Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468124	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Piggott Family Medical Clinic	425 W Jackson Street, Piggott, AR	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Through observation, review of manfacturer's package insert and interview it was determined that the laboratory failed to amend the expiration date of nine of nine cartidges for the determination of glycolated hemoglobin (A1c Hgb) when moved from refrigerated storage and placed at room temperature. Findings follow: A) Review of the manufacturer's storage requiements for Afinion A1c Hgb cartridges revealed a storage temperature requirement of 2 degrees C. to 8 degrees C. or 90 days at room temperature, and the date placed at room temperature must be documented. B) During a tour of the laboratory on September 15, 2022 at 11:35 a.m., nine Afinion A1c Hgb cartiridges, lot # 10217313 expiration date 2024-05-11 , were observed in a laboratory drawer without an amended expiration date or date of when the cartridges were placed at room temperature. C) When asked at the time, the testing personnel, (# seven on the CMS 209 form) stated that the cartridges were currently in use and the date of placing them at room temperature or an amended expiration date was not on the cartridges or a container in which they were kept.
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: Through review of laboratory policy and procedure, observation and interview it was determined that the laboratory failed to label 11 of 58 specimen collection containers with patient name and unique patient identifier. Findings follow: A) During a tour of the laboratory on 9/15/22 at 11:20 a.m. one of eight EDTA blood specimens and one of seven serum specimens in a rack labeled "Monday", and four of nineteen EDTA specimens and seven of fourteen serum specimens in a rack labeled "Tuesday" were observed in the laboratory refrigerator labeled with the patients first and last names only. B) Review of the laboratory policy and procedure revealed that specimen containers are to be labeled with the patient's first and last names and the patient's date of birth or unique identifier. C) In an interview on 9/15/22 at 11:25 a.m. , the laboratory staff members (#1 and #7 on the CMS 209 form) confirmed that the specimens identified above lacked proper patient identification on the containers as required by policy and procedure.