

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0679417	(X3) Date Survey Completed 08/22/2023
Name of Provider or Supplier Chi Health Schuyler Laboratory	Street Address, City, State 104 West 17th Street, Schuyler, NE	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Individual Quality Control Plan (IQCP) for mononucleosis testing, review of the 2023 patient testing log for mononucleosis testing, and an interview with technical consultant #1 and compliance specialist, the laboratory failed to have a complete IQCP for mononucleosis testing. Findings are: 1. Review of the IQCP for mononucleosis testing revealed an incomplete IQCP. The IQCP was missing the risk assessment for mononucleosis testing. 2. Review of the 2023 patient testing log revealed thirteen mononucleosis tests performed in 2023. 3. Interview with technical consultant #1 and compliance specialist on 8/22/2023 at 2:25 PM confirmed the laboratory had the risk assessment missing from the mononucleosis IQCP.</p>
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</p>

results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory's list of tests performed, review of 2023 EPOC instrument patient log, review of two patient reports, review of method comparison documentation, and interview with technical consultant #1 and compliance specialist the laboratory failed to have a complete system that twice annually evaluated the relationship between test results using different methodologies for chemistry analytes sodium, potassium, and chloride. Findings are: 1. Review of the laboratory's list of tests performed revealed the laboratory performs testing for sodium, potassium and chloride on the Dimension EXL 200 instrument. 2. Review of the 2023 EPOC instrument patient log revealed two patients had chemistry testing for sodium, potassium, and chloride performed using the EPOC instrument. 3. Review of the two patient reports revealed the results for sodium, potassium, and chloride were resulted on 7/24/2023 and 7/30/2023 using the EPOC instrument result. 4. Review of the laboratory's method comparison revealed the last complete method comparison was performed on 8/7/2020. The laboratory presented data on a method comparison started on August 2023 but the evaluation of the data was not complete and the method comparison did not have laboratory director approval. 5. Interview with the technical consultant #1 and compliance specialist on 8/22/2023 at 12:34 PM confirmed the laboratory had failed to have a complete method comparison for the analytes sodium, potassium, and chloride performed on the Dimension EXL 200 and EPOC instrument.