

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0415402	(X3) Date Survey Completed 09/28/2023
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 an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with the American Association of Bioanalysts (AAB) PT program representative confirmed the laboratory's SUBSEQUENT unsuccessful PT performance for the hematology analytes red blood cells and hematocrit (See D2130) and the initial unsuccessful PT performance for the specialty of hematology and the following hematology analytes: cell identification/white blood cell differential, hemoglobin, and white blood cells (See D2130 and D2131).</p>

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 an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with the American Association of Bioanalysts (AAB) PT program representative confirmed the laboratory's initial unsuccessful PT performance for the hematology analytes cell identification/white blood cell differential, hemoglobin, and white blood cells for two consecutive PT events in 2023 (events one and two) and the subsequent unsuccessful PT performance for the hematology analytes red blood cells and hematocrit for two of three PT events in 2021 (events one and three) and two consecutive PT events in 2023 (events one and two). Findings include: 1. Review of the CASPER Report 0155D, generated on 9-01-2023, and the AAB PT records the laboratory received the following unsatisfactory analyte scores: INITIAL Cell Identification/White Blood Cell Differential EVENT 1, 2023 40% Unsatisfactory EVENT 2, 2023 0% Unsatisfactory Hemoglobin EVENT 1, 2023 20% Unsatisfactory EVENT 2, 2023 0% Unsatisfactory White Blood Cells EVENT 1, 2023 60% Unsatisfactory EVENT 2, 2023 0% Unsatisfactory SUBSEQUENT Red Blood Cells EVENT 1, 2021 60% Unsatisfactory EVENT 3, 2021 60% Unsatisfactory EVENT 1, 2023 20% Unsatisfactory EVENT 2, 2023 0% Unsatisfactory Hematocrit EVENT 1, 2021 60% Unsatisfactory EVENT 3, 2021 60% Unsatisfactory EVENT 1, 2023 20% Unsatisfactory EVENT 2, 2023 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 09-27-2023 at 10:25 AM, confirmed the subsequent unsuccessful PT performance for the hematology analytes red blood cells and hematocrit and the initial unsuccessful PT performance for cell identification/white blood cell differential, hemoglobin, and white blood cells.

D2131

HEMATOLOGY

CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with the American Association of Bioanalysts (AAB) PT program representative the laboratory failed to achieve satisfactory performance for the specialty of hematology for two consecutive PT events in 2023 (events one and two) resulting in the initial unsuccessful PT performance for the overall specialty of hematology. Findings include: 1. Review of the CASPER Report 0155D, generated on 09-01-2023, and AAB PT records, the laboratory received the following unsatisfactory scores for the specialty of hematology. HEMATOLOGY EVENT 1, 2023 40% Unsatisfactory EVENT 2, 2023 0% Unsatisfactory 2. A phone interview with the AAB PT

representative on 09-27-2023 at 10:25 AM, confirmed the initial unsuccessful performance for the overall specialty of hematology.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with an AAB PT program representative the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the specialty of hematology (see D6016) resulting in the laboratory's initial unsuccessful PT performance for the overall specialty of hematology and the following hematology analytes: cell identification/white blood cell differential, hemoglobin, and white blood cells for two consecutive PT events (event one and two) in 2023 and the subsequent unsuccessful PT performance for the hematology analytes red blood cells and hematocrit for two of three PT events in 2021 (events one and three) and two consecutive events in 2023 (events one and two).

D6016

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with an AAB PT program representative the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the specialty of hematology resulting in the laboratory's initial unsuccessful PT performance for the overall specialty of hematology (D2131) and the following hematology analytes (D2130): cell identification/white blood cell differential, hemoglobin, and white blood cells for two consecutive PT events (event one and two) in 2023 and the subsequent unsuccessful PT performance for the hematology analytes red blood cells and hematocrit (D2130) for two of three PT events in 2021 (events one and three) and two consecutive events in 2023 (events one and two).