

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0399870	<b>(X3) Date Survey Completed</b>  07/19/2022
<b>Name of Provider or Supplier</b>  Metropolitan Pediatrics	<b>Street Address, City, State</b>  14050 Nicollet Ave Suite 300, Burnsville, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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:</p> <ul style="list-style-type: none"> <li>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of five reportable ranges obtained during performance verification activities completed in 2022 were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a. m. on 07/19/22. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities on the XP-300 for Red Blood Cells, White Blood Cells, Hemoglobin, Hematocrit, and Platelets were completed in May 2022 as indicated in laboratory records. 4. The upper limit of the reportable range for Hemoglobin (HGB) in the Sysmex XP-300 Automated Hematology Analyzer procedure found in the Laboratory Procedure Manual did not reflect the actual reportable range value obtained by the laboratory during the PV. The values listed in the procedure were the manufacturer's stated reportable ranges. See below. Analyte PV Procedure HGB 0-22.4 0.1-24.0 5. The laboratory was given five business days to provide documentation showing the HGB reportable range in the XP-300 analyzer software had been updated to reflect the laboratory's PV values. 6. In an interview at 1:25 p.m. on 07/19/22, TP1 and the Operations Manager (OM) confirmed the above finding. 7. In an email received at 8:</li> </ul>

37 a.m. on 07/25/22, the OM provided documentation from the manufacturer indicating the reportable range study performed at implementation was a verification study and the results were within manufacturer guidelines. The manufacturer did not indicate the analyzer software had been updated to reflect the laboratory's HGB PV values. .

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure four of five testing personnel were assessed at least annually in 2021 through testing Microbiology, Chemistry, and Hematology previously analyzed specimens, blind samples, or proficiency testing samples. Findings are as follows: 1. The laboratory performed moderate complexity Urine Cultures (UC), Urine Sediment (US), and Hematology (CBC) testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 07/19/22. 2. Laboratory records indicated five of five testing personnel (TP) performed the above moderate complexity tests in 2021. Proficiency testing or blind sample competency assessments were not found for four of five TP in 2021 laboratory records as indicated below. TP Missing assessments TP1 UC, US, CBC TP3 US TP4 CBC TP5 US, CBC 3. The laboratory was unable to provide the missing blind sample evaluation documents upon request. 4. In an interview at 12:00 p.m. on 07/19/22, TP1 confirmed the above finding.