Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D1042208	02/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Cancer Center	1600 South Lake Park Ave #1101, Hobart, IN	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in an approved proficiency testing (PT) program for five of five analytes (white blood cell count (WBC), red blood cell count (RBC), hemoglobin (HGB), hematocrit (HCT), and platelet count (PLT)) tested using the Medonic M-Series Automatic Hematology Analyzer in the specialty of Hematology from January 2021 to December 2021. Findings include: 1. The laboratory's policy "Proficiency Testing" (signed by the lab director on 6/5/2020) states that "the laboratory participates in the proficiency testing program through the American Proficiency Institute (API)." 2. On 02/08/2022 at 11: 28 am, SP1 (testing person) acknowledged that PT was not performed with API for 2021. At 11:29 am, SP1 and SP2 (testing person) confirmed that the laboratory was not enrolled in a PT program for 2021. 3. Review of patient (PT#1-PT#7) medical records indicated that complete blood counts (CBC) with white blood cell differentials (w/DIFF), which includes the five analytes tested with the Medonic M-Series Automatic Hematology Analyzer, were run in 2021 without PT being performed for the following: PT#1 on 01/28/2021 PT#2 on 01/05/2021 PT#3 on 04/12/2021 PT#4 on 07/20/2021 PT#5 on 09/08/2021 PT#6 on 11/17/2021 PT#7 on 12/15/2021 4. Annual test volume for the specialty of Hematology is approximately 41,206.

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 record review and interview, the laboratory failed to include the correct address of the laboratory that performed the complete blood count with white blood cell differential (CBC w/DIFF) test for seven of seven patient (PT#1-PT#7) test reports reviewed. Findings: 1. Review of seven patient (PT#1-PT#7) test reports indicated that the incorrect laboratory address was listed. 2. On 02/08/2022 at 12:12 pm, SP1 confirmed that the address on the patients' test reports was different from the address of the laboratory that performed the test. 3. Annual test volume for the specialty of Hematology is approximately 41,206.
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 record review and interview, the laboratory director failed to ensure that the laboratory was enrolled in an approved proficiency testing program for 2021 (refer to D6015); failed to ensure the laboratory established and followed written quality assessment policies for 2021(refer to D6021); and failed to ensure competency assessment policies were established and followed for three of three testing personnel (refer to D6031).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that the laboratory was enrolled in an approved proficiency testing program for five of five

	analytes (white blood cell count (WBC), red blood cell count (RBC), hemoglobin (HGB), hematocrit (HCT), and platelet count (PLT)) tested using the Medonic M-Series Automatic Hematology Analyzer in the specialty of Hematology from January 2021 to December 2021. Findings include: 1. The laboratory's policy "Proficiency Testing" (signed by the lab director on 6/5/2020) states that "the laboratory participates in the proficiency testing program through the American Proficiency Institute (API)." 2. On 02/08/2022 at 11:28 am, SP1 (testing person) acknowledged that PT was not performed with API for 2021. At 11:29 am, SP1 and SP2 (testing person) confirmed that the laboratory was not enrolled in a PT program for 2021. 3. Review of patient (PT#1-PT#7) medical records indicated that complete blood counts (CBC) with white blood cell differentials (w/DIFF) which includes the 14 of 14 analytes tested with the Medonic M-Series Automatic Hematology Analyzer were run in 2021, without PT being performed for the following: PT#1 on 01/28/2021 PT#2 on 01/05/2021 PT#3 on 04/12/2021 PT#4 on 07/20/2021 PT#5 on 09/08/2021 PT#6 on 11 /17/2021 PT#7 on 12/15/2021 4. Annual test volume for the specialty of Hematology is approximately 41,206.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that the laboratory established and followed a written quality assessment policy for twelve of twelve months (January through December 2021) reviewed. Findings include: 1. On 02/08/2022 at 2:38 pm, upon request for a written quality assessment policy, SP1 (testing person) confirmed that the laboratory was not following a written quality assessment policy. 2. Review of "Qualty (sic) Assessment Suggested Calendar For Review" (dated February 2021, not signed by the laboratory director) indicated Proficiency testing is reviewed in April, July, and October. 3. Review of "Proficiency Testing General" (signed and dated by SP1 on April 23, 2021) indicated that the following parameters were deemed acceptable: A) "All proficiency testing is performed according to CLIA guidelines" B) "All testing documentation, submission forms, [and] attestation forms [are] retained" C) "A review of graded results has been conducted and is documented". 4. On 2/8/2022 at 11:29 am, SP1 and SP2 (testing person) confirmed that the laboratory was not enrolled in a PT program for 2021.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical

	phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that a written policy for assessing competency was established and followed for three of three testing personnel (SP1, SP2, SP4). Findings include: 1. Review of "Delegation of Laboratory Responsibilities" (signed by the laboratory director on 7/1/2020) indicated that SP1 (testing person) was delegated to be responsible for technical consultant responsibilities. These responsibilities included "Ensuring policies and procedures are established for monitoring personnel competency" and "Ensuring all personnel have been appropriately trained and demonstrate competency". 2. On 02/08 /2022 at 1:52 pm, upon request for the written policies for monitoring personnel competency, SP1 indicated that the laboratory was not following a written policy for assessing testing personnel competency.
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 record review and interview, the laboratory director failed to ensure two of two personnel (SP1 and SP2) performing the duties of a technical consultant (TC) were qualified personnel (refer to 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 possess qualifications that are equivalent to those required for such certification; 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 one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated

	specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure two of two (SP1 and SP2) personnel performing the duties of a technical consultant (TC) meet qualification requirements. Findings include: 1. The document "Delegation of Laboratory Responsibilities" (signed by the laboratory director on 7/1/2020) showed that SP1 was delegated to be responsible for TC responsibilities. These responsibilities included: - "Enrolling the laboratory in an approved proficiency program" - "Implementing acceptable quality assessment and quality control programs" - "Ensuring all personnel have been appropriately trained and demonstrate competency" - "Ensuring policies and procedures are established for monitoring personnel competency" 2. On 02/08/2022 at 10:20 am, SP1 acknowledged that their highest level of education was an Associate of Science in Medical Laboratory Technology. 3. Review of competency assessment evaluations from April 2021 for testing personnel (SP2 and SP4) indicated that SP1 was performing these evaluations. 4. On 02/08/2022 at 1:55 pm, SP1 indicated that only SP2 observed SP1 for SP1's 2021 competency assessment. 5. Review of the 2021 competency assessment documentation for SP1 (conducted in April 2021) indicated that SP2 signed off as the observer who was performing SP1's competency evaluation. 6. Review of SP2's education documentation indicated that SP2 was a high school graduate.