

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D0721195	<b>(X3) Date Survey Completed</b> 09/20/2022
<b>Name of Provider or Supplier</b> Lakeview Specialty Hospital & Rehab	<b>Street Address, City, State</b> 1701 Sharp Rd, Waterford, WI	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, observation of the CELL-DYN Emerald hematology analyzer, and interview with testing personnel, the laboratory did not retain the date the current box of diluent was put into use on the CELL-DYN analyzer. Findings include: 1. Review of laboratory records showed two reagent logs in use in the laboratory. The 'CELL-DYN Emerald Diluent Log' showed the current diluent in use was lot 1324, opened on February 17, 2022 and expired on August 31, 2022. A second diluent log from the analyzer, printed on February 1, 2022 showed the most recent entry on the log was September 8, 2021, lot number 1260, expiration date March 31, 2022. 2. Observation of the diluent in use on the CELL-DYN analyzer on September 14, 2022 at 12:27 PM showed the diluent was lot 1260 and that the diluent expired on March 31, 2022. 3. Interview with testing personnel (staff A) on September 14, 2022 at 12:45 PM confirmed the records did not show when the current box of diluent was installed on the analyzer and revealed staff A was not able to retrieve a current report from the analyzer. During further interview staff A said a service technician installed the current box of diluent on the analyzer when the technician was on site to resolve issues with the analyzer and found the diluent was empty. Staff A confirmed the laboratory had no documentation of the site visit of the service technician.</p>
<b>D5016</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.1210</p>

If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on surveyor review of laboratory records and procedures and interview with testing personnel, the laboratory did not meet the requirements specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. Findings include: 1. The laboratory did not document software updates for the two i-STAT analyzers in 2021 or 2022. See D5429. D5429 is a repeat deficiency previously cited on January 5, 2015. 2. The laboratory did not perform and document thermal probe function checks every six months as required for two i-STAT analyzers used in the laboratory. See D5431. 3. The laboratory did not test external quality control materials every 30 days in 2021 as required by their individualized quality control plan (IQCP) for testing performed on two i-STAT analyzers. See D5445 Item 1. 4. The laboratory did not perform external quality control testing on lot numbers of test cartridges prior to use for patient testing. See D5445 Item 2. D5445 is a repeat deficiency previously cited on November 30, 2016. 5. The laboratory did not evaluate and define the relationship between test results obtained on the two i-STAT analyzers in 2021 or 2022. See D5775. D5775 is a repeat deficiency previously cited on January 5, 2015. 6. The laboratory did not perform an annual quality assessment review of their IQCP for testing on the i-STAT analyzers in 2021. See D5791. D5791 is a repeat deficiency previously cited on October 4, 2018. D5016 is a repeat deficiency previously cited on January 5, 2015.

**D5024**

**HEMATOLOGY**  
CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on surveyor review of laboratory records, procedures, and manufacturer's instructions, observation of reagents, supplies and instruments, and interview with testing personnel, the laboratory did not meet the requirements specified in 493.1230 through 493.1256. Findings include: 1. The laboratory did not label hematology controls with reduced open expiration dates. See D5415. D5415 is a repeat deficiency previously cited on March 13, 2013. 2. The laboratory used expired diluent on the CELL-DYN analyzer for patient testing. See D5417. 3. The laboratory did not perform and document calibration or calibration verification of the CELL-DYN analyzer in 2021. See D5437. 4. The laboratory used two lot numbers of PT/INR (prothrombin time / international normalized ratio) test cartridges with the i-STAT analyzers for patient testing without testing external controls. See D5445 Item 2. D5445 is a repeat deficiency previously cited on November 30, 2016. D5024 is a repeat deficiency previously cited on March 13, 2013.

**D5205**

**COMPLAINT INVESTIGATIONS**  
CFR(s): 493.1233

The laboratory must have a system in place to ensure that it documents all complaints

and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with testing personnel, the laboratory does not have a system to record problems and the investigation of complaints. Findings include: 1. Review of laboratory records showed no evidence of documentation of complaints or problems in the laboratory. 2. Interview with testing personnel (staff A) on September 14, 2022 at 3:15 PM revealed a patient was tested with the CELL-DYN Emerald hematology analyzer and an abnormal high white cell count was reported. The test was also sent to a reference laboratory and the white cell count was normal. Testing at a later date showed the same results; the white cell count was high when tested on the CELL-DYN analyzer and normal when sent to the reference laboratory. Staff A confirmed this situation occurred after service of the CELL-DYN analyzer on June 15, 2022 and confirmed there was no documentation of the problem or the corrective actions taken. Further interview confirmed the laboratory did not have a system in place to document all complaints and problems reported to the laboratory or to document any investigations or corrective actions taken.

