

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2129843	(X3) Date Survey Completed 03/16/2021
Name of Provider or Supplier Wildflower Pediatrics	Street Address, City, State 11609 Anderson Mill Road, Austin, TX	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and procedures, test reports, and interview, the laboratory failed to redact the Complete Blood Count (CBC) indicies with flags on 2 of 2 test reports reviewed with flags. Findings follow.</p> <ol style="list-style-type: none"> 1. Review of the Medonic M Series user manual, under Chapter 9: Parameter and System Information Messages, section 9.2 System Information Messages starting on page 71 stated, "The system software monitors a number of analytical and system functions and will display information that indicates the possible attention of the operator. This information will alert the operator to check the system or sample or institute selected troubleshooting procedures." Multiple error flags were listed, including BD which stated under "Action:" Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 2. Review of the laboratory's policy and procedure titled CBC Medonic M-series, effective 6/22/2017, on page 2 under Patient Testing stated, "See the User's manual (pages 71-76 for system information message descriptions. The diff flags (BD, NM, OM and TM) indicate a possible problem with the accuracy of the results and should not be reported. Collect a new sample and repeat the testing. If the flag is still present, then the flagged results must be marked through on the printed report and the results should not be entered in the EMR." 3. Review of instrument printouts from the patient's chart showed a. ID # 1822, at sequence 6928, tested on 11/16/2020, and b. ID # 2338, at sequence 7355, tested on 02/01/2021, reported the White Blood Cell Differential results including Granulocytes %, Mids %, Lymphocytes %, absolute

Granulocytes, absolute Mids, and absolute Lymphocytes with the BD flag. 4. Review of the EMR showed 1 of 2 reports with flags were reported into the EMR. a. ID #2338 reported the Lymphocytes and Neutrophils. 5. Interview with the technical consultant on March 16, 2021 at 1130 hours in the office confirmed the testing person should have marked thru the results with the flags, and acknowledged she reviewed this with the staff on March 4, 2021. Interview with testing personnel #3 on March 16, 2021 at 1135 hours in the office confirmed the flagged results were not marked thru, and #2338 had been reported in the EMR. KEY EMR= Electronic Medical Record