

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0415402	(X3) Date Survey Completed 12/15/2021
Name of Provider or Supplier Associates In Pediatrics	Street Address, City, State 1015 Summit St, Elgin, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) reports, lack of documentation, and interview, the laboratory failed to successfully participate in their PT program for the specialty of Hematology (D2130).</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p>

This STANDARD is not met as evidenced by:
 Based on record review, lack of documentation, and interview, the laboratory failed to attain satisfactory performance for Leukocytes Count (WBC) and Hemoglobin (Hgb) during the year of 2021. Findings: 1. The American Association of Bioanalysts (AAB) proficiency testing (PT) documents from 2019 to 2021 and procedures manual were reviewed. 2. The AAB-PT reports on December 15, 2021 at 10:30 AM, revealed the laboratory received unsuccessful PT performance for the Hematology analytes as listed below: HEMATOLOGY Leukocytes Count, WBC - Event #3, 2021 = 60% - Unsatisfactory Hemoglobin (Hgb) - Event #3, 2021 = 60% - Unsatisfactory 3. Review of the PT policy revealed the following instructions: "Follow up on all unacceptable performance with corrective action documentation. This must be done in consultation with the Technical Consultant or Laboratory Director:" 4. The laboratory failed to follow PT policies and procedures to investigate PT failures and take appropriate corrective action for WBC and Hemoglobin testing when failure scores were received. 5. On December 15, 2021 at 12:30 PM, Staff KL confirmed the above findings.

D2130

HEMATOLOGY
 CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
 Based on record review, lack of documentation, and interview, the laboratory failed to achieve satisfactory performance for the Hematology analytes erythrocyte count (RBC) and hematocrit (HCT) during the years of 2020 and 2021. Findings include: 1. The American Association of Bioanalysts (AAB) proficiency testing (PT) documents from 2019 to 2021 and procedures manual were reviewed. 2. The AAB-PT reports on December 15, 2021 at 10:30 AM, revealed the laboratory received unsuccessful PT performance for the Hematology analytes as listed below: HEMATOLOGY Erythrocyte Count, RBC - Event #1, 2021 = 60% - Unsatisfactory Erythrocyte Count, RBC - Event #3, 2021 = 60% - Unsatisfactory Hematocrit (Hct) - Event #1, 2020 = 60% - Unsatisfactory Hematocrit (Hct) - Event #3, 2021 = 60% - Unsatisfactory 3. Further review showed the PT failures that occurred during Event 3 of 2021 were not noted and the laboratory failed to provide any documented evidence the failures were investigated and corrective actions implemented, if required, by the laboratory director (LD) or technical consultant (TC). 4. Review of the PT policy revealed the following instructions: "Follow up on all unacceptable performance with corrective action documentation. This must be done in consultation with the TC or LD:" 5. The laboratory failed to follow PT policies and procedures to investigate PT failures (unsatisfactory results) and take appropriate corrective action for RBC and Hematocrit testing when failure scores were received. 6. On December 15, 2021 at 12:30 PM, Staff KL confirmed the above findings.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to ensure that all proficiency testing (PT) reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for years of 2020 and 2021. Findings include:

1. The American Association of Bioanalysts (AAB) for 2019, 2020, and 2021 and PT policies and procedures manual were reviewed.
2. The LD failed to ensure Staff KL followed the established PT policies and procedures to investigate and evaluate PT failures and identify any problems that require corrective actions. See D2016, D2121 and D2130.
3. Review of AAB-PT reports revealed the following scores for Urine Sediment Analysis: Event 2 of 2020 - 50% - Failure Event 2 of 2021 - 50% - Failure Event 3 of 2021 - 50% - Failure
4. The LD failed to ensure the above scores were investigated and possible retraining provided for the participating testing personnel.
5. On December 15, 2021 at 12:30 PM, Staff KL confirmed the above findings.