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation of hematology quality control (QC) material, review of procedures and the manufacturer's instructions and assay sheet, and interview with testing personnel, testing personnel did not label three of three opened QC vials with the shortened open expiration date. Findings include: 1. Observation of hematology QC vials in the laboratory refrigerator on September 14, 2022 at 12:20 PM revealed three control vials (Levels 1, 2, and 3) in a cup. The vials showed no date opened or a revised expiration date. 2. The 'CELL DYN Operation Procedure' included, "Check the expiration date and open-vial stability information on the QC package insert. Write the opened date on the QC vial." 3. Review of the manufacturer's instructions and assay sheet for the controls showed opened control vials have a reduced expiration date of eight days from the date opened. 4. Interview with testing personnel (Staff A and B) on September 14, 2022 at 12:45 PM confirmed testing personnel opened the hematology control vials used for quality control testing with the CELL-DYN analyzer and had not written the opened date or reduced expiration date on the three vials. D5415 is a repeat deficiency previously cited on March 13, 2013.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the CELL-DYN Emerald hematology analyzer, interview with testing personnel, and review of patient test results, the laboratory reported thirty-eight Complete Blood Count (CBC) patient test results using expired CELL-DYN Emerald Diluent in June and August 2022. Findings include: 1. Observation of the CELL-DYN Emerald hematology analyzer on September 14, 2022 at 12:27 PM revealed the diluent in use was lot number 1260 with an expiration date of March 31, 2022 (2022-03-31). 2. Interview with testing personnel (staff A) on September 14, 2022 at 12:45 PM confirmed personnel used expired diluent for patient testing and further interview at 2:00 PM revealed the diluent had been put on the analyzer for use on June 15, 2022. 3. Review of patient test reports showed personnel tested thirty-seven patient samples on the CELL-DYN analyzer from June 17 - 30, 2022 and tested one patient sample on August 8, 2022.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and records and interview with testing personnel, the laboratory did not document twice annual software updates in 2021 or 2022 for two of two i-STAT analyzers. Findings include: 1. The 'QCP and Individual Quality Control Plan for POC i-STAT Cartridges' procedure includes the following statement in section 9, 'General Test System', "Update software then check each meter with external electronic QC." 2. Review of laboratory records showed no documentation of software updates for the two i-STAT analyzers. (Serial numbers 380580 and 380625.) 3. Interview with testing personnel (staff A) on September 14, 2022 at 3:00 PM confirmed the laboratory had not documented twice annual software updates for the two i-STAT analyzers in 2021 or 2022. D5429 is a repeat deficiency previously cited on January 5, 2015.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and records and interview with testing personnel, the laboratory did not perform and document three of four thermal probe function checks in 2021 for the two i-STAT analyzers. Findings include: 1. The 'QCP and Individual Quality Control Plan for POC i-STAT Cartridges' procedure includes the following statement in section 9, 'General Test System', "Ensure the

thermal probe check is performed every 6 months on each meter." 2. Review of laboratory records showed personnel performed and documented the thermal probe function check for each of the two i-STAT analyzers as follows: Serial 380625: performed April 23, 2020, next performed February 24, 2022. Serial 380580: performed December 8, 2020, December 6, 2021, and February 24, 2022. 3. Interview with testing personnel (staff A) on September 14, 2022 at 3:00 PM confirmed the laboratory had no records for the i-STAT six-month thermal probe function checks in 2021 for two events on Serial 380625 and one event on Serial 380580.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on surveyor review of laboratory records and procedures and interview with testing personnel, the laboratory did not perform and document calibration or calibration verification of the CELL-DYN Emerald hematology analyzer every six months in 2021 as required by the laboratory's procedures. Findings include: 1. Review of records for the CELL-DYN Emerald hematology analyzer showed no evidence that testing personnel calibrated the analyzer or performed calibration verification in 2021. 2. Review of the 'CELL-DYN Emerald Operation' procedure showed the procedure required calibration verification at least every six months. 3. Interview with testing personnel (staff A) on September 14, 2022 at 3:00 PM confirmed the laboratory had no records available to show the laboratory calibrated or performed calibration verification every six months in 2021.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Item 1: Based on surveyor review of laboratory procedures and records and interview with testing personnel, the laboratory did not perform external control procedures

