Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D1042208	04/11/2019
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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Repeat Deficiency Based on document review and interview, the laboratory failed to test proficiency testing (PT) samples in the same manner it tests patient specimens for one of five testing events reviewed (Event 1, 2018), for three of six analytes (white blood cell (WBC) count, platelet count, and hemoglobin) in the speciality of hematology. Findings included: 1. Review of policies/procedures indicated the following: a. A policy/procedure titled: "Proficiency Testing," signed by the Laboratory Director on 8-16-2017, read: "Survey samples are treated as patient samples." b. A policy/procedure titled: "Panic Value Policy," approval date unknown, read: "All panic values are to be repeated..." and indicated panic values included: 1) WBC count of less than 1,000 or greater than 100,000 microliters (uL) 2) Platelet count of less than 30 uL 3) Hemoglobin of less than 8.0 grams per deciliter (g/dL) 2. Review of PT documentation for PT testing event 1, 2018 indicated the following PT samples were tested twice, though analyzer printouts did not indicate panic values for the PT samples: a. Sample"HEM1" was tested on 3-20-2018 at "15:21:50" and again on the same date at "15:24"41." b. Sample"HEM2" was tested on 3-20-2018 at "15:25: 57" and again on the same date at "15:27:08." c. Sample "HEM4" was tested on 3-20-2018 at "15:32:09" and again on the same date at "15:33:20." e. Sample "HEM5" was

	tested on 3-20-2018 at "15:38:20" and again on the same date at "15:41:46." 3. In interview on 4-11-2019 at 1:30 PM, SP1 acknowledged four PT samples were not tested in the same manner as patient testing. SP1 acknowledged four of the PT samples were tested in duplicate, when there were no panic values noted on the test reports.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 document review and interview, the individual testing proficiency samples and the laboratory director failed to attest to the routine integration of proficiency testing (PT)samples into the patient workload using the laboratory's routine methods for four of five testing events reviewed (Event 3, 2017; Event 1, 2018; Event 2, 2018; and Event 1, 2019). Findings included: 1. Review of PT attestation statements indicated the following: a. The individual performing PT testing did not sign attestation statements, to indicate proficiency samples were tested in the same manner as patient samples, for the following PT testing events: Event 3, 2017; and Event 1, 2018. b. The laboratory director and/or designee did not sign attestation statements, to indicate proficiency samples were tested in the same manner as patient samples, for the following PT testing events: Event 3, 2017; Event 1, 2018; Event 2, 2018; and Event 1, 2019. 2. In interview on 4-11-2019 at 1:30 PM, SP1 acknowledged the following: a. The individual performing PT testing did not sign PT attestation statements for the following PT testing events: Event 3, 2017; and Event 1, 2018. b. The laboratory director did not have a designee and did not sign PT attestation statements for the following PT testing events: Event 3, 2017; Event 1, 2018; Event 2, 2018, and Event 1, 2019.
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 document review and interview, the laboratory failed to follow established competency policies and procedures for two of two testing personnel reviewed (SP1 and SP2, Testing Personnel). Findings included: 1. Review of policy/procedure titled: "Competency,"approved by the laboratory director on 8-19-2015, read: "The Lab Director will..." a. "...directly observe test performance..." b. "...Assess test performance using previously analyzed samples..." c. "...Assessment of problem solving..." d. "...Evaluate and document testing personnel performance at least semiannually for the first year..." 2. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the Laboratory Director on 4-9-2019, indicated SP1 and SP2 were testing personnel. 3. Review of personnel records indicated the following: a. Competency evaluations for SP1 and SP2 did not include direct observation of test

	performance, an assessment of test performance using previously analyzed samples, and an assessment of problem solving skills by the Laboratory Director for SP1 and SP2. b. SP2, hire date May, 2017, had one competency assessment for 2017 (dated 5-23-2017) and one competency assessment for 2018 (dated 7-15-2018). 4. Review of patient records indicated the following: a. SP1 performed patient testing on Patient #5 (11-20-2018); Patient #6 (3-11-2019); Patient #7 (3-11-2019); and Patient #8 (3-11-2019). b. SP2 performed patient testing on Patient #1 (12-11-2018); Patient #2 (12-19-2019); Patient #3 (3-22-2019); and Patient #4 (12-24-2018). 5. In interview on 4-11-2019 at 12:52 PM, SP2 confirmed testing on Patients #1 through #4 were performed by SP2. 6. In interview on 4-11-2019 at 12:57 PM, SP1 confirmed testing on Patients #5 through #8 were performed by SP1. 7. In interview on 4-11-2019, at 1:30 PM, SP1 confirmed the hire date for SP2 was in May, 2017 and confirmed there was no semiannual competency for SP2 performed. SP1 further acknowledged competency assessment didn't include direct observation of test performance, as assessment of test performance using previously analyzed samples, and an assessment of problem solving skills.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on document review and interview the laboratory failed to identify and correct problems with competency assessment for two of two testing personnel reviewed (SP1 and SP2) during 2018 and 2019. Findings included: 1. Review of competency assessment documentation for SP1 and SP2 indicated: a. The following elements of competency assessments were missing for SP1 and SP2: direct observation of test performance, an assessment of test performance using previously analyzed samples, and an assessment of problem solving skills. b. Competency assessment was not performed twice in the first year of employment for SP2, hire date May, 2017. 2. Review of "Quality Assessment Personnel Training and Evaluation General" indicated the following: a. Quality assessment reviews of competency was held annually, on 1-3-2018 and 1-28-2019 and both reviews were signed by the laboratory director. b. One of the "Measured Parameters" included "Documentation of a six month initial evaluation or annual evaluation" and was indicated to be "acceptable" during both reviews (1-3-2018 and 1-28-2019). 3. In interview on 4-11-2019 at 1:30 PM, SP1 acknowledged quality assessment documentation, dated 1-3-2018 and 1-28-2019, indicated competency assessments were "acceptable," though SP2 did not receive a competency twice in the first year of employment and there were missing elements of competency assessments for SP1 and SP2.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on document review, interview, and observation, the laboratory director failed to ensure an approved correction action plan was followed when proficiency testing (PT) results were unacceptable for one of five PT testing events reviewed (Event 3, 2018), for monocytes/mixed and neutrophils/granulocytes in the speciality of hematology. Findings included: 1. Review of policy/procedure titled: "Proficiency Testing," approved by the laboratory director on 8-16-2017, read: "Any unacceptable results will be followed up. Specimens will be rerun and action will be taken in order to correct the problem." 2. Review of PT testing event 3, 2018 indicated an "unacceptable" result for PT sample HSY-14 for neutrophils/granulocytes and monocytes/mixed and an overall White Blood Cell Differential score of 87%. "Proficiency Testing Performance Evaluation" form read: "Specimen HSY-14 repeated. Results attached." 3. In interview on 4-11-2019 at 1:30 PM, SP2 acknowledged the lab repeated PT sample HSY-14, but did not create a corrective action plan for the error. 4. On 4-11-2019 at 1:30 PM, SP2 was observed writing "Random Error" on the "Proficiency Testing Evaluation" form.