

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0993032	(X3) Date Survey Completed 07/01/2024
Name of Provider or Supplier Catholic Medical Center Laboratory	Street Address, City, State 100 Mcgregor St, Manchester, NH	
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	A validation survey was conducted on 6/13/2024, 6/14/2024, and 7/1/2024, the laboratory was found out of compliance with the CLIA regulations. The following conditions were not met: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
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, the laboratory failed to verify the accuracy of oxygen (O2) saturation performed on the AVOXimeter in 2023 and 2024. Findings include: 1. Review of 2023 and 2024 proficiency testing records revealed the laboratory did not participate in proficiency testing for O2 saturation. 2. The laboratory could not provide documentation at the time of survey that it had verified accuracy two times in 2023 and in 2024. 3. Interview on 6/14/24 at 8:20 a.m. with the Technical Supervisor (TS) of Point of Care Testing confirmed the laboratory did not perform proficiency testing on the AVOXimeter. The TS revealed that the laboratory did not verify twice annually the accuracy of O2 saturation performed on the AVOXimeter in the cardiac catheterization laboratory.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a</p>

procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory (lab) failed to meet chemistry, general immunology, and hematology analytic systems requirements in 2022, 2023, and 2024. Findings include: 1. The lab's procedure manual for i-STAT CG8+ testing failed to include reference ranges for capillary whole blood, venous cord blood, and arterial cord blood in use and available on 5 of 5 test reports reviewed from November 2022, July 2024, and March 2024. Refer to D5403. 2. The lab failed to establish performance specifications for a FDA-modified i-STAT CG8+ test system. Refer to D5423. 3. The lab's control procedure for coagulation testing on the TEG6S failed to include two materials of different concentration. Refer to D5447. 4. The lab's control procedures for rupture of membrane (ROM) failed to document control test results. Refer to 5481.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with laboratory staff, the laboratory failed to have a policy for i-STAT CG8+ cartridge that included arterial and venous cord blood specimen types, step-by-step instructions for collection and testing of arterial and venous cord blood specimens, and reference intervals for arterial and venous cord blood specimens. Findings include: 1. Review on 7/1/24 of five patient records from, 11/22/22, 7/14/2023, and 3/30/24 revealed the test reports for cord blood testing included reference intervals for arterial whole blood, venous whole blood, capillary whole blood, venous cord blood, and arterial cord blood for testing using the i-STAT CG8+ cartridge. The CG8+ cartridge includes the following analytes: sodium, potassium, ionized calcium, glucose, hematocrit, hydrogen concentration (pH), oxygen partial pressure, and carbon dioxide partial pressure. 2.

Review on 7/1/24 of the laboratory's policy titled "POCT 312 i-STAT 1 System CG8+ Cartridge", dated 10/24/23, revealed no reference ranges for capillary whole blood, venous cord blood, and arterial cord blood. Further review of the procedure revealed venous and cord blood specimens were not included as acceptable specimens and no instruction was provided for collection and testing of the cord blood specimens. 3. Interview on 7/1/24 at 12:05 p.m. with the Technical Supervisor for Point of Care Testing confirmed the above findings.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory (lab) failed to establish performance specifications for a modified FDA-cleared i-STAT CG8+ test system used in 2022, 2023, and 2024. Findings include: 1. Review on 6/14/2024 of the package insert for the i-STAT CG8+ test cartridge revealed it was intended for use with arterial, venous, and capillary whole blood specimens. CG8+ test cartridge includes the following measured analytes: sodium, potassium, ionized calcium, glucose, hematocrit, hydrogen concentration (pH), oxygen partial pressure, and carbon dioxide partial pressure. 2. Electronic mail (email) correspondence between the FDA and the Stage Agency on 6/18/2024 revealed the use of cord blood specimens on the i-STAT CG8+ test cartridge has not been approved by the FDA and use of cord blood specimens defaults to high complexity testing and performance specifications must be established for the modified test. 3. On 7/1/2024, the lab was asked to provide the test performance specifications (accuracy, precision, reportable range, analytic specificity, analytic sensitivity, and reference ranges) established for arterial and venous cord blood specimen testing on the i-STAT CG8+ cartridge and the lab was unable to provide any documentation. 4. Interview on 7/1/2024 at 10:40 a.m. with the Technical Supervisor for Point of Care Testing revealed the lab did not establish any of the test performance specifications before implementing cord blood testing on the i-STAT CG8+ test cartridge and began this testing in 2017. Total volume for the CG8+ test cartridge in 2022, 2023, and 2024 is 178, 238 and 110 respectively.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different

concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to include two control materials of different concentrations when performing activator F (ActF), kaolin heparinase, adenosine diphosphate, and arachidonic acid tests included with the Platelet Mapping Cartridge on the TEG 6S instrument in 2023 and 2024. Findings include: 1. Review of quality control records for the Platelet Mapping Assay Cartridge on the TEG 6S instrument from March 2023 to present revealed two levels of controls, normal (n) and abnormal (ab), run on 3/10/23, 7/24/23, 10/9/23, and 5/6/24. The control reports did not include acceptable ranges for each of the four analytes. Further review of control results revealed the results for the normal and abnormal ActF controls, for the above dates, were: 10.7 9 (n) and 9.4 (ab); 9.6 (n) and 9.3 (ab); 10.8 (n) and 10.7 (ab); 15.0 (n) and 15.1 (ab) respectively. 2. Interview on 6/13/24 at 10:15 a.m. with The Technical Supervisor in Hematology revealed the laboratory used a sample drawn from a healthy donor for the normal control and they spike a sample for the abnormal control. Interview also revealed acceptable ranges in use for quality controls were the laboratory's established reference ranges for normal and abnormal. 3. Review of the laboratory's established reference range for Platelet Mapping revealed that the range for ActF was 2-19 IFU.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based in record review and interview, the laboratory failed to document all control procedures performed for the Rupture of Membranes (ROM) plus test. Findings include: 1. Review on 6/14/24 of the "ROM plus Liquid QC" log for 10/30/23 to present, revealed the laboratory indicated on the log if the liquid control was acceptable - "Yes" or "No", not the test result "positive" or "negative". 2. Interview on 6/14/24 at 9:20 a.m. with the Technical Supervisor for Point of Care Testing confirmed the above finding.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of laboratory (lab) records and interview with laboratory personnel, the laboratory failed to indicate the name and address of the laboratory location where the test was performed and the specimen source on the test report for five of five reports reviewed between November 2022 and March 2024. Findings include: 1. Review on 7/1/24 of five cord blood specimen test reports from 11/22/2022, 7/14/2023, and 3/30/2024 revealed "VCRD" or "ACRD" and "SCN" or "NICU" under notes for hydrogen concentration (pH). The other analytes performed under the CG8+ cartridge did not include the specimen type code or test location code. The lab name and location was not included anywhere on the test reports. The CG8+ test cartridge includes the following measured analytes: sodium (Na), potassium (K), ionized calcium (iCa), glucose (Glu), hematocrit (Hct), hydrogen concentration (pH), oxygen partial pressure (pO2), and carbon dioxide partial pressure. 2. Interview on 7/1/24 at 11:45 with the Technical Supervisor (TS) for Point of Care Testing confirmed the above finding. The TS revealed VCRD stands for venous cord blood or ACRD is arterial cord blood; and SCN is special care nursery and beginning in 2024 the SCN unit was renamed NICU (neonatal intensive care). SCN and NICU is the location where the i-STAT was used to perform the testing on cord blood using the CG8+ test cartridge.

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 staff interview, the laboratory failed to provide the reference intervals for chemistry and hematology testing using arterial and venous cord blood specimen testing on the i-STAT CG8+ cartridge in 2022, 2023, and 2024. Findings include: 1. Review on 7/1/2024 of the lab's policy titled "POCT 312 i-STAT 1 System CG8+ Cartridge", dated 10/24/23, revealed the following reference ranges (arterial (A) and venous (V) whole blood: Na: (A and V) 134-146 mmol/L K: (A and V) 3.5-5.1 mmol/L iCa: (A and V) 1.07 - 1.27 mmol/L Glu: (A and V) 36-89 mg/dL Hct: (A and V) 40.0-51.0% pH: (venous) 7.31-7.41 pO2: (venous) 70-100 mm/Hg 2. Review on 7/1/24 of five cord blood specimen test reports revealed the following reference ranges did not match the procedure ranges (V for Venous, NS for specimen type not specified): Na: (NS) 131-144 mmol/L K: (NS) 3.2-5.7 mmol/L iCa: (NS) 1.00 - 1.5 mmol/L Glu: (NS) 36-89 mg/dL Hct: (NS) 35.0-49.0% pH: (V) 7.32-7.42 pO2: (V) 25-40 mm/Hg 3. Interview on 7/1/24 at 11:45 with the Technical Supervisor (TS) for Point of Care Testing confirmed the above findings. The TS revealed the laboratory believed arterial and venous cord blood specimens were the same as arterial and venous whole blood specimens (respectively).