every thirty days as defined by their Individualized Quality Control Plan (IQCP) for the i-STAT analyzer for four of four cartridge types reviewed. Findings include: 1. Review of the "QCP and Individual Quality Control Plan for POC i-STAT Cartridges" procedure showed the manufacturer's external quality control requirements included, "2 levels of external liquid Quality Control (QC) must be performed:" "Every 30 days on each analyzer". The procedure also stated, "We have determined that the manufacturer's QC protocol is sufficient for this test, as performed in our laboratory, when the supplemental components outlined above are utilized to control identified risks". The laboratory director approved the procedure on October 28, 2016. 2. Review of quality control records from 2021 for four of the six cartridge types used in the laboratory showed testing personnel did not perform external QC every thirty days. Review of four cartridge types showed personnel documented performance of two levels of external QC in 2021 as shown below: Prothrombin Time / International Normalized Ratio (PT/INR): Monthly in January through July and December. Personnel did not document control testing in August through November. B-type natriuretic peptide (BNP) January 19, February 25, April 1, April 30, May 20, June 13. Troponin: January 21, February 25, May 12, May 20, June 13, September 1, December 7. EG7+ cartridge: February 2, February 25, April 29, May 20, June 13, July 25. No other QC records from 2021 were available for these four cartridge types. QC was not performed every thirty days in four of twelve months for the PT/INR cartridge, eight of twelve months for the BNP and EG7+ cartridges, and seven of twelve months for the Troponin cartridge. 3. Review of patient test records showed personnel performed patient testing with each of the four reviewed cartridge types from August through December 2021. (See D6004.) 4. Interview with testing personnel (staff A) on September 14, 2022 at 2:45 PM confirmed personnel did not perform external quality control testing on the i-STAT analyzers every thirty days in 2021 as required in the IQCP. Item 2: Based on surveyor review of laboratory procedures and records and interview with testing personnel, the laboratory did not perform external control procedures with each new lot used for patient testing as defined by their Individualized Quality Control Plan (IQCP) for the i-STAT analyzer for two of two cartridge types reviewed. Findings include: 1. Review of the 'QCP and Individual Quality Control Plan for POC i-STAT Cartridges' procedure showed the manufacturer's external quality control requirements included, "2 levels of external liquid Quality Control (QC) must be performed:" "On every new lot number and every new shipment of cartridges on each analyzer." The procedure also stated, "We have determined that the manufacturer's QC protocol is sufficient for this test, as performed in our laboratory, when the supplemental components outlined above are utilized to control identified risks". The laboratory director approved the procedure on October 28, 2016. 2. Review of patient test records showed personnel performed patient testing for Prothrombin Time / International Normalized Ratio (PT/INR) and Chemistry panels (CHEM8+) with the following lot numbers: PT/INR Lot number / Dates used / number of patient tests T22179 / August 17 - September 1, 2022 / 23 patients T22196 / September 2 - 9 / 5 patients CHEM8+ H22124 / August 19 - September 14, 2022 / 25 patients 3. Review of QC records showed no external liquid QC test results for PT/INR Lot T22179 or T22196 or CHEM8+ lot H22124. 4. Interview with testing personnel (staff A) on September 14, 2022 at 2:45 PM confirmed testing personnel did not perform external quality control testing on the i-STAT analyzers for every new lot number and every new shipment as required in their IQCP. D5445 is a repeat deficiency previously cited on November 30, 2016.

**D5775**

COMPARISON OF TEST RESULTS  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
Based on surveyor review of laboratory records and interview with testing personnel, the laboratory did not evaluate and define the relationship between the two i-STAT analyzers twice annually in 2021 or 2022. Findings include: 1. Review of laboratory records showed no evidence the laboratory evaluated or defined the relationship between testing performed on the two i-STAT analyzers, serial number 380625 and 380580, twice annually in 2021 or 2022. 2. Interview with testing personnel (staff A) on September 14, 2022 at 3:00 PM confirmed the laboratory did not evaluate or define the relationship between test results obtained on the two i-STAT analyzers in 2021 or 2022. D5775 is a repeat deficiency previously cited on January 5, 2015.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on surveyor interview with testing personnel and review of laboratory records, the laboratory has not documented corrective actions completed since June 2022 when the laboratory determined the CELL-DYN Emerald hematology analyzer was not functioning as expected. Findings include: 1. Interview with testing personnel (staff A) on September 14, 2022 at 9:15 AM revealed the CELL-DYN Emerald hematology analyzer was not functioning as expected and the laboratory was not using the analyzer for patient testing. 2. Review of laboratory records showed no documented evaluation or corrective actions taken to bring the analyzer back into use. 3. Further interview with staff A on September 14, 2022 at 12:45 PM revealed the laboratory had the analyzer serviced in June 2022. Staff A said the service technician changed parameters in the analyzer and testing personnel noted issues with patient results since then. (See also D5205.) Further interview confirmed the laboratory had no documentation of the service call and had no routine method for documenting corrective actions taken when instrumentation is not functioning within expected operating parameters.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the

