Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450024	10/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Wamego Health Center	711 Genn Drive, Wamego, KS	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the non-waived test list, lack of procedure for review, patient test information and interview, the laboratory failed to have a written procedure for the Siemens RapidPoint 500e analyzer available to and followed by, laboratory personnel. Findings: 1. Review of the non-waived test list revealed the RapidPoint 500 e was used to perform the regulated analytes pH, pCO2 and pO2. 2. Request was made to review the procedure(s) for the operation of the RapidPoint 500e. 3. No procedure(s) were made available at the time of survey. 4. Review of reported patient results revealed 38 patient's results were released from 4/1/22 to 10/10/22 4. Interview with the General Supervisor (GS) #1 on 10/10/22 at 1:45 p.m. confirmed, the laboratory failed to have a written procedure for the Siemens RapidPoint 500e analyzer available to and followed by, laboratory personnel.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS-209 Laboratory Personnel Report, competency assessment documentation, Technical Supervisor (TS) Responsibilities policy and interview, the Technical Supervisors failed to evaluate the competency to perform immunohematology testing for seven of seven high complexity testing personnel for the year 2021 and to date of survey 2022. Findings: 1. Review of the CMS-209 Laboratory Personnel Report found seven individuals listed as high complexity testing personnel (TP) that had performed immunohematology testing at this site for more than six months. 2. Review of the competency assessments for seven of seven TP revealed no TS of immunohematology signature on the 2021 and to date 2022 competencies. 3. Review of the TS responsibilities policy revealed four individuals designated as TS for immunohematology delegated under (8) to: "Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results." 4. Interview with GS#1 10/10/22 at 1:50 p.m. confirmed, the Technical Supervisors failed to evaluate the competency to perform immunohematology testing for seven of seven high complexity testing personnel for the year 2021 and to date of survey 2022.