D6108

LABORATORY TECHNICAL SUPERVISOR
CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and staff interview, the point of care testing (POCT) Technical Supervisor (TS) failed to perform responsibility requirements in 2022, 2023 and 2024. The POCT TS failed to establish test performance characteristics for cord blood testing using the i-STAT CG8+ test cartridge. Refer to D6115. The POCT TS failed to perform assessments of test performance for point of care testing personnel in 2022, 2023, and 2024. Refer to D6125.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and 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 record review and staff interview, the Technical Supervisor (TS) point of care testing failed to establish test performance characteristics (accuracy, precision, reportable range, analytic sensitivity, analytic specificity, and reference ranges) for arterial and venous cord blood specimen testing using the i-STAT CG8+ cartridge. Findings include: 1. Review on 6/14/2024 of the package insert for the i-STAT CG8+ test cartridge revealed it was intended for use with arterial, venous, and capillary whole blood specimens. CG8+ test cartridge includes the following measured analytes: sodium, potassium, ionized calcium, glucose, hematocrit, hydrogen concentration (pH), oxygen partial pressure, and carbon dioxide partial pressure. 2. Electronic mail (email) correspondence between the FDA and the Stage Agency on 6/18/2024 revealed the use of cord blood specimens on the i-STAT CG8+ test cartridge has not been approved by the FDA and use of cord blood specimens defaults to high complexity testing and performance specifications must be established for the modified test. 3. Interview on 7/1/2024 at 10:40 a.m. with the Technical Supervisor for Point of Care Testing revealed the lab did not establish performance specifications before implementing cord blood testing on the i-STAT CG8+ test cartridge and began this testing in 2017. Total volume for the CG8+ test cartridge in 2022, 2023, and 2024 is 178, 238 and 110 respectively.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory's evaluation of the competency of personnel performing point of care testing failed to include the assessment of test performance in 2022, 2023, and 2024. Findings include: 1. Review on 6/13/24 of the laboratory's listing of tests performed revealed the laboratory performs the following point of care testing: Chem 8+ (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide), ACT (activated clotting time), creatinine, and CG8+ (sodium, potassium, ionized calcium, glucose, hematocrit, hydrogen concentration (pH), oxygen partial pressure, and

carbon dioxide partial pressure) test cartridges on the iSTAT; citrated kaolin, citrated kaolin with heparinase, citrated rapidTeg, citrated functional fibrinogen, and Platelet Mapping adenosine-5' diphosphate (ADP) & arachidonic acid (AA) on the TEG6s; Rupture of Membranes Test (ROM+); O2 saturation on the AVOXimeter; blood gases (pH, pO2, and pCO2) on the rapid point. 2. Review on 6/13/24 of the laboratory's personnel list revealed 273 testing personnel performed any one or more of the point of care tests listed in the above finding. 3. Review on 6/13/24 of competency assessments for 14 personnel who performed point of care laboratory testing revealed 11 personnel's evaluation of competency did not include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 4. Interview on 6/13/24 at 12:15 p.m. with the Technical Supervisor for Point of Care Testing and respiratory testing personnel revealed competencies for the assessment of test performance was only assessed for the limited number of personnel who participated in proficiency testing and for Respiratory testing personnel who were assessed using blind testing of control samples on the rapidpoint instrument. All personnel who did not participate in proficiency testing, had not been assessed for test performance through either testing previously analyzed specimens or internal blind testing samples.

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on record review and staff interview, three of six point of care testing personnel records reviewed failed to meet qualification requirements for high complexity chemistry and hematology testing in 2022, 2023, and 2024. Refer to D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At

least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, three of six point of care testing personnel failed to meet qualification requirements for high complexity chemistry and hematology testing in 2022, 2023, and 2024. Findings include: 1. Electronic mail (email) correspondence between the FDA and the Stage Agency on 6/18/2024 revealed the use of cord blood specimens on the i-STAT CG8+ test cartridge has not been approved by the FDA and use of cord blood specimens defaults to high complexity testing. 2. Review on 7/1/2024 of six personnel records for testing personnel (TP) from the neonatal intensive care unit (NICU) revealed three (TP1, TP2, and TP3) of the six TP records did not have documentation of qualifications to perform high complexity testing using cord blood specimens with i-STAT CG8+ cartridge. TP1's record included an Associate's Degree in Nursing; TP2's record included a high school diploma; and TP3's record included a Bachelor of Science degree without specifying the major. There were no other qualifying documentation included in the records. 3. Interview on 7/1/2024 at 11:00 a.m. with the Technical Supervisor (TS) for point of care testing confirmed TP1, TP2, and TP3 did not meet qualification requirements for high complexity testing. The TS revealed the i-STAT was believed to be moderate complexity testing using the manufacturer's "CG8+" test

cartridge with cord blood samples and all 34 NICU testing personnel qualifications had been assessed by the laboratory for moderate complexity testing and not for high complexity testing.