

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407513	(X3) Date Survey Completed 05/01/2019
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 manager, the laboratory failed to achieve successful participation for the mycology identification test method. Unsatisfactory results had been received in two of three PT events (College of American Pathologists F-C 2018 and American Proficiency Institute 2019 Microbiology 1st event) resulting in unsuccessful PT participation. Refer to D2046.</p>
D2046	<p>MYCOLOGY CFR(s): 493.827(e)</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 the federal proficiency testing (PT) reports 155D and 153D and interview with the laboratory manager, the laboratory failed to achieve a satisfactory score of 80% or above for the mycology identification test method for two of three events (College of American Pathologists [CAP] J-C 2018 and American Proficiency Institute [API] 2019 Microbiology 1st event). Findings include: 1. Review of the laboratory's CASPER Reports 153D and 155D revealed the laboratory had received unsatisfactory scores (less than 80%) for the mycology identification test method in each of the two events identified above. Review of the individual PT reports revealed:

- a. CAP J-C 2018 mycology identification score = 70%. *F-13 was reported as *Candida albicans* acromonium species. The acceptable results were *Candida albicans*, *Candida albicans/dubliniensis*, *Candida* species, or yeast, referred for ID. *F-16 was reported as *Mucor* species. The acceptable results were *Rhizopus* species, Mucorales presumptive identification, or mold recognized referred.
- b. API 2019 Microbiology 1st Event mycology identification score = 60%. *MY-04 was reported as *Acremonium* species. The acceptable response was *Pseudallescheria boydii*. *MY-05 was reported as *Curvularia* species. The acceptable response was *Alternaria* species.

Interview on 5/1/2019 with the laboratory manager confirmed the failure. She stated the laboratory had recently replaced their microbiology analyzer and had experienced staffing issues in microbiology. She had been reviewing patient reports to ensure no patients had been affected. The laboratory was considering referral of fungal isolates for identification in the future.