

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406287	(X3) Date Survey Completed 09/08/2023
Name of Provider or Supplier Lake Region Healthcare Barnesville	Street Address, City, State 209 2nd Street Se, Barnesville, 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
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> <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 one 2021 non-graded proficiency testing (PT) results for a non-regulated analyte when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Vaginal Wet Preparation testing, which falls under the specialty of Microbiology, as confirmed by the Technical Consultant during a tour of the laboratory at 9:05 a.m. on September 8, 2023. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. One Vaginal Wet Preparation result from the 2021 Hematology/Coagulation PT 3rd event was not graded by API due to lack of consensus. See below. Sample ID Analyte VKP-03 Vaginal Wet Preparation 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above sample was not present in laboratory records. Evaluation of the non-graded result was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded result upon request. 5. Requirements for the evaluation of non-graded PT results was not included in the Proficiency Testing procedure found in the Lab Procedure Manual. 6. In an interview at 10:08 p.m. on September 8, 2023, the Technical Consultant confirmed the above finding. ** This is a repeat deficiency from the September 22, 2021 recertification survey** .</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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in an Individualized Quality Control Plan (IQCP) four times in 8 months in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:05 a.m. on September 8, 2023. 2. An Abaxis Piccolo Chemistry test system was observed as present and available for use during the tour. 3. Two levels of external control material was required every 31 days as established in the IQCP procedure found in the laboratory's IQCP for the Abaxis Piccolo. 4. The laboratory exceeded the 31 day QC performance time interval four times in the time frame reviewed, January 1, 2023, through September 8, 2023, as indicated in Monthly Piccolo QC log. QC was performed as follows: QC Done QC Due 01/12/23 N/A 02/21/23 02/12/23 03/06/23 OK 5/23/23 04/06/23 07/06/23 06/23/23 08/16/23 08/06/23 5. In an interview at 11:25 a.m. on September 8, 2023, the TC confirmed the above finding. .