Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0926958	(X3) Date Survey Completed 01/30/2024
Name of Provider or Supplier Integris Health Medical Group	**Street Address, City, State** 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 recertification survey was performed on 01/30/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and office manager at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for storage and expiration dates of testing kits. Findings include: EXPIRED REAGENTS: (1) On 01/30/2024 at 1:00 pm, testing person #1 stated waived testing was performed in the sick area of the clinic; (2) Observation of the sick area on 01/30/2024 at 01:00 pm identifed two Hemoccult Developer bottles, lot #75009H, that expired on 09/2023; (3) The findings were discussed with testing person #1 who stated on 01/30/2024 at 1:00 pm, the developers were expired and still available for use. TEMPERATURE MONITORING: (1) Observation of the store room and interview with testing person #1 on 01/30/2024 at 12:00 pm, identified the following: (a) 11 boxes of Quidel QuikVue Influenza A+B test kits, lot # 708943, storage temperature of 15-30 degrees Celsius; (b) One box of Quidel QuickVue RSV tests, lot # 708024, storage temperature of 15-30 degrees Celsius; (c) Seven boxes of Sure-Vue Strep A test kits, lot # 0000695055, storage temperature of 2-30 degrees Celsius. (2) Interview with testing person #1 on 01/30/2024 at 12:00 pm confirmed the laboratory was not monitoring the temperature of the store room.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the clinic manager, the laboratory failed to have a written policy to assess the competency of the technical consultant, based on the position responsibilities as listed in Subpart M, for one of one person. Findings include: (1) A review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the technical consultant, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of January 2022 through the current date identified competencies, based on job responsibilities, had not been performed for one of one person listed as the technical consultant; (3) The findings were reviewed with the clinic manager who stated on 01/30/2024 at 1:00 pm a policy had not been written and competencies had not been performed.