following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of testing records and interview with testing personnel, the laboratory has not maintained a record system that identifies which testing personnel performed the complete blood count (CBC) analysis on the CELL-DYN Emerald hematology analyzer for 134 of 134 samples analyzed from August 18 through November 30, 2021. Findings include: 1. Review of patient result printouts from the CELL-DYN Emerald hematology analyzer from August 18 through November 30, 2021 showed 134 reports with the "Operator ID" on the report identified as "2829". The printouts showed testing personnel analyzed fifteen samples in August, thirty-five in September, sixty-six in October and eighteen in November 2021. The reports do not show any other testing personnel identifiers. Review of other testing records from the i-STAT analyzer showed staff A, staff D, staff E, staff F and staff H performed testing from August 18 through November 30, 2021. 2. Interview with testing personnel (Staff A) on September 14, 2022 at 3:30 PM confirmed multiple staff members performed testing on the hematology analyzer and the laboratory did not develop and maintain a method for identifying which testing personnel performed patient testing on the CELL-DYN Emerald hematology analyzer.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on surveyor review of procedures and laboratory records and interview with testing personnel, the laboratory did not follow their procedures for annual evaluation of the Individualized Quality Control Plan (IQCP) for i-STAT testing in 2021 or 2022. Findings include: 1. Review of the 'Continuous Quality Monitoring' procedure showed Part B included the following statements. "For all test systems that utilize an Individualized Quality Control Plan (IQCP), an IQCP deviation form will be used to document what the deviation was and what the corrective actions where (sic)." "The IQCP deviation forms will be utilized to review the effectiveness of the IQCP at the end of each year." 2. Review of laboratory records showed proficiency testing failures for i-STAT tests in 2021 and missing quality control events in 2021 and 2022. (See also D5445 and D6016.) The record review showed no evidence of IQCP deviation forms in 2021 or 2022 and no quality assessment documentation for the i-STAT IQCP in 2021. 3. Interview with testing personnel (staff A) on September 14, 2022 at 2:45 PM confirmed staff A knew of no records showing completion of IQCP deviation forms or a quality assessment of the IQCP for i-STAT testing. D5791 is a repeat deficiency previously cited on October 4, 2018.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of previous and current CMS (Centers for Medicare and Medicaid Services) Form 2567 (Statement of Deficiencies and Plan of Correction) and allegation of compliance, personnel, proficiency testing and patient test records and interview with testing personnel and facility staff, the laboratory director has not provided overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The laboratory director did not discontinue patient testing as stated in the submitted allegation of compliance to citations on CMS Form 2567 survey event NDDE. See D6004, item 1. 2. The laboratory director did not ensure the laboratory maintained corrective actions to prevent recurrence of previously cited deficiencies. See D6004, Item 2. 3. The laboratory director did not ensure proficiency testing samples were tested and reported as required. See D6016. 4. The laboratory director did not ensure testing personnel had the credentials and training required prior to testing patient samples. See D6029. 5. The laboratory director did not specify in writing the duties of each person performing patient testing and did not identify which tests each individual was authorized to perform. See D6032.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Item one: Based on surveyor review of the laboratory's submitted allegation of compliance for survey event NDDE and the CMS (Centers for Medicare and Medicaid Services) Form 2567 'Statement of Deficiencies and Plan of Correction', proficiency testing (PT), and patient testing records and interview with testing personnel, the laboratory director misrepresented the corrective actions taken in the laboratory and had not discontinued testing after August 18, 2021 as stated in the allegation of compliance. Findings include: 1. In the Plan of Correction Form F-00344 submitted by the laboratory for the PT monitoring survey dated January 10, 2022, event NDDE11, the laboratory stated, "Patient testing was suspended on August 18th, 2021 due to the lack of qualified personnel to perform the testing." The CMS Form 2567 for survey event NDDE showed the laboratory did not participate successfully in PT for the regulated analytes of Chloride, Carbon Dioxide, Creatinine, Glucose, Blood Gases (pCO<sub>2</sub>, pH, pO<sub>2</sub>), potassium, sodium, and urea nitrogen. 2. Review of

