

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2147391	(X3) Date Survey Completed 11/07/2024
Name of Provider or Supplier Purohit Pediatric Clinic Grandview	Street Address, City, State 3686 Grandview Parkway, Birmingham, AL	
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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Reichert Bilirubinometer Bilirubin Quality Control (QC) logs, QC procedures for Bilirubin, and an interview with the Testing Personnel (TP) #1, the laboratory failed to ensure two levels of QC were documented prior to Proficiency Testing (PT). The surveyor noted no QC was documented for six out of six PT events from 2023 and 2024. The findings include: 1. A review of the Reichert Bilirubinometer Bilirubin QC records revealed no evidence of documented QC testing prior to performing the following PT events: a) 2023 Chemistry First Event b) 2023 Chemistry Second Event c) 2023 Chemistry Third Event d) 2024 Chemistry First Event e) 2024 Chemistry Second Event f) 2024 Chemistry Third Event 2. A further review of the Quality Control Procedures for Bilirubin revealed "The lab personnel is required to document control dates, ranges, and results..." The Clinical Laboratory Improvement Amendments require "treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations." The laboratory documents QC for patients and should also document QC for PT samples. 3. TP #1 confirmed these finding during the exit conference on 11-07-2024 at 2:20 PM.</p>