Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0926958	03/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Integris Health Medical Group	1715 N 5th St, Ponca City, OK	

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	The initial survey was performed on 03/22/2022. The findings were reviewed with the laboratory manager, office manager, and laboratory director during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the office manager, laboratory manager and laboratory director, the laboratory failed to demonstrate the reportable range for one of one new test system. Findings include: (1) On 03/22/2022 at 01:10 pm, the laboratory manager stated: (a) The laboratory began performing CBC (Complete Blood Count) testing using the Medonic analyzer on 03/11/2021. (2) A review of the performance specification records did not include any evidence the laboratory had demonstrated the reportable ranges for each analyte; (3) On 03/22/2022 at 02:40 pm, the laboratory manager stated the reportable ranges had not been demonstrated.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 12 of 12 months. Findings include: (1) On 03 /22/2022 at 01:10 pm, the laboratory manager stated: (a) CBC (Complete Blood Count) testing was performed using the Medonic analyzer. (2) A review of the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs: (a) Daily Maintenance (i) Clean the aspiration and pre-dilute probes using an alcohol wipe; (ii) Remove possible traces of salt crystals or blood at the top of the aspiration and pre-dilute probes, probe rinse cup, and around top of sampling device probe inlet using a paper tissue with a disinfecting solution. (3) A review of maintenance records for 12 months (March 2021 through March 2022) revealed the following: (a) There was no evidence the daily maintenance had been documented as performed during the review period. (4) The records were reviewed with the laboratory manager. The laboratory manager stated on 03/22/2022 at 03:15 pm, the maintenance had been performed but not documented.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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 and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the office manager, laboratory manager and the laboratory director, the laboratory director failed to ensure that persons performing moderate complexity testing had the appropriate training for two of four testing persons. Findings include: (1) On 03/22/2022, a review of personnel records revealed the following: (a) Testing Person #1 - This person was hired to perform patient CBC (Complete Blood Count) testing using the Medonic analyzer. There was no documentation of initial training; (b) Testing Person #2 - This person was hired to perform patient CBC (Complete Blood Count) testing using the Medonic analyzer. There was no documentation of initial training. (2) The findings were reviewed with the laboratory manager. On 03/22/2022 at 02:15 pm the laboratory manager stated there was no additional documentation to prove the above persons had been initially trained to perform moderate complexity testing.