Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0327089	(X3) Date Survey Completed 10/09/2025
Name of Provider or Supplier Medical Center At Caverna, The	**Street Address, City, State** 1501 South Dixie Hwy, Horse Cave, KY	

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
D0000	A Recertification Survey was initiated on 10/08/2025 and concluded on 10/09/2025. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on laboratory policy review, laboratory document review, and interview, the laboratory failed to provide evidence of a self-evaluation for 1 of 28 proficiency testing (PT) events that were returned as not graded by the PT provider. Findings included: A laboratory policy titled, "Proficiency Testing," dated 11/07/2024, revealed, "B. Upon receipt of the data summary from the Proficiency Testing Program, the Laboratory Director/Manager will evaluate the report. The proficiency report will be reviewed for the following: 1. Ungraded results." A laboratory document titled, "American Proficiency Institute (API) Proficiency Testing Performance Evaluation, 2025 - Chemistry Core - 2nd Event," dated 07/01/2025, revealed the following analytes (a substance undergoing chemical analysis) and samples marked as not graded: Total Bilirubin, samples CH-07, CH-09, & CH-10 and Folate, samples IA-07 and IA-09. The document failed to reveal notation of the ungraded analytes/samples on the performance evaluation page or a participant summary sheet. During an interview on 10/08/2025 at 2:45 PM, the Technical

	Supervisor (TS) stated that he had noted the ungraded results at the time the proficiency testing report was received but could not explain why the self-evaluation had not been performed. This confirmed the findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, laboratory document review, and interview, the laboratory failed to perform a periodic function check of a repetitive diluent dispenser used in an immunohematology procedure for 24 of 24 months reviewed. Findings included: On 10/09/2025 at 9:45 AM, an observation revealed a (Company Name) Repetitive 1.0 ml (milliliter) dispenser in a laboratory refrigerator. A laboratory document titled, "CMS [Centers for Medicare & Medicaid Services]-116," dated 10/08/2025, revealed the laboratory employed the (Company Name) blood typing system for performing antibody screening under the specialty Immunohematology and sub-specialty of Antibody Detection. An undated laboratory document titled, "[Company Name] Dispenser - Repetitive Dispenser of 0.5 or 1.0 mL, Instructions for Use," revealed the section titled, "Calibration Check," specified, "A calibration check should be done as part of a routine laboratory quality control schedule and after each repair." During the survey, a review of laboratory procedures and maintenance documents failed to reveal a requirement to perform the indicated calibration checks and failed to reveal documentation that the calibration checks had been performed. During an interview on 10/09/2025 at 12:35 PM, the Technical Supervisor (TS) stated that he was not aware of the calibration check requirement and confirmed that the calibration checks had not been performed. This confirmed the findings.