

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0385384	<b>(X3) Date Survey Completed</b>  02/06/2019
<b>Name of Provider or Supplier</b>  Sanford Sheldon Medical Center	<b>Street Address, City, State</b>  118 North Seventh Avenue, Sheldon, IA	
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>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records, the Laboratory Test List &amp; Annual Volume form, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 02/06/2019, the laboratory failed to enroll in an approved proficiency testing program for the subspecialty of bacteriology for three out of three years from 2017-2019. The findings include: 1. The Laboratory Test List &amp; Annual volume form indicated that the laboratory performed limited bacteriology testing, including throat cultures. 2. At the time of the survey, personnel identifier #3 confirmed that the laboratory did not enroll in an approved proficiency testing program for the subspecialty of bacteriology (throat cultures) from 2017-2019.</p>
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> 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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) logs, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 3:45 pm on 02/06/2019, the laboratory failed to perform two levels of urine drug screen QC weekly for 22 out of 27 weeks from 04/01- 09/30/2018. The findings include: 1. The laboratory implemented and began using the Medtox urine drug screen test system in August 2017. 2. The laboratory's IQCP stated that QC would be performed with each new lot of tests and weekly. 3. The laboratory received five new lots of tests from 04/11- 09/06 /2018: \*Lot TD067M19, expiration 12/31/19 (Received 04/11/2018) \*Lot TD080C20, expiration 03/31/20 (No receipt date recorded) \*Lot TD081C20, expiration 03/31/20 (Received 05/25/2018) \*Lot TD091D20, expiration 04/30/20 (Received 07/09/2018) \*Lot 604022, expiration 06/30/20 (Received 09/06/2018) 4. The laboratory performed QC on the following dates: \*04/11/2018 (Lot TD067M19) \*05/21/2018 (Lot TD080C20) \*06/30/2018 (Lot TD081C20) \*08/12/2018 (Lot TD091D20) \*09/16 /2018 (Lot 604022) 5. At the time of the survey, personnel identifier #3 confirmed that the laboratory only performed QC with each new lot of tests and not weekly.