Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0990491	10/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hshs St Vincent Hospital Regional Cancer Centers	1726 Shawano Ave, Green Bay, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with the Technical Consultant /Technical Supervisor (Staff A), the Laboratory Director or designee did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for one of two hematology PT events to date in 2025. Findings include: 1. Review of WSLH PT records revealed no evidence the Laboratory Director or designee signed the attestation forms for the second hematology PT event in 2025. 2. Interview with Staff A on October 8, 2025, at 9:20 AM confirmed the Laboratory Director or designee did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for the second hematology PT event in 2025.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory proficiency testing (PT) records, Wisconsin State Laboratory of Hygiene (WSLH) PT records, and interview with the Technical Consultant/Technical Supervisor (Staff A), the laboratory did not retain documentation of the handling, preparation, processing, examination, and each step in the testing and reporting of results for one of one hematology PT event in 2023 that occurred within the past two years. Findings include: 1. Review of the laboratory's PT records showed no evidence of testing records, reporting forms, and signed attestation statements for the third hematology PT event in 2023. 2. Review of WSLH PT website revealed the "PT Evaluation Report" for the third hematology PT event in 2023 was built October 23, 2023, less than two years ago. 3. Interview with Staff A on October 8, 2025, at 9:20 AM stated the laboratory inadvertently disposed of the PT records from 2023, and confirmed that laboratory did not retain documentation of the handling, preparation, processing, examination, and each step in the testing and reporting of results for one of one hematology PT event in 2023 occurring within the past two years.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Technical Consultant/Technical Supervisor (Staff A), the laboratory did not retain patient test records, including instrument printouts, quality control (QC), maintenance records, including function checks, and comparison studies for testing performed in the laboratory from October 1, 2023, through December 31, 2023, three months out of the two years that records are required to be retained. Findings include: 1. Review of laboratory records revealed no evidence of analytic systems records for testing performed from October 1, 2023, through December 31, 2023, including: -Sysmex "XS-1000i Maintenance Log" including documentation of corrective action on the instrument -Sysmex instrument printouts of patient test results -"Hematak Stainer Log" including documentation of corrective action for the stainer -"Hematology Manual Entry Log" for manual white blood cell (WBC) counts -"Manual Platelet Log" including documentation of QC, comparison studies between hemacytometer and Sysmex, and manual platelet counts -Laboratory temperature/humidity checks for room, refrigerator, and freezer 2. Interview with Staff A on October 8, 2025, at 12:40 PM stated the laboratory inadvertently disposed of the analytic system records from 2023, and confirmed the laboratory did not have records for testing performed in the laboratory for three months of the past two years, from October 1, 2023, through December 31, 2023.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) (a)(6) Test reports. Retain or be able to retrieve a copy of the original report

	(including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following: (a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d). (a)(6)(ii) Pathology test reports for at least 10 years after the date of reporting This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Technical Consultant/Technical Supervisor (Staff A), the laboratory did not retain critical results notification records, a component of the patient test report, from October 1, 2023, through December 31, 2023, three months of the past two years that records are required to be retained. Findings include: 1. Review of laboratory records revealed no evidence of critical results notification records, a component of the patient test report, from October 1, 2023, until December 31, 2023. 2. Interview with Staff A on October 8, 2025, at 12:10 PM revealed the laboratory used the "Critical Results Log" to document the notification of critical results to the patient's provider and the laboratory did not record this information electronically into the laboratory information system. Further interview stated the laboratory inadvertently disposed of the paper records from 2023, and confirmed the laboratory did not have critical results notification records, a component of the patient test report, for three months of the past two years, from October 1, 2023, through December 31, 2023.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory policies, forms, personnel records, and interview with the Technical Consultant/Technical Supervisor (TC/TS), Staff A, the laboratory's policy for competency assessment did not establish a complete process for evaluating the competency of personnel performing delegated responsibilities in three of three Clinical Laboratory Improvement Amendment (CLIA) regulations named positions, Technical Consultant (TC), Technical Supervisor (TS), and General Supervisor (GS). Findings include: 1. Review of the "Competency Assessment Policy", effective May 29, 2024, revealed the policy indicated "the medical director will deem Technical Supervisor, Technical Consultant, or designee competent to perform competency assessment of colleagues". The policy did not mention the GS. The policy also did not include a process for competency evaluation, including when competency is assessed after the personnel have been delegated to the TC, TS, and GS positions, and the frequency at which competency is assessed thereafter. 2. Review of the "Competency Assessment for General Supervisor" form revealed responsibilities that are outside of the scope of GS responsibilities as per the CLIA regulations. 3. Review of laboratory records for Staff B revealed a form signed by the former Laboratory Director on January 4, 2024, "Competency Assessment for General Supervisor/Technical Consultant" that was not inclusive of all CLIA responsibilities of the GS and TC. 4. Interview with Staff A on October 8, 2025, at 8:40 AM confirmed that the laboratory's policy did not address a process, including time and

	frequency for evaluating the competency of personnel performing delegated responsibilities in the TC, TS, and GS positions, and the forms the laboratory had in place were not inclusive of all CLIA responsibilities for the TC, TS, and GS positions.
