Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0454747	12/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Family Medicine	3307 Bill Schock Boulevard, Falls City, NE	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on surveyor observation, the laboratory's quality assurance policy, interview with the technical consultant, and interview with the Advanced Practice Registered Nurse (APRN), not designated as a testing personnel and not listed on the CMS 209 form, the laboratory failed to follow policies to ensure positive identification of a patient's specimen. 1. Surveyor observation of one of one capillary sample reveled the capillary sample was unlabeled. 2. The laboratory's quality assurance policy states "inappropriate labeled samples will be rejected and recollected." 3. Interview with the technical consultant on 12/8/2022 at 11:25 AM revealed the sample was not rejected but the sample was tested by the APRN. 4. Interview with the APRN on 12/8/2022 at 11:40 AM confirmed the APRN performed a hematology test on the unlabeled capillary sample. The APRN indicated she forgot to throw the sample away after testing it.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

	rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory and interview with the technical consultant, the laboratory failed to properly label twenty of twenty blood samples, six of six urine samples, and one of one capillary sample observed with the patient's first and last name, patient's date of birth, date and time of collection, and the initial's of collector per the laboratory policy. 1. During observation on 12/8/2022 at 11:20 AM, surveyor observed twenty blood samples labeled only with patient's first and last name. 2. During observation on 12/8/2022 at 11:20 AM, surveyor observed three urine samples labeled only with patient's first and last name and three urine samples labeled only with date of collection and patient's first and last name. 3. During observation on 12/8/2022 at 11:20 AM, surveyor observed one capillary sample with no label. 3. The written procedure for specimen labeling stated staff are to label specimens with the patient's first and last name, patient's date of birth, date and time of collection, and the initial's of collector. 4. The technical consultant confirmed during an interview on 12/8/2022 at 11:25 AM the laboratory did not follow its policy for labeling specimens.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on interviews with the Advanced Practice Registered Nurse and interviews with the technical consultant the technical consultant failed to provide technical and scientific oversight and failed to provide training for individuals performing testing. Refer to D6036 and D6045.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the instrument print out that the hematology instrument generated from testing the unlabeled capillary sample by the Advance Practice Registered Nurse (APRN), interview with the Advanced Practice Registered Nurse (APRN), and interview with the technical consultant revealed the technical consultant failed to provide technical and scientific oversight. 1. Review of the instrument print out that the hematology instrument generated from testing the unlabeled capillary sample revealed an instrument flag of "AG" on the platelet results. 2. Interview with the APRN on 12/8/2022 at 11:40 AM confirmed the the instrument print out that the hematology instrument generated after the unlabeled capillary sample was tested by the APRN had a flag of "AG" on the platelet result. The APRN confirmed the APRN did not know what the "AG" platelet flag result means. 3. Interview with the technical

	consultant on 12/8/2022 at 11:50 AM confirmed there was no training on the "AG" platelet flag.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) 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; This STANDARD is not met as evidenced by: Based on interview with the Advance Practice Registered Nurse (APRN), not designated as a testing personnel and not listed on the CMS 209 form, and interview with the technical consultant the technical consultant failed to provide training for the Advanced Practice Registered Nurse (APRN). 1. Interview with the APRN on 12/8 /2022 at 11:40 AM confirmed the APRN performed hematology testing on an unlabeled capillary sample and confirmed the APRN was not trained to perform hematology testing. 2. Interview with the technical consultant on 12/8/2022 at 11:50 AM confirmed the APRN was not on the CMS 209 form and was not trained to perform hematology testing.