the technical consultant (TC) #1, the laboratory failed to establish and verify the i-STAT's reference ranges (normal values) for the laboratory's patient population for the Chem 8+ cartridge performed on the i-STAT analyzer from February 8, 2021 to February 8, 2023. Findings: 1. Observed one of one i-STAT analyzer in the laboratory with serial number (#389654) available for use. 2. Review patient results reports (#K000646131) for CHEM 8+ (i-STAT) listed reference ranges for the following analytes: Glucose, blood urea nitrogen (BUN), Sodium, Potassium, Chloride, Hematocrit, Creatinine, and Ionized Calcium. 3. No patient population verification studies for i-STAT Chem8+ chemistry cartridge was available for review to support the references ranges (normal ranges) listed in the i-STAT procedure and the laboratory's patient results reports. 4. Interview with the TC #1 on February 8, 2023, at 2:00 PM, stated the reference ranges (normal values) were established by a VITROS chemistry analyzer located at a separate laboratory from February 8, 2021 to February 8, 2023.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p>

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the review of employees' annual competency files for 2021 and 2022, the CMS-209 Laboratory Personnel Report, and an interview with the technical consultant (TC) #1, the technical consultant failed to follow the written procedure and perform annual competency assessments for 12 out of 16 established testing personnel performing testing on the i-STAT analyzer platform for the year 2022. Findings: 1. A review of annual competency records for the year 2022 lacked i-STAT annual competencies for 12 out of 16 testing personnel (TP-1, TP-2, TP-7, TP-8, TP-9, TP-10, TP-11, TP-12, TP-13, TP-16, TP-17, and TP-18). 2. A review of the "Quality Management Policy, Point of Care" signed by the laboratory director revealed the technical consultant failed to follow procedures as stated, "CLIA regulations are followed concerning competency and training frequency; initial training, 6 month evaluation followed by yearly competency evaluation after." 3. Interview with the TC #1 on February 8, 2023, at 10:40 AM, stated that 2022 annual competencies were missed for the i-STAT.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of employee competency files for 2021 and 2022, CMS-209 Laboratory Personnel Report, and interview with the technical consultant (TC) #1, the technical consultant failed to follow the laboratory's procedures to evaluate new employee's initial competency (training) prior to patient testing and six-month competency for six out of nine new testing personnel (TP) performing moderate-level diagnostic tests from January 7, 2021 to February 8, 2023. Findings: 1. A review of employee competency evaluations for TP-3, TP-4, TP-5, TP-6, TP-18 and TP-19 lacked documentation of training, initial and/or six-month competency to include the six regulatory requirements for assessment of competency. 2. A review of the "Quality Management Policy, Point of Care" signed by the laboratory director revealed the technical consultant failed to follow procedures as stated, "CLIA regulations are followed concerning competency and training frequency; initial training, 6 month evaluation followed by yearly competency evaluation after." 3. Interview with the TC #1 on February 8, 2023, at 10:30 AM, confirmed these findings.

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on record review of testing personnel records for years 2021 and 2022, and interview with Technical Consultant (TC) #1, the laboratory failed to ensure that two out of the 19 testing personnel listed on the CMS-209 Personnel Report Form had the appropriate educational background and training prior to performing moderate-level diagnostic tests. (See D6065, 6046 and 6053)

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on a record review and an interview with the Technical Consultant (TC) #1, the laboratory failed to ensure that two out of the 19 testing personnel (TP) listed on the CMS-209 Personnel Report Form were qualified to perform moderate-level diagnostic testing on the Abbott i-STAT analyzer or Coagucheck analyzer from December 19, 2021, to February 8, 2023. Findings: 1. The laboratory failed to provide documentation of appropriate education for two out of the 19 testing personnel (TP #5, and TP #18) listed on the CLIA CMS-209 form. 2. A review of the test volume report for Abbott i-STAT analytes and Coagucheck analyzer revealed 83 BUN, 83 Calcium, 83 Chloride, 83 Creatinine, 83 Glucose, 83 Potassium, 83 Sodium, 82 Hematocrit, 24 Troponin and 546 INR patient tests were performed from January 31, 2022, to January 31, 2023. 3. An interview with TC#1 on February 8, 2023 at 10:20 AM confirmed the laboratory failed to verify the qualifications of two of the 19 testing personnel that performed moderate-level diagnostic testing from December 19, 2021, to February 8, 2023.