Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405317	(X3) Date Survey Completed 05/05/2022
Name of Provider or Supplier Sanford Tracy Medical Center	**Street Address, City, State** 251 5th St E, Tracy, 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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) 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. 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) result for a regulated analyte when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:25 a.m. on 05/05/22. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. One Blood Cell Identification (BCID) result from the second 2021 Hematology/Coagulation PT event was not graded by API. See below. Sample ID Analyte BCI-07 BCID 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 analyte was not present in laboratory records. Evaluation of the non-graded result was not found in laboratory records. 5. The laboratory's electronic Proficiency Testing procedure found in the PolicyTech software included direction to evaluate non-graded PT results. The laboratory was unable to provide an evaluation of the non-graded result upon request. 6. In an interview at 11:15 a.m. on 05/05/22, the GS confirmed the above finding. .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). 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 Bacteriology, Mycology, and Bacteriology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:25 a.m. on 05/05/22. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. One Vaginal Wet Preparation (VWP) result from the third 2021 Hematology /Coagulation PT event was not graded by API due to lack of consensus. See below. Sample ID Analyte VKP-03 VWP 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. 5. The laboratory's electronic Proficiency Testing procedure found in the PolicyTech software included direction to evaluate non-graded PT results. The laboratory was unable to provide an evaluation of the non-graded result upon request. 6. In an interview at 11:15 a.m. on 05 /05/22, the GS confirmed the above finding. .