

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0036438	(X3) Date Survey Completed 07/02/2019
Name of Provider or Supplier Snow Health Center--Eastern Michigan University	Street Address, City, State 213 Snow Health Center, Ypsilanti, MI	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to rotate proficiency testing samples among all testing personnel who routinely perform patient testing for 6 (1 event in 2017, 3 events in 2018, and 2 events in 2019) of 6 testing events reviewed. Findings include: 1. Review of the CMS-209 signed by the director on 7/2/19 listed 2 testing personnel for moderate and high complexity testing and 2 testing personnel for moderate complexity testing. 2. A review of the American Academy of Family Physicians (AAFP) proficiency testing documents revealed Testing Personnel #1 and Testing Personnel #2 were the only testing personnel listed on the attestation for 6 proficiency testing events. The following are the events performed: a. Third event of 2017 i. Bacteriology ii. Endocrinology iii. Hematology iv. Microscopy b. First event of 2018 i. Bacteriology ii. Endocrinology iii. Hematology iv. Microscopy c. Second event of 2018 i. Bacteriology ii. Endocrinology iii. Hematology iv. Microscopy d. Third event of 2018 i. Bacteriology ii. Endocrinology iii. Hematology iv. Microscopy e. First event of 2019 i. Bacteriology ii. Endocrinology iii. Hematology iv. Microscopy f. Second event of 2019 i. Bacteriology ii. Endocrinology iii. Hematology iv. Microscopy 3. A review of the laboratory's 'Proficiency Testing' policy revealed a section stating, "all PT specimens will be tested in the same manner as patient specimens. All testing personnel are required to perform tests in any or all events." 4. An interview on 7/2/19 at approximately 11:45 am with the TC confirmed proficiency testing had not been rotated among all testing personnel.</p>

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

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 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 record review and interview with the Technical Consultant (TC), the laboratory failed to perform quality control as required for endocrinology testing for 1 (patient #02053793) of 17 patient charts reviewed. Findings include: 1. A review of patient charts revealed patient #02053793 had a qualitative serum Human Chorionic Gonadotropin (hCG) test reported on 6/19/19. 2. A record review of the laboratory's "External Quality Control Log" revealed the last recorded quality control testing for "QuickVue hCG combo kit" was completed on 1/8/19. 3. When requested, the TC was not able to provide the surveyor with documentation of an Individualized Quality Control Plan (IQCP) implemented in the laboratory. 4. A review of the "Policy and Procedure Manual" revealed a section stating, "the QuickVue hCG (serum) kit, being a moderately complexity test, will have 2 levels of external QC performed each day these are performed on patient samples in the laboratory." 5. An interview on 7/2/19 at 11:45 am the TC confirmed two different levels of external controls had not been performed each day of testing for the qualitative serum hCG test.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and interview with the Technical Consultant (TC), the laboratory failed to provide the educational requirements for 1 (Testing Personnel #4) of 4 testing personnel performing moderately complex testing. Refer to D6065. This is a repeat condition from the 11/16/16 survey.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have

successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure all testing personnel met the educational requirements at 493.1423 for 1 (Testing Personnel #4) of 4 testing personnel. Findings include: 1. A record review of testing personnel credentials revealed a lack of documentation of educational requirements for Testing Personnel #4 performing moderately complex laboratory testing. 2. During the interview on 7/2/19 at 10:03 am, the TC confirmed the above findings. 3. The laboratory was given five additional days to supply the necessary educational documents. The documents were not received. This is a repeat deficiency from the 11/16/16 survey.