

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  53D0666137	<b>(X3) Date Survey Completed</b>  08/23/2018
<b>Name of Provider or Supplier</b>  Star Valley Medical Center	<b>Street Address, City, State</b>  901 Adams Street, Afton, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<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 reports review and confirmation by the laboratory manager, the laboratory failed to achieve successful participation for partial Carbon Dioxide (pCO2) in 2 consecutive proficiency testing events (the 1st and 2nd American Proficiency Institute (API) testing events of 2018). Findings include: 1. The laboratory failed to attain a pCO2 score of at least 80% for the 1st and 2nd API events of 2018. (See D2087.) 2. In an interview with the laboratory manager on 08/28/2018 via email the laboratory manager confirmed they received scores of less than 80% for the 1st and 2nd API events of 2018.</p>

**D2087**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on proficiency testing reports review and interview with staff, the laboratory failed to attain a score of at least 80% for partial pressure Carbon Dioxide (pCO<sub>2</sub>) for the 1st and 2nd American Proficiency Institute (API) 2018 testing events. Findings include: 1. API proficiency testing reports reviewed included documentation the laboratory scored 40% for pCO<sub>2</sub> the first event of 2018 failing results for specimens: a. BG-01 t:he lab reported 42mmHg. The acceptable range was 47-58. b. BG-02 the lab reported 65mmHg. The acceptable range was 74-88. c. BG-04 the lab reported 25mmHg. The acceptable range was 29-39. 2. API proficiency testing reports reviewed included documentation the laboratory scored 60% for pCO<sub>2</sub> the Second event of 2018 failing results for specimens: a. BG-09 t:he lab reported 31mmHg. The acceptable range was 40-51. b. BG-0 the lab reported 20mmHg. The acceptable range was 23-33. 3. In an interview with the laboratory manager via email on 08/28/2018, the laboratory manager confirmed the laboratory failed to achieve successful participation for 2 consecutive proficiency testing events for pCO<sub>2</sub> test results.

**D5809**

**TEST REPORT**

CFR(s): 493.1291(e)

The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

This STANDARD is not met as evidenced by:

Based on new instrument verification records review, lack of documentation and interview with staff, the laboratory failed to provide pertinent updates to clients when test method changes occurred that affected test results for 10 of 31 tests verified for the new Architect immunoassay instrument. Findings include: 1. The laboratory verification records reviewed for the new Architect instrument included documentation the laboratory compared the new test method to the previous test method via correlation studies. Correlation studies of patient samples compared using the previous and new methods for B-type natriuretic Peptide (BNP), Carcinoembryonic Antigen (CEA), Dehydroepiandrosterone (DHEA), Estradiol, Ferritin, Follicle Stimulating Hormone (FSH), Insulin, Lutenizing hormone, Progesterone, and Testosterone included bias percentages of greater than 20% from the previous test method. BNP bias 37.8% FSH bias 21.18% CEA bias 29.7% Insulin bias 52.44% DHEA bias 32% LH bias 32.47% Estradiol bias 30.8% Prolactin bias 27% Ferritin bias 23.0% Testosterone bias 157% 2. In an interview conducted on 08/23 /2018 at approximately 6:00 P.M. staff confirmed the laboratory did not provide updates to clients that advised them of the changes in the new method's normal ranges.