PT records in the laboratory showed the laboratory received failing scores (0%) for all samples in the following events from the Wisconsin State Laboratory of Hygiene (WSLH): WSLH PT 2021 Blood Gas 2; including results from the i-STAT CHEM8+ panel and EG7+ panel cartridges (Chloride (Cl), Carbon Dioxide (CO<sub>2</sub>), Creatinine, Glucose, Hematocrit %, Hemoglobin, Ionized Calcium, pCO<sub>2</sub> (partial pressure CO<sub>2</sub>), pH (potential of Hydrogen), pO<sub>2</sub> (partial pressure O<sub>2</sub>), Potassium, Sodium, and Urea Nitrogen (BUN) . WSLH shipped the PT samples on July 6, 2021. The result form included this handwritten statement, "No patient testing performed since 8/18/21. No qualified personnel." signed by the technical consultant and dated 11/13/21 and the laboratory director and dated 11/18/21. WSLH PT 2021 Cardiac 3; including BNP (B-type natriuretic peptide), CKMB (creatinine kinase, MB fraction), and Troponin. WSLH shipped the PT samples on September 27, 2021. The result form included this handwritten statement, "No patient testing performed since 8/18/21 since no qualified personnel." signed by the technical consultant and the laboratory director and dated 11/7/21. WSLH PT 2021 Blood Gas 3; including results from the i-STAT CHEM8+ panel and EG7+ panel. WSLH shipped the samples on November 1, 2021. The result form included this handwritten statement, "No patient testing performed since 8/18/21. No qualified personnel." signed by the technical consultant and the laboratory director and dated 2/5/22. WSLH PT 2021 HemeReg 3; including results from the CELL-DYN Emerald hematology analyzer and i-STAT PT/INR cartridge. WSLH shipped the samples on September 13-14, 2021. The result form included this handwritten statement, "No patient testing performed as of 8/18/21. No qualified personnel." signed by the technical consultant and the laboratory director and dated 11/13/21.

3. Review of patient test records showed patient testing continued after August 18, 2021; the review revealed the following patient test reports from August 18, 2021 through February 2022. August 18-31, 2021 CHEM 8+ (Date / number of patient results) August 18 / 4 August 19 / 1 August 20 / 5 August 23 / 1 August 24 / 2 August 26 / 3 August 27 / 3 August 30 / 2 August 31 / 2 EG7+ August 24 / 1 PT/INR August 20 - 31 / 8 CKMB and Troponin August 26 / 1 CELL-DYN August 20 - 31 / 15 September 2021 (Cartridge type / number of tests) BNP / 8 CHEM 8+ / 74 EG7+ / 2 PT/INR / 22 CELL-DYN / 35 October 2021 BNP / 3 CHEM 8+ / 98 EG7+ / 2 PT /INR / 25 CELL-DYN / 66 November 2021 CHEM 8+ / 20 EG7+ / 1 PT/INR / 19 CELL-DYN / 18 December 2021 BNP / 2 CHEM 8+ / 12 CKMB and Troponin / 1 PT /INR / 13 January 2022 CHEM8+ / 15 PT/INR / 14 February 2022 CHEM8+ / 1 PT /INR / 33

4. Interview with testing personnel (staff A) on September 14, 2022 at 10:00 AM confirmed testing personnel in the laboratory performed testing between August 18, 2021 and February 2022 while the director and technical consultant had stated no patient testing was performed and confirmed the laboratory director misrepresented the discontinuation of patient testing in the Allegation of Compliance for survey event NDDE11 and in the statements on the PT result forms.

Item 2: Based on surveyor comparison of previous CMS (Centers for Medicare and Medicaid Services) 2567 (Statement of Deficiencies and Plan of Correction) forms and deficiencies cited on the current Form CMS 2567 and interview with testing personnel, the laboratory director did not maintain corrective actions to ensure compliance with previously cited regulations. Findings include:

1. The following deficiencies were cited on CMS 2567 forms from prior surveys and are also cited on this Form CMS 2567: D5016 Routine Chemistry Condition previously cited January 5, 2015. D5024 Hematology Condition previously cited March 13, 2013. D5415 Test Systems, Equipment, Instruments, Reagent previously cited March 13, 2013. D5429 Maintenance and Function Checks previously cited January 5, 2015. D5445 Control Procedures previously cited November 30, 2016. D5775 Comparison of Test Results previously cited January 5, 2015. D5791 Analytic Systems Quality Assessment previously cited October 4, 2018. D6033 Technical Consultant - Moderate Complexity Condition previously cited