D5789	TEST RECORDS CFR(s): 493.1283(b) (b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on surveyor review of test records and interview with the Technical Consultant /Technical Supervisor (Staff A), the laboratory did not retain instrument printouts generated by the Sysmex XS-1000i analyzer of automated hematology tests performed on the instrument for the past two of two years. Findings include: 1. Review of laboratory records revealed the Sysmex analyzer generates printouts of patient test results on samples requiring further workup. 2. Interview with Staff A on October 8, 2025, at 12:40 PM revealed testing personnel add handwritten comments, notes, and reminders on the instrument printouts and that the laboratory discards instrument printouts generated by the Sysmex after one day. Further interview confirmed the laboratory did not retain instrument printouts of patient test results containing handwritten comments, notes, and reminders generated by the Sysmex for the past two of two years.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on surveyor review of Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, laboratory policy and records, and interview with the Technical Consultant/Technical Supervisor (Staff A), the Laboratory Director did not follow up on problems that require corrective action for one of one hematology PT event in 2024. Findings include: 1. Review of WSLH PT records from the third hematology PT event in 2024 revealed the laboratory failed one of five of the challenges for erythrocytes (RBC). 2. Review of the laboratory's policy "Proficiency Testing Medical Oncology Laboratories", effective March 10, 2016, section V. Unacceptable Results Investigation revealed, "All documentation of the investigation must be signed by the Laboratory Director". 3. Review of the "Proficiency Test Corrective Action Check List" that the laboratory completed after receiving the failure on the RBC challenge revealed no evidence the Laboratory Director signed the form, indicating the Laboratory Director was not involved in follow up on problems requiring corrective action. 4. Interview with Staff A on October 8, 2025, at 9:20 AM confirmed the information in the policy that the Laboratory Director must sign the documentation of the investigation, and that the Laboratory Director was not involved in the corrective action follow up for the third hematology PT event in 2024.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Item 1: Based on surveyor review of laboratory records and interview with the Technical Consultant/Technical Supervisor (TC/TS), Staff A, the Laboratory Director did not specify, in writing, delegation of all responsibilities for three of three Clinical Laboratory Improvement Amendments (CLIA) regulations named positions, Technical Consultant (TC), Technical Supervisor (TS), and General Supervisor (GS). Findings include: 1a. Review of laboratory records revealed the current Laboratory Director delegated responsibility for submission and review of quality control, proficiency testing submission and review, and annual colleague competency evaluation to Staff A on June 4, 2025. 1b. Review of laboratory records revealed Staff A delegated staff orientation and annual colleague competency evaluations to three staff members, Staff C, D, and E on June 6, 2025. 1c. Further review of laboratory records showed no evidence the Laboratory Director delegated, in writing, the other TC responsibilities identified at 493.1413, TS responsibilities identified at 493.1451, and GS responsibilities identified at 493.1463. 2. Interview with Staff A on October 7, 2025, at 4:30 PM confirmed the Laboratory Director did not delegate all TC/TS regulatory responsibilities and confirmed the Laboratory Director or designee did not delegate all regulatory responsibilities of the GS. Item 2: Based on surveyor review of laboratory records and interview with the current Technical Consultant/Technical Supervisor (TC/TS), Staff A, the previous Laboratory Director did not delegate, in writing, the responsibility for completing the annual testing personnel competence assessment in 2024 for one of one previous TC/TS who was also testing personnel (Staff B). Findings include: 1. Review of annual competency assessment records for testing personnel (Staff B) from 2024 revealed Staff A, who was a testing personnel in 2024, signed the competency assessment attestation for Staff B. The attestation stated, "Based upon successful completion of this competency assessment, the employee is deemed to be competent to perform patient testing unsupervised." 