

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0692147	(X3) Date Survey Completed 05/26/2023
Name of Provider or Supplier First Choice Immediate Care Mcreeary	Street Address, City, State 1900 North Hwy 27, Whitley City, KY	
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
D0000	A Recertification Survey was initiated on 05/26/2023 and concluded on 05/26/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation, document review, and interview, the laboratory failed to perform and verify accuracy, precision, and reportable range of 1 of 1 test instruments. Findings included: During the laboratory tour on 05/26/2023 at 10:05 AM, an Abbott I-Stat was observed. Testing Personnel-1 (TP-1) stated the facility acquired the instrument "a few months ago." Per TP-1, staff used the Abbott I-Stat to perform the troponin, creatine kinase-myocardial band (CK-MB), basic metabolic panel (BMP), and B-type natriuretic peptide (BNP) tests. Review of the testing procedure for the "I-Stat" showed prior to patient testing, staff performed QC and calibrations on 03/30/2023. Further review revealed it was signed and approved by the Laboratory Director (LD) on 04/03/2023. During an interview on 05/26/2023 at 11:55 AM, TP-1 stated the I-Stat instrument was previously used at another clinic and then moved to its present location. On 05/26/2023 at 12:23 PM, TP-1 presented the Surveyor with the installation and performance specification records from the installation of the instrument at the prior location, dated 08/28/2019. TP #1</p>

acknowledged there was no performance specification verification to include accuracy, precision, and reportable range for the instrument at the current laboratory. (Review of the "I-Stat" testing showed the laboratory performed 18 tests with the I-Stat from 04/13/2023 through 05/26/2023.)