Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0995625	09/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Wickersham Health Campus	1421 Premier Dr, Mankato, 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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to take corrective action for unsatisfactory proficiency testing (PT) scores after evaluating non-graded Hematology and Chemistry results in two of ten events in 2021, 2022 and 2023. Findings are as follows: 1. The laboratory performed manual blood cell differential and microscopic urinalysis testing, which fall under the specialties of Hematology and Chemistry respectively, as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m. on September 28, 2023. 2. The laboratory performed PT using the College of American Pathologists (CAP) provider. 3. One Blood Cell ID result from the KP-C 2021 Blood Cell ID, Photographs event and one Urine Sediment ID result from the CM-A 2023 Clinical Microscopy event was not graded by CAP due to lack of participant or referee consensus [27]. See below. Sample ID Analyte Reported Result BCP-24 Blood Cell ID Lymphocyte CMP-05 Urine Sediment ID Erythrocyte Dysmorphic 4. The laboratory reviewed the data summary from CAP for the Blood Cell ID and found that 1.4 % of the responding laboratories resulted the cell as a Lymphocyte and that 76.3% reported it as a Blast. The laboratory reviewed the data summary from CAP for the Urine Sediment ID and found that 29.9 % of the responding laboratories resulted the cell as a Erythrocyte Dysmorphic and that 57.3% reported it as a Leukocyte. The

	laboratory did not take corrective action for the unacceptable responses. 5. Requirements for the evaluation of non-graded PT results was included in the Proficiency Testing Procedure, signed by the Laboratory Director on 05/16/2022. On page 4 of the procedure, Evaluation of Proficiency Testing Results, the staff were directed to fill out an Exception Report if the result of the non-graded result due to lack of consensus was not acceptable. 6. In an interview at 10:35 a.m. on September 28, 2023, the Technical Consultant confirmed the above finding and further confirmed the laboratory had not filled out an Exception Report as directed by procedure documenting the corrective action the laboratory took for either event. .