

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D1101610	<b>(X3) Date Survey Completed</b> 03/12/2019
<b>Name of Provider or Supplier</b> Health Concepts Urgent Care Llc	<b>Street Address, City, State</b> 5410 Sheridan Lake Road, Rapid City, SD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 3/12/19. The Health Concepts Urgent Care LLC laboratory was found not in compliance with the following requirement: D5805.
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient specimen reports, patient electronic medical records, annual test volume form, quality assurance (QA) reports, and interview with the laboratory director, the laboratory failed to identify the full address of the laboratory that had performed testing on two of two sampled patient specimen reports (requisition numbers 035177 and RC135095) so a provider viewing those results could contact the testing laboratory in the event additional information or interpretation were needed. During the twelve month timeframe from 1/1/18 through 12/31/18 there were 19,262 complete blood counts (CBC) reported without the full address of where those tests had been done. Findings include: 1. Observation and review of the patient test result reports at 3:50 p.m. on 3/12/19 revealed: a. The print copy from the laboratory's information system (LIS) of requisition number 035177's CBC performed on 12/11/18 identified the performing laboratory as Health Concepts UC Lab. The laboratory's full address was not included. b. Both the report window</p>

and the print copy from the LIS of requisition number RC135095 Hepatitis C viral ribonucleic acid quantitative nucleic acid amplification test performed on 3/11/19 identified the performing laboratory as Sanford Lab. The report did not specify its full address. Review of the QA activities that had been performed since 1/1/18 revealed no monitoring of the information included on the test report. Interview at 3:50 p.m. on 3/12/19 with the laboratory director: \*CBC results were manually entered into the LIS. \*Reference laboratory results were downloaded into the LIS and should have included the testing laboratory's address. \*Laboratory reports were printed and faxed to the ordering providers. \*He was unaware the patient test reports did not identify the full address of the testing laboratory.