January 5, 2015 and May 4, 2020. D6053 Technical Consultant Responsibilities previously cited January 5, 2015 and November 30, 2016. 2. Interview with testing personnel (staff A) on September 14, 2022 at 3:30 PM confirmed the laboratory director did not maintain corrective actions to ensure compliance with previously cited regulations.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor review of proficiency testing (PT) and patient testing records and interview with testing personnel, the laboratory did not submit results for four of nine regulated PT events in Chemistry and Hematology in 2021 when patient testing was performed. Findings include: 1. Review of PT records in the laboratory showed the laboratory received failing scores (0%) for all samples in the following events from the Wisconsin State Laboratory of Hygiene (WSLH): WSLH PT 2021 Blood Gas 2; including results from the i-STAT CHEM8+ panel and EG7+ panel cartridges. WSLH shipped the PT samples on July 6, 2021. The result form included this handwritten statement, "No patient testing performed since 8/18/21. No qualified personnel." signed by the technical consultant and dated 11/13/21 and the laboratory director and dated 11/18/21. WSLH PT 2021 Cardiac 3; including BNP (B-type natriuretic peptide), CKMB (creatin kinase, MB fraction), and Troponin. WSLH shipped the PT samples on September 27, 2021. The result form included this handwritten statement, "No patient testing performed since 8/18/21 since no qualified personnel." signed by the technical consultant and the laboratory director and dated 11/7/21. WSLH PT 2021 Blood Gas 3; including results from the i-STAT CHEM8+ panel and EG7+ panel. WSLH shipped the samples on November 1, 2021. The result form included this handwritten statement, "No patient testing performed since 8/18/21. No qualified personnel." signed by the technical consultant and the laboratory director and dated 2/5/22. WSLH PT 2021 HemeReg 3; including results from the CELL-DYN Emerald analyzer and i-STAT PT/INR cartridge. WSLH shipped the samples on September 13-14, 2021. The result form included this handwritten statement, "No patient testing performed as of 8/18/21. No qualified personnel." signed by the technical consultant and the laboratory director and dated 11/13/21. The four reports from the WSLH showed "No result(s) received". 2. Review of patient test records showed patient testing continued after August 18, 2021; the review revealed the following patient test reports from August 18, 2021 through February 2022: August 18-31 CHEM 8+ (Date / number of patient results) August 18 / 4 August 19 / 1 August 20 / 5 August 23 / 1 August 24 / 2 August 26 / 3 August 27 / 3 August 30 / 2 August 31 / 2 EG7+ August 24 / 1 PT/INR August 20 - 31 / 8 CKMB and Troponin August 26 / 1 CELL-DYN August 20 - 31 / 15 September 2021 (Cartridge type / number of patient tests) BNP / 8 CHEM 8+ / 74 EG7+ / 2 PT/INR / 22 CELL-DYN / 35 October 2021 BNP / 3 CHEM 8+ / 98 EG7+ / 2 PT/INR / 25 CELL-DYN / 66 November 2021 CHEM 8+ / 20 EG7+ / 1 PT/INR / 19 CELL-DYN / 18 December 2021 BNP / 2 CHEM 8+ / 12 CKMB and Troponin / 1 PT/INR / 13 January 2022 CHEM8+ / 15 PT/INR / 14 February 2022

