Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D0910619	**(X3) Date Survey Completed** 08/29/2023
Name of Provider or Supplier Associates In Pediatrics	**Street Address, City, State** 2971 W Algonquin Rd, Algonquin, IL	
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**
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 review of laboratory records, lack of documentation, and interview with testing personnel (TP), the laboratory director failed to ensure 31 of 32 testing personnel listed on the Laboratory Personnel Report (CLIA Form CMS - 209) received appropriate training and documentation of the demonstration to accurately provide and report hematology complete blood count (CBC) patient specimen testing in 2022 and 2023. Findings include: 1. Review of the "Certificate of Completion (TP 32) - Key Operator Training for the Boule Medonic M Series Hematology Analyzer form and lack of documentation revealed the laboratory failed to document training for TP 1 through TP 31 prior to analyzing CBC patient test specimens. 2. On 08/29 /2023 at 12:30 p.m., TP 13 confirmed the above finding.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP), the technical consultant (TC) failed to evaluate the competency for 31 of 32 testing personnel listed on the Laboratory Personnel Report (CLIA Form CMS - 209) at least semiannually during the first year of testing hematology complete blood count (CBC) patient specimens in 2022 and 2023. Affecting a total of 419 tests performed. Findings include: 1. Review of the laboratory's "Individual Competency Evaluation - Associates in Pediatrics (2023)" forms and lack of documentation revealed the laboratory failed to evaluate and document the semiannual competency for TP 1 through TP 18 and TP 20 through TP 32 during the first year of testing CBC patient specimens. A total of 419 patient tests performed from 01/12/2022 to date of survey (08/29/2023). a. Hematocrit: 58 patient tests b. Hemoglobin: 187 patient tests c. Platelet Count: 58 patient tests d. RBC Count: 58 patient tests e. WBC Count: 58 patient tests 2. On 08/29/2023 at 12:30 p. m., TP 13 confirmed the above finding.