

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0519862	(X3) Date Survey Completed 10/16/2019
Name of Provider or Supplier So Big Horn Co Hospital	Street Address, City, State 388 Us Hwy 20 South, Basin, WY	
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 American Proficiency Institute (API) report review, Centers for Medicare and Medicaid Services, (CMS) Casper 153 and 155 reports review, and E-Mail interview concluded on 10/16/2019, the laboratory failed to successfully participate in proficiency testing for Chloride (CL) in two consecutive testing events and a subsequent failure (the 2nd and the 3rd events of 2018 and the second event of 2019). (See D2096.)</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

Failure to achieve satisfactory performance for the same analyte or test in 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 American Proficiency Institute (API) report review, CMS CASPER 153 and 155 reports review, and E-mail confirmation of test results, the laboratory failed to successfully participate in 2 consecutive proficiency testing events for Chloride, (CL) (API events 2 and 3 of 2018 and the 2nd event of 2019). Findings include: 1. API summary evaluation reports review for the second and third Chemistry events of 2018 included summary scores of 60% Chloride scores for the for the 2nd and 3rd API events of 2018 and a score of 20% for the 2nd API event of 2019. 2. Casper reports for 3 out of 4 events reviewed included Chloride scores of 60% for the 2nd and 3rd events of 2018, and 20% for the 2nd event of 2019. 3. In an E-mail interview begun on 10/03/2019 and continued to 10/16/2019, the laboratory technical supervisor confirmed the laboratory failed the 2nd API event of 2019 making 3 out of 4 Chloride failures.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on American Proficiency Institute (API) proficiency testing reports review, CASPER 153 and 155 reports review, and confirmation by the laboratory staff, the laboratory director failed to ensure corrective actions taken following two consecutive Chloride failures in 2018 as evidenced by the subsequent Chloride failure in the 2nd API testing event of 2019. (See D6092).

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on on American Proficiency Institute (API) proficiency testing reports review, CASPER 155 report review, and confirmation by the laboratory staff, the laboratory director failed to ensure the laboratory corrective action plan for two consecutive Chloride proficiency testing failures for the 2nd and 3rd events of 2018 corrected the problem to prevent recurrence in the 2nd API event of 2019. (See D2096).