

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0982094	(X3) Date Survey Completed 02/04/2025
Name of Provider or Supplier Children's Hospital Of Wi-Fox Valley	Street Address, City, State 130 2nd St, Neenah, WI	
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 completed on February 4, 2025, the laboratory was found out of compliance with the CLIA regulations. The condition not met: D 6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant
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 surveyor review of personnel records and procedures and interview with the Administrative Director - Laboratory (Staff A), the laboratory did not have a documented competence evaluation for one of one Point of Care Testing (POCT) Coordinator Technical Consultant (TC) that had been in their role more than one year (Staff B) and did not have documented competence evaluations for ten of ten "Super User" technical consultants that were delegated responsibility for testing personnel competence assessments. Findings include: 1a. Review of personnel records revealed a 'Lead/Senior Tech Competence Assessment' form for Staff B with an assessment period of January 1, 2023, through December 31, 2023. The form did not include signatures of the employee or the manager and did not indicate the evaluation was specific for this laboratory. No evidence of documented competence assessment of Staff B in fulfilling their responsibilities as a technical consultant at this laboratory in 2024 was available. 1b. Review of personnel records for ten technical consultants identified as Super Users showed no evaluation of competence in performing assessments of testing personnel during 2023 or 2024. 2. Review of procedures for competence assessment showed an annual requirement for assessing technical consultants' competence in fulfilling their responsibilities. 3. Interview with Staff A on February 4, 2025, at 12:55 PM confirmed documentation of competence</p>

assessment of Staff B in fulfilling their technical consultant responsibilities at this laboratory was not available. During email communication on February 10, 2025, Staff A stated the signed copy of the 2023 competence assessment for Staff B could not be found, stated assessments for 2024 for Staff B were in process, and provided a form for documenting Super User competence in evaluation of testing personnel.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with a Point of Care Testing (POCT) Coordinator (Staff C), the laboratory did not complete one of the last three calibration verifications for the two i-STAT analyzers within six months of the prior calibration verification. Findings include: 1. Review of calibration verification records for the laboratory's two i-STAT analyzers showed the laboratory performed calibration verification procedures in April and December 2023 and in April and September 2024. 2. Interview with Staff C on February 4, 2025, at 11:40 AM confirmed the laboratory did not perform the i-STAT calibration verifications every six months and confirmed the laboratory performed a calibration verification in December 2023 that was due in October 2023.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of submitted survey forms, personnel records and interview with the Administrative Director and a Technical Consultant, one of eight reviewed individuals identified as technical consultants did not meet the academic qualification

requirements of 493.1411 of this subpart. Findings include: 1. One identified technical consultant did not have the required academic credentials to meet the qualification requirements. See D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) 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; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on surveyor review of the submitted Centers for Medicare and Medicaid Services (CMS) Form, CMS-209 'Laboratory Personnel Report (CLIA)' and personnel records and interview with the Administrative Director - Laboratory (Staff A) and a Technical Consultant (Staff C), one of eight reviewed technical consultants did not meet the academic qualification requirements as a technical consultant. Findings

include: 1. Review of the submitted CMS-209 form signed by the laboratory director on December 9, 2024, showed twelve individuals identified as technical consultants. Academic credentials were reviewed for eight of the identified technical consultants. 2. Review of personnel records provided during the survey and by email showed Staff D held a bachelor's degree in Health and Wellness Management and an Associate of Applied Science degree in Respiratory Therapy. Review of transcripts from University of Wisconsin (UW) La Crosse, UW Stevens Point, Concordia University, and Western Technical College failed to provide evidence Staff D met the technical consultant educational requirements for moderate complexity testing. 3. Interview with Staff A and Staff C on February 4, 2025, at 11:15 AM confirmed Staff D was delegated responsibility for competence evaluation of testing personnel, a technical consultant responsibility.