CHEM8+ / 1 PT/INR / 33 3. Interview with testing personnel (staff A) on September 14, 2022 at 10:00 AM confirmed the laboratory director did not ensure testing personnel tested PT samples as required and confirmed testing personnel did not submit PT results to WSLH for Cardiac event three, Blood Gas events two and three, and Hematology event three in 2021 when testing personnel were performing and reporting patient test results.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on surveyor review of patient test reports and personnel records and interview with testing personnel and email correspondence with the quality coordinator, the laboratory director did not ensure, prior to performing patient testing, that six of six testing personnel who performed patient testing in the laboratory since October 2021 had the appropriate education, and that three of six testing personnel received training appropriate to the testing performed in the laboratory. Findings include: 1. Review of patient test reports since October 2021 showed testing was performed by staff A, B, D, E, F, and G. 2. Review of personnel records in the laboratory showed no records were available for staff F and G. 3. Review of testing personnel credentials during the survey revealed the laboratory and human resources department did not have documentation showing testing personnel met the minimum academic qualifications for performing moderate complexity testing for staff A, B, D, E, F, or G. Staff A provided documentation of their credentials during the survey. 4. Email correspondence with the quality coordinator (staff I) on September 20, 2022 at 3:56 PM provided the names of testing personnel staff F and G, confirmation of the dates of testing for testing personnel, and credentials for testing personnel B, D, E, F, and G. 5. Review of training documentation in the laboratory showed a blank training form for staff E and no records for staff F and G. 6. Interview with testing personnel (staff B) on September 14, 2022 at 8:45 AM confirmed laboratory and facility management had not requested documentation of earned academic credentials prior to performing patient testing. 7. Interview with testing personnel (staff A) on September 14, 2022 at 11:30 AM confirmed credentials were not available in the human resources department or the laboratory, that credentials of testing personnel had not been evaluated prior to staff performing patient testing, and that training records were not available for all testing personnel.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with testing personnel, the laboratory director has not specified in writing the responsibilities and duties of four of four testing persons reviewed that showed which tests and procedures each individual was authorized to perform, whether supervision was required, and whether consultant or director review was required prior to reporting patient test results. Findings include: 1. Review of laboratory records showed no consolidated record documenting the responsibilities and duties of each consultant and test person. Review of the Competency Assessment forms showed the form includes a "Trainee Competency Score" with three options: Fully Authorized, Supervision Required, or not authorized to perform. The 'i-STAT Competency Assessment form' for staff D showed staff H completed the competence evaluation for PT/INR and did not complete the Trainee Competency Score. The 'i-STAT Competency Assessment' form for staff E showed staff H completed the competence evaluation, staff H did not identify which cartridge types were evaluated and did not complete the Trainee Competency Score. The form did not show the technical consultant evaluated competence of staff E. No training or competency records were available for staff F and G. 2. Interview with testing personnel (staff A) at 3:00 PM confirmed the director had not specified in writing the responsibilities of each testing person and consultant.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**

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 patient test records and laboratory records, observation of laboratory analyzers, and interview with testing personnel, the technical consultant did not provide technical oversight in accordance with 493.1413 of this subpart. Findings include: 1. The technical consultant did not resolve technical problems with the CELL-DYN Emerald hematology analyzer since at least July 1, 2022. See D6043. 2. The technical consultant did not ensure patient test results from the CELL-DYN Emerald hematology analyzer were not reported until corrective actions were completed. See D6044. 3. The technical consultant did not evaluate competence for all staff members that performed testing. See D6046. 4. The technical consultant did not complete a semiannual performance evaluation during the first year of testing for staff A. See D6053. D6053 is a repeat deficiency previously cited on November 30, 2016 and January 5, 2015. D6033 is a repeat deficiency previously cited on January 5, 2015 and May 4, 2020.

**D6043**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:

Based on surveyor review of patient testing records and laboratory records and interview with testing personnel, the technical consultant had not resolved the technical problems with the CELL-DYN Emerald hematology analyzer since at least July 1, 2022. Findings include: 1. Interview with testing personnel (staff A) on September 14, 2022 at 9:15 AM revealed testing personnel were not currently using the CELL-DYN Emerald hematology analyzer for patient testing. 2. Review of patient test records showed no CELL-DYN patient reports in July 2022, one patient test report in August 2022, and no patient test reports to date in September. 3. Review of laboratory records showed no documentation of any issues or corrective actions taken to address problems with the CELL-DYN analyzer. 4. Interview with testing personnel (staff A) on September 14, 2022 at 2:00 PM confirmed the technical consultant had not taken remedial actions and had not resolved technical problems with the CELL-DYN Emerald hematology analyzer.

**D6044**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:

Based on surveyor interview with testing personnel, observation of the CELL-DYN Emerald hematology analyzer, and review of patient test records, the technical consultant had not ensured patient test results were not reported until corrective actions had been taken and the CELL-DYN test system was functioning properly. Findings include: 1. Interview with testing personnel (staff A) on September 14, 2022 at 9:15 AM revealed testing personnel were not currently using the CELL-DYN Emerald hematology analyzer for patient testing. 2. Observation of the CELL-DYN Emerald hematology analyzer showed no indication the analyzer was not available for patient testing. 3. Review of patient test reports showed testing personnel tested a patient sample with the CELL-DYN Emerald hematology analyzer on August 8, 2022. 4. Further interview with testing personnel (staff A) on September 14, 2022 at 12:45 PM confirmed testing personnel were not to use the CELL-DYN analyzer for patient testing after July 1, 2022 and that the technical consultant did not ensure patient testing was not performed until corrective actions were taken.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(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 surveyor review of patient test reports, procedures, and laboratory personnel records and interview with testing personnel and email correspondence with the quality coordinator, the technical consultant did not evaluate competency of four of six testing personnel that performing testing between August 2021 and February 2022. Findings include: 1. Review of patient test reports from August 2021 through February 2022 showed evidence of testing performed by staff A, D, E, F, G and H. 2. The 'Personnel Competency' procedure states, "Documented competency is required for each individual including each test the individual is authorized to perform." The procedure also states, "The technical consultant will assist the laboratory director and monitor the competency process to ensure that this procedure is completed and all personnel remain competent." 3. Review of laboratory personnel records showed records for staff A, D, and E. The competency evaluation records for staff D and E were signed by another testing personnel (staff H). The records showed Staff H does not meet the academic qualification requirements for a technical consultant. No personnel records were available in the laboratory for staff F or staff G. 4. Email correspondence with the quality coordinator (staff I) on September 20, 2022 at 3:56 PM provided identification of staff F and G and confirmation of the dates of testing for staff F and G. 5. Interview with testing personnel (staff A) on September 14, 2022 at 11:30 AM confirmed there were no records showing evaluation of competence for staff F and G and no evidence the technical consultant evaluated competence of staff D or E.

