

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0415159	(X3) Date Survey Completed 02/13/2019
Name of Provider or Supplier Associates In Pediatrics	Street Address, City, State 1020 Schaumburg Rd, Streamwood, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and laboratory records and interview with testing personnel; the laboratory failed to have a written or electronic request for patient testing. Findings include: 1. Review of the laboratory's policies and procedures revealed that orders for testing are documented in the patients' electronic medical records. 2. At 11:00 AM on February 13, 2019 the surveyor selected a total of 7 patient's names from the laboratory's patient testing log. One of 7 patients did not have a request for Complete Blood Count testing dated 11/26/2018. However, there was documentation on the testing log which reads as follows: "not enough blood collected results abnormal." 3. Review of the corresponding patient's test records revealed that no results were reported for the patient whose results were documented as "not enough blood collected results abnormal" on 11/26/2018. 4. At 12:30 PM on February 13, 2019, testing personnel confirmed the surveyor's findings.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's policies, procedures manual, laboratory records, patients' test records and interview with testing personnel; the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. There were no written procedures that describes the laboratory's process for assessing (monitoring) analytic systems and documenting its activities. 2. Review of testing logs show that, on 11/26/2018, the laboratory documented a patients Complete Blood Count (CBC) with the following notation: "not enough blood collected results abnormal." 3. Review of the corresponding patient's test record shows that on 11/26/2018 there was no documentation to show that a CBC test was ordered, nor documentation to show that a CBC test result was reported. 4. There was no documentation to show corrective actions were taken on 11/26/2018 when there was "not enough blood collected results abnormal." 5. At 12:30 PM on February 13, 2019, testing personnel confirmed the surveyor's findings.