

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405586	(X3) Date Survey Completed 01/10/2019
Name of Provider or Supplier Stevens Community Medical Center	Street Address, City, State 400 East First Street, Morris, MN	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Toxicology and Microbiology testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 1/9/19 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) as PT provider. 3. The laboratory received non-graded results from API due to no consensus for the events and tests listed below. Event = 2018 Chemistry Miscellaneous 1st Event Sample ID = UDS-02 Test = Urine Drug Screen - Opiates Event = 2018 Microbiology 2nd Event Sample ID = UR-06 Test = MIC Testing (Piperacillin / Taxobactum) 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 1/3/19 at 2:00 p.m., GS1 confirmed the above findings. .</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p>

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 1/9/19 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) as PT provider. 3. The laboratory received non-graded results from API due to no consensus for the events and tests listed below. Event = 2017 Chemistry Core 1st Event Sample ID = CH-01 Test = Free Thyroxine Event = 2018 Hematology / Coagulation 1st Event Sample ID = BFL-01 & BFL-02 Test = PMN* (CSF* Body Fluid)(%) 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 1/3/19 at 2:00 p.m., GS1 confirmed the above findings. *PMN = Poly Nuclear Neutrophil *CSF = Cerebrospinal Fluid .

D5439

CALIBRATION AND CALIBRATION VERIFICATION
 CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform calibration verification on a Coagulation analyzer at least every 6 months. Findings are as follows: 1. The laboratory performed Coagulation testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 1/9/19 at 10:05 a.m. 2. A Beckman Coulter ACL ELITE coagulation analyzer was observed as present and available for use during the tour of the laboratory. 3. The laboratory exceeded the 6 month calibration verification interval for D Dimer testing performed on the coagulation analyzer on one occasion in the time period reviewed; February 2017 through January 2019 . See below. Date of calibration 6/20/17 Date of calibration 3/28/18 Time elapsed 9 Months 4. In an interview on 1/10/19 at 2:25 p.m., the GS1 confirmed the above finding. .

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 1 of 1 new testing personnel received a competency evaluation at least semiannually during the first year of patient specimen testing. Findings are as follows: 1. Testing Personnel 10 (TP10) was listed on the Laboratory Personal Report (CLIA) Form CMS-209 as a part time testing personnel with a hire date of 8/30/17. 2. Initial training records indicated TP10 was deemed competent to perform independent laboratory testing in October 2017. 3. A semiannual competency assessment for TP10 was not completed within the first year of patient specimen testing as follows: Testing Area Date Completed Special Chemistry September, 2018 Serology October, 2018 Immunohematology December, 2018 Urinalysis December, 2018 Coagulation December, 2018 Hematology December, 2018 Microbiology December, 2018 4. In an interview on 1/03/19 at 12:15 p.m., the General Supervisor confirmed a semiannual competency evaluation had not been completed on-time. .