

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1022917	(X3) Date Survey Completed 11/21/2024
Name of Provider or Supplier Birth And Beyond Pediatrics, Pc	Street Address, City, State 10011 S Yale, Suite 200, Tulsa, 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 11/21/2024. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the lead testing person on at the conclusion of the survey.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the lead testing person, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test method. Findings include: (1) On 11/21/2024 at 09:00 am, the lead testing person stated the laboratory began performing CBC (Complete Blood Count) testing using the Beckman Coulter DxH 500 analyzer on 09/10/2024; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Red Blood Cell - 0.77 - 8.03 x10⁶/uL (b) Hemoglobin - 2.12 - 18.74 g/dL (3) Interview with the lead testing person on 11/21 /2024 at 12:30 pm confirmed the laboratory was using the following manufacturer's reportable ranges: (a) Red Blood Cell - 0.20 - 8.00 x 10⁶/uL (b) Hemoglobin - 0.20 - 25.00 g/dL</p>