

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407513	(X3) Date Survey Completed 10/07/2019
Name of Provider or Supplier Huron Regional Medical Center	Street Address, City, State 172 Fourth Street 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory supervisor, the laboratory failed to achieve successful participation for the subspecialty of Endocrinology. Unsatisfactory results had been received in two of three PT events (2019 Chemistry Core first and second events) resulting in unsuccessful PT participation. Refer to D2108.</p>
D2108	<p>ENDOCRINOLOGY CFR(s): 493.843(g)</p>

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) and CASPER reports, and interview with the laboratory manager, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the subspecialty of Endocrinology in two out of three events (2019 Chemistry Core first and second events), resulting in unsuccessful performance. Findings include: 1. Review of CASPER reports 153D and 155D revealed the API PT scores for the subspecialty of Endocrinology were less than the 80% required per CLIA requirements found at CFR 493.86 (a): a. 2019 Chemistry Core first event- Endocrinology score = 30%. - Free thyroxine score = 0%. - Thyroid stimulating hormone (TSH) score = 20%. - Thyroxine score = 0%. b. 2019 Chemistry Core second event- Endocrinology score = 75%. - HCG quantitative score = 20%. - TSH score = 80%. Interview with the laboratory manager on 10/4/19 revealed: *She was aware of the scores and had conducted an investigation into the unacceptable PT results. a. The 2019 first PT event unacceptable PT results were due to technician error. The laboratory staff member processed the same PT sample multiple times instead of running all 5 PT samples for the affected test methods. b. The 2019 second PT event HCG unacceptable PT results were due to technician error. The laboratory staff member failed to investigate multiple samples with similar results. c. The 2019 second PT event TSH unacceptable PT result was due to clerical error.