

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2288538	(X3) Date Survey Completed 03/27/2024
Name of Provider or Supplier Ar Rural Diagnostics Pcr, Llc	Street Address, City, State 19 Medical Plaza, Suite 20, Mountain Home, 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
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation and an interview with laboratory staff the laboratory failed to follow established written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic systems. Findings include: A. The "PCR Testing Quality Control" policy (effective date 10/6/2023) included: "Recording Keeping: Quality Control data must be kept for each batch of patients samples run and must include: the date the batch was run, the batch number, QC outcome, any notes, comments, problems, or troubleshooting steps that were followed. Keep record as either hard copy (#6 PCR QC Log Form) or as electronic format as a part of LIS or EHR system for a minimum of 2 yrs. CLIA Director or designee must review log monthly. B. The PCR QC Log Form for 3 of 3 months (December 2023, January 2024, and February 2024) examined were reviewed by the Technical Supervisor, not the Laboratory Director. C. These findings were confirmed by the Technical Supervisor during an interview at 10:57am on 3/27/24. The Technical Supervisor confirmed there was no delegation authorization for them to review the QC log instead of the Laboratory Director.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Through a review of personnel files for the one testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to authorize one of one testing personnel to perform testing without direct supervision. Survey findings include: A) During a review of personnel files for testing personnel listed on form CMS-209 (Personnel #1) it was noted one of one testing personnel failed to have written authorization, from the laboratory director, to perform testing without direct supervision. B) In an interview, at 10:37 am on 03/27/24, laboratory employee #1 (as listed on the form CMS-209) confirmed the lack of written authorizations for employees to perform testing.