2. During an interview on October 8, 2025, at 8:40 AM Staff A stated she was asked to and performed the competency assessment for Staff B, and confirmed the previous Laboratory Director did not delegate this responsibility in writing. Item 3: Based on surveyor review of Centers for Medicare and Medicaid Services (CMS) Form 209, "Laboratory Personnel Report (CLIA)", laboratory records, and interview with the Technical Consultant/Technical Supervisor (Staff A), the Laboratory Director did not maintain a current list of assigned duties/responsibilities for one of one personnel, Staff B. 1. Review of the CMS Form 209 received for this survey and signed by the Laboratory Director on September 30, 2025, revealed Staff B was identified only as testing personnel. 2. Review of laboratory records revealed a form signed by the current Laboratory Director on May 20, 2025, designating Staff B as a Technical Consultant with oversight of the annual colleague competency evaluation. 3. Interview with Staff A on October 7, 2025, at 4:30 PM revealed Staff B is no longer in the Technical Consultant role, and confirmed the information on the CMS Form 209 was correct at the time of the survey. Further interview confirmed the delegation for Staff B was not current and that the Laboratory Director had not maintained a

	current list of assigned duties and responsibilities.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) (b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory quality control (QC) and maintenance records for the Sysmex XS-1000i hematology analyzer, and interview with the Technical Consultant/Technical Supervisor (Staff A), a testing personnel did not correctly document QC activities and instrument maintenance performed for one of 30 days in September 2024. Findings include: 1. Review of the Sysmex Insight report for September 2024 revealed the laboratory did not report QC for September 30, 2024. 2. Review of the laboratory's Sysmex "XS-1000i Maintenance Log" for September 2024 revealed a testing personnel documented performance of QC on September 30, 2024, and the "Troubleshooting/QC Events/Errors" section of the log was blank. 3. Interview with Staff A on October 8, 2025, at 11:20 AM revealed the laboratory took the analyzer out of service on September 30, 2024, due to errors during the analyzer start up and the laboratory did not perform any patient tests on that day. Further interview confirmed the electronic log on the Sysmex XS-1000i analyzer showed QC was not run, and confirmed a testing personnel did not correctly document the QC activities and the instrument maintenance/troubleshooting performed on the "XS-1000i Maintenance Log". Item 2: Based on surveyor review of laboratory policies and quality control (QC) records, and interview with the Technical Consultant/Technical Supervisor (Staff A), a testing personnel did not follow the laboratory's procedure for performing new QC lot crossover studies for the Sysmex XS-1000i hematology analyzer for one of one QC lot crossover studies reviewed in 2024. Findings include: 1. Review of Section II.d. New QC lot crossover or parallel studies in the "Sysmex XS-1000i Managing QC Policy", revised February 5, 2021, revealed ten data points for each of the three levels of QC must be established before the lot can be acceptable for use in QC testing. 2. Review of the Sysmex Insight reports for in-use QC lot #4008, expiration March 29, 2024, and new QC lot #4064, expiration May 3, 2024, revealed the following: 2a. Data entries for the new QC lot #4064 started on March 22, 2024. From March 22, 2024 to March 27, 2024, the report showed the laboratory captured six data points for each of the three QC levels. 2b. On March 28, 2024, the Sysmex Insight report showed runs for Level 1 and Level 2 on the new QC lot #4064 and runs for Level 3 on the in-use QC lot #4008. 2c. A note on the Sysmex Insight report indicated a testing personnel accepted the QC results on the runs for Level 1 and Level 2 on the new QC lot #4064 and for Level 3 on the in-use QC lot #4008 as acceptable QC results for March 28, 2024, and proceeded with patient testing on the Sysmex. 3. Interview with Staff A on October 8, 2025, at 10:45 AM confirmed a testing personnel did not follow laboratory procedures when they accepted the QC results of the new lot for patient testing prior to the completion of the new QC lot crossover studies for one of one QC lot crossover studies reviewed in 2024.