

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407501	(X3) Date Survey Completed 04/24/2019
Name of Provider or Supplier Huron Clinic Foundation Ltd	Street Address, City, State 111 Fourth St Se, Huron, SD	
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 for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 4/24/19. The Huron Clinic Foundation LTD laboratory was found not in compliance with the following requirement: D5775.
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) activities, annual test volume form, and interview with testing personnel A, the laboratory failed to establish criteria for acceptable differences between one of one test performed by multiple methodologies (manual white blood cell differential versus automated). That method comparison had not been evaluated twice a year in 2017 or 2018 to determine if their differences had been acceptable. Findings include: 1. Review of the laboratory's 2017 and 2018 QA activities revealed there had been no comparison testing for white blood cell differential manual versus automated. Review of the annual test volume form revealed 660 manual differential patient tests had been performed from 1/1/18 through 12/31/18 without comparison to the automated method. Interview on 4/24/19 at 10:25 a.m. with testing personnel A revealed the laboratory had not documented the twice a year comparisons between manual and automated differentials.</p>