Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468970	(X3) Date Survey Completed 06/19/2024
Name of Provider or Supplier Conway Regional Medical Clinic -Russellville	**Street Address, City, State** 108 Skyline Drive, Russellville, 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
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 1 of 13 urine specimen collection containers with patient name and unique patient identifier. Findings follow: A) During a tour of the laboratory on 6/19/24 at 2:02pm one of thirteen urine specimen cups was observed on the laboratory bench labeled with the patients initials 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 6/19/24 at 2:03pm, the laboratory staff member (testing personel #1 on the CMS 209 form) confirmed that the specimen identified above lacked proper patient identification on the container as required by policy and procedure.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Through review of the laboratory's policy and procedure for "Quality Control" (QC), review of quality control Levy-Jennings charts for April through October of 2023 , review of the technical consultants QA review notes, lack of documentation and interview it was determined that the laboratory failed to recognize or take corrective action on six of six months data reviewed when quality control for platelet assays demonstrated a shift in values. Findings follow: A) Review of the laboratory's policy and procedure for QC revealed that "QC data is reviewed for trends and shifts to determine established acceptance criteria. When trends and/or shifts occur, corrective action is taken and documented." B) Review of QC reports from April to October of 2023 for Platelet assays performed on the Sysmex XP300 showed the high level control was at or below the mean for from April to OCtober of 2023. C) Upon request, the laboratory was unable to provide documentation that the shifts identified above had been identified and corrective action taken. D) Review of the Technical Consultants QA review notes for all of 2023 revealed there was no mention of shifts or trends for Platlet assays and no corrective action in regard to Platlet assays was identified. E) In an interview on 6/19/24 at 02:15pm the technical consultant confirmed that the QC values for Platelets were shifted below the target mean from April through October 2023 and no corrective actions were taken or documented.