

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0356003	(X3) Date Survey Completed 07/27/2021
Name of Provider or Supplier Northwest Cancer Center	Street Address, City, State 3800 Saint Mary Drive Suite 302, Valparaiso, 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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and interview the laboratory failed to enroll in proficiency testing (PT) for six of six analytes (blood urea nitrogen (BUN), creatinine, sodium (NA), potassium (K+), chloride (Cl), and glucose) tested using the I-Stat CHEM8+ (blue) cartridge in the subspecialty of Routine Chemistry from February 7, 2020 to the day of the survey. Findings include: 1. On 7/27/2021, at 11:20 am during the tour of the laboratory an i-Stat was observed to be available for use in the laboratory. 2. Review of the letter from Abbot Point of Care, Inc, dated February 2020 indicated, effective February 28th, 2020... "the i-STAT CHEM8+ (blue) cartridge is no longer CLIA-waived." This cartridge tests include sodium, potassium, chloride, blood urea nitrogen (BUN), ionized calcium, total amount of carbon dioxide (TCO2), glucose, creatinine and hematocrit. 3. Review of the Federal Drug Administration Clinical Laboratory Improvement Amendments (CLIA) data base for test categorization i-STAT BLUE CHEM8+ Cartridge for BUN, NA, K+, Cl, and glucose is categorized as moderate complex effective 2/7/2020. 4. In interview on 7/27/2021, at 1:11 pm, SP#2 confirmed the laboratory was using the CHEM8+(blue) cartridge</p>

and tests BUN, NA, K+, CL, and glucose. SP#2 further acknowledged that the laboratory was not enrolled in proficiency testing (PT) for these analytes. 5. Annual test volume for the subspecialty of Routine Chemistry is 508.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview the laboratory failed to include two controls of different concentrations (liquid external controls) daily for six of six analytes (blood urea nitrogen (BUN), creatinine (CREA), sodium (NA), potassium (K+), chloride (Cl), and glucose) tested using the I-Stat CHEM8+ (blue) cartridge in the subspecialty of Routine Chemistry for four of five patient tests (PT # 7-PT10) reviewed. Findings include: 1. On 7/27/2021, at 11:20 am during the tour of the laboratory an i-Stat was observed to be available for use in the laboratory. 2. Review of the letter from Abbot Point of Care, Inc, dated February 2020 indicated, effective February 28th, 2020... "the i-STAT CHEM8+ (blue) cartridge is no longer CLIA-waived." This cartridge tests include sodium, potassium, chloride, blood urea nitrogen (BUN), ionized calcium, total amount of carbon dioxide (TCO2), glucose, creatinine and hematocrit. 3. Review of the Federal Drug Administration Clinical Laboratory Improvement Amendments (CLIA) data base for test categorization i-STAT BLUE CHEM8+ Cartridge for BUN, NA, K+, Cl, and glucose is categorized as moderate complex effective 2/7/2020. 4. Review of i-STAT patient records indicated the following patients were tested without daily external quality control (QC): Patient Test Date Test(s) Last External QC PT#7 2/10/2021 BUN, CREA 1/25/2021 PT#8 3/23/2021 NA,K+,CL 2/26/2021 PT#9 4/26/2021 NA, K+,CL 4/1/2021 PT#10 6/8/2021 BUN, CREA 6/1/2021 5. In interview on 7/27/2021, at 1:11 pm, SP#2 confirmed the laboratory was using the CHEM8+(blue) cartridge and tests BUN, NA, K+, CL, and glucose. SP#2 acknowledged that the laboratory was performing liquid external quality control monthly and each lot and shipment and did not perform external quality control daily. SP#2 further confirmed that the laboratory had not completed an Individualized Quality Control Plan (IQCP). 6. Annual test volume for the subspecialty of Routine Chemistry is 508.