**D6048**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
 CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:  
 Based on surveyor review of five of five patient test reports, previous Centers for Medicare and Medicaid Services (CMS) Form 209, 'Laboratory Personnel Report (CLIA)' and personnel records, and interview with testing personnel, the technical consultant did not review test reports to ensure testing personnel appropriately reported troponin and CKMB (creatin kinase, MB fraction) when a BNP (B-type natriuretic peptide) was ordered. Findings include: 1. Review of patient test reports showed the laboratory reported BNP, troponin and CKMB patient test results on a single form. Five of five BNP tests performed by staff D in October 2021 showed CKMB and Troponin results were reported with a slashed zero (0) when CKMB and Troponin were not ordered. 2. Review of competence evaluation records for staff D showed the technical consultant had not evaluated competence of staff D. Records showed staff H evaluated competence of staff D for performing PT/INR i-STAT tests. No documentation for competence evaluation of staff D for BNP testing was available. 3. Review of the Centers for Medicare and Medicaid Services (CMS) Form 209, Laboratory Personnel Report (CLIA) from the previous survey on December 8, 2020 showed staff H did not meet the minimum qualifications as a technical consultant. 4. Interview with testing personnel (staff A) on September 14, 2022 at 2:30 PM confirmed the CKMB and Troponin reports were marked with a slashed zero which could be interpreted as a negative test result, and that the technical consultant

had not evaluated test reports to ensure appropriate reporting of test results. Further interview revealed testing personnel had been instructed that a slashed zero was an acceptable method to report when the test was not performed.

**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 surveyor review of laboratory records and procedures and interview with testing personnel, the technical consultant did not perform a semiannual evaluation of the performance of one of one new testing personnel that had been performing testing for more than one year. Findings include: 1. Review of laboratory records showed documented training for staff A in May 2021 and annual competence evaluation in July 2022. No evidence of a semiannual evaluation is present. 2. The 'Personnel Competency' procedure states, "Personnel are required to have competency evaluated at least semiannually during the first year the individual performs patient testing." 3. Interview with testing personnel (Staff A) on September 14, 2022 at 9:22 AM confirmed a semiannual evaluation of performance was not completed. D6053 is a repeat deficiency previously cited on November 30, 2016 and January 5, 2015.

**D6067**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) 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) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on surveyor review of patient testing records, training records and interview with testing personnel, the laboratory has not ensured that six of six testing personnel that performed testing since October 2021 received training to ensure testing personnel had the skills, knowledge and awareness to reliably perform patient testing. Findings include: 1. Review of patient testing records showed staff A, B, D, E, F, and G performed patient testing since October 2021. 2. Review of the 'i-STAT Fingertick Training and Assessment' form used to document training for i-STAT testing showed the form did not show testing personnel received training in performance of maintenance, troubleshooting and calibration procedures, reagent stability and

storage, quality control procedures, or factors that could influence test results. 3. Review of personnel records showed no training documentation for i-STAT testing other than the 'i-STAT Fingerstick Training and Assessment' form. The training form for staff E was not completed or signed, no records were available for staff F or G. 4. Review of quality control records for the i-STAT analyzers showed testing personnel did not perform control testing for i-STAT cartridges as required by the manufacturer or the laboratory procedures. See D5445. 5. Review of i-STAT records showed staff did not perform or did not document function checks and software upgrades. See D5429 and D5431. 6. Interview with testing personnel (staff A) on September 14, 2022 at 2:30 PM confirmed testing personnel did not receive the necessary training to fully implement the quality control and maintenance procedures in the laboratory and ensure reliable patient testing.