Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2165967	05/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Mitchell Family Medicine, Llc	924 State Hwy 77, Marion, 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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: . Based on a review of laboratory policy and interviews with laboratory staff, it was determined the laboratory failed to document criteria for acceptable quality control for Chemistry. Survey findings include: A. Laboratory policy "Quality Control Protocol" states "..If one control level is outside the expected range (app 2SD (sic approximately 2 Standard deviations)) for only one day but within 3SD the run may be accepted" and "New lots of control material are verified before use. This is accomplished by running at least one day of the old control with the new. The mean value for these runs must fall within the expected range of the manufacturer. The control ranges for the respective analytes are kept for two years." B. The surveyor reviewed chemistry quality control documentation for November 2025, February, 2026, and March 2026. Records documented a lot change for the "CHEM01" Lyphocheck Unassayed Chemistry Control (new lot 93401) occurred 11/11/25. Records documented one of ten runs for the level one CHEM01 control was omitted from the new lot validation, for all analytes. For Lipase, six of eight runs were omitted from the new lot mean calculation. C. Upon request, the lab was unable to provide documentation showing the mathematical criteria that led to the exclusion of certain

	runs from the mean calculation for the new lot. D. Upon request, the laboratory was not able to provide methods or criteria for control range and mean adjustments outside of new lot introductions. C. In an interview, at 3:03pm on 5/12/26, the Technical Consultant confirmed that the policy did not clearly specify the mathematical thresholds and procedures for adjusting means and standard deviations for chemistry controls.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on review of Technical Consultant's quality assurance reports, chemistry quality control records, laboratory policy, and interview with staff, it was determined that the laboratory failed to document effective corrective action to prevent recurrence of chemistry control baseline mean adjustments that fall outside laboratory policy. Survey finding follow: A. A review of the technical consultant's quality assurance report for November 13/18, 2025 stated ""the control review for the Vitros (Ortho Vitros 5600 Chemistry Analyzer) again showed several issues with controls. I met with Laboratory Director and Testing Personnel . The ongoing control issues were discussed and the options to correct the issue. A new corrective action form was put into place . I returned on the 18th and the controls are looking better. The staff is now aware of the proper way to do a lot to lot conversion." B. A review of the Laboratory Quality Control Policy stated "Procedure for Corrective Action - 1. The following steps should be followed when a control performance is unacceptable: a. DO NOT REPORT PATIENT RESULTS b. Review the procedure for any identifiable errors. c. Repeat the control. NOTE: If the repeated result is still outside of the expected range, documented corrective action should be initiated. d. If the problem still persists: 1. Prepare new controls and rerun 2. Check reagents for quantity, contamination or expiration. Change as needed. 3 Check the calibration data; recalibration may be neccessary. 4 Check instrument functions to ensure proper operation. Perform maintenance if needed. e. If the problem remains, call specfic manufacturer for technical assistance either by calling direct or using the Hot-Line number. f. Document all correctrive action on the remedial action worksheet in the appopriate section. g. If quality control was out of range due to a specific condition, once the condition is corrected the patient samples previously run must be checked for accuracy. If patient checks are within 5% of the original results, patient samples may be reported as originally resulted. If patient samples do not repeat within 5% of the original value, a corrected report must be issues, the physician notified, and the corrections documented in Corrective Action Log. Both the original and corrected report filed must be retained for a period of two years. LIMITS New lots of control material are verified before use. This is accomplished by running at least one day of the old control with the new. The mean value for these runs must fall within the expected range of the manufacturer. The control ranges for the respective analytes are kept for two years." C. Upon request, policy that detailed the criteria and methods to change chemistry control means and ranges were not provided. D. Review of quality control records showed mean baseline changes of Lipase Level 1 controls on 11/12

	/25, 11/13/25, 11/18/25, and 11/21/25. Lipase Level 2 controls had baseline changes on 11/12/25, 11/18/25, and 11/21/25. Alanine Aminotransferase Level 1 controls had two baseline changes on 4/16/26. Intact Parathyroid Hormone Level 1 controls had baseline changes on 3/26/26, 4/1/26, 4/15/26, and 4/17/26. E. In an interview on 3:53 pm on 5/12/26 the Technical Consultant confirmed that the chemistry control issues referred to in the November 2025 quality assurance report were still ongoing.