

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2072399	<b>(X3) Date Survey Completed</b> 02/05/2020
<b>Name of Provider or Supplier</b> 1st Choice Pediatrics	<b>Street Address, City, State</b> 1205 North 6th Street, Longview, TX	
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>D5411</b>	<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 manufacturer's instructions, laboratory documentation for 2018 and 2019 and staff interview, the laboratory failed to follow manufacturer's instructions for documentation of reagent replenishment for the Sysmex XP-300 hematology analyzer. Findings: 1. In the section titled "Reagent Replacement," the user's manual for the Sysmex XP-300, referring to the periodic replacement of reagents, states: "Document the change in the Reagent Replenishment Record." (XP-300 Quick Guide-Document Number 1051-CFL, Revision 1, page 7, item 9) 2. Blank forms for recording this were available, but not filled out with the information indicated. 3. In an interview at the site on 02-05-2019, the clinic manager confirmed that the forms were not being used and could not provide evidence that the information was being recorded elsewhere. .</p>
<b>D5431</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p>

	<p>This STANDARD is not met as evidenced by:</p> <p>. Based on review of manufacturer's instructions, laboratory documentation for 2018 and 2019 and staff interview, the laboratory failed to document background checks for the Sysmex XP-300 hematology analyzer. Findings: 1. In the section titled "Daily Operating Procedures," the user's manual for the Sysmex XP-300 states: "Record the background check on a daily checklist or keep a copy of the printout for documentation." (XP-300 Quick Guide-Document Number 1051-CFL, Revision 1, page 2, Power On/Self Check, item 2) 2. Blank forms for recording this were available, but not filled out with the information indicated. 3. In an interview at the site on 02-05-2019, the clinic manager confirmed that the forms were not being used and could not provide instrument printouts to verify performance of background checks. .</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on review of personnel competency verification documentation for 2018, 2019 and 2020, the laboratory technical consultant (CMS form 209) failed to evaluate the competency of 5 of 5 testing personnel using the required criteria. Findings: 1. Personnel training and competency documentation was reviewed. For 5 of 5 testing personnel listed, no competency verification specific to moderate complexity testing was found or could be offered. In an interview at the site on 02-05-2020, the clinic manager indicated a sheet marked "Skills Proficiency Checklist" and stated, "this is what we use for competency." The tests on the sheet did not include the required methods for evaluating competency for moderate complexity hematology testing and were not signed by the laboratory technical consultant. Note: the laboratory director and technical consultant are one and the same. .</p>
<p><b>D6047</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on review of personnel competency verification documentation for 2018, 2019 and 2020, the laboratory technical consultant failed to evaluate the competency of 5 of 5 testing personnel by direct observation of routine patient test performance. Refer to D 6046. .</p>
<p><b>D6048</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(ii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.</p>

	<p>This STANDARD is not met as evidenced by:  . Based on review of personnel competency verification documentation for 2018, 2019 and 2020, the laboratory technical consultant failed to evaluate the competency of 5 of 5 testing personnel by monitoring the recording and reporting of test results. Refer to D 6046. .</p>
<p><b>D6049</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>  CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by:  . Based on review of personnel competency verification documentation for 2018, 2019 and 2020, the laboratory technical consultant failed to evaluate the competency of 5 of 5 testing personnel by review of quality control records and preventive maintenance records. Refer to D 6046. .</p>
<p><b>D6050</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>  CFR(s): 493.1413(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.</p> <p>This STANDARD is not met as evidenced by:  . Based on review of personnel competency verification documentation for 2018, 2019 and 2020, the laboratory technical consultant failed to evaluate the competency of 5 of 5 testing personnel by direct observation of performance of instrument maintenance and function checks. Refer to D 6046. .</p>