

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2147391	(X3) Date Survey Completed 11/24/2020
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Hematology quality control records and function checks for the Medonic, a review of the online Operators' Manual, and an interview with the laboratory manager, the surveyor determined the laboratory staff failed to ensure acceptable background counts were achieved, prior to running patient specimens. This affected four days in 2019 of random quality control/function checks review for eleven months in 2019 and 2020. The findings include: 1. A review of the quality control and function check records for 2019 and 2020 revealed the following: a) On 3/29/19, 4/05/19 and 4/12/19: all parameters (White Blood Cell Count, Red Blood Cell Count, Hemoglobin and Platelet Count) coded DP, diluent system problem - run prime cycle. No repeat performance of the function checks were documented. b) On 7/18/19, the platelet count of the background check read 18 High (acceptable range is 0 -10). No repeat performance of the function check was documented. 2. In an interview on 11/24/2020 at 11:34 AM, the surveyor asked the Laboratory Manager (LM) what staff were trained to do, when background counts are outside of acceptable ranges. The LM stated the background count should be repeated. When asked what should be done if a diluent flag was obtained, the LM stated the system should be primed and the background count should be rerun. The surveyor discussed with the laboratory</p>

manager the validity of results if the background count fails. 3. A review of the online Operators' Manual for the Medonic, page 38, section 5.2 Startup Sequence, revealed the following: "...When complete the background count results are displayed. If the results are acceptable (see table for accepted background values according to section 5.3)... Note If the background count results have a H (high) indicator press [RERUN] and follow the screen instructions to analyze the background count again..."