

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1082475	(X3) Date Survey Completed 04/27/2021
Name of Provider or Supplier All Childrens Pediatric Clinic Pa	Street Address, City, State 4221 North Conway Suite D, Palmhurst, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing quarterly maintenance on the Sysmex XP-300 as required by the manufacturer for 4 quarters in 2020 and the 1st quarter of 2021. The findings were: 1. Review of laboratory policy "7.001" no laboratory director approval date it stated, "5. Evaluate maintenance schedule, ensure that all of manufacturer's recommendations are followed and that maintenance procedures are being done as required." 2. Review of the manufacturer's instructions for the Sysmex XP-300 (Code No. AU553517) under "12. Cleaning and Maintenance" it stated, "... Every 3 months (or every 4500 samples) - Clean the SRV (see 12.8)." 3. Review of the laboratory's Sysmex XP-300 maintenance records from January 2020 to March 2021 revealed quarterly maintenance (clean sample rotor valve) was not documented as performed for 15 months. 4. An interview with the technical consultant on April 27, 2021 at 15:30 hours in the patient exam room confirmed the findings.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)</p>

The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of instrument and patient test records and interview with facility personnel, the laboratory failed to provide documentation of having a mechanism in place to ensure the identity of testing personnel performing CBCs (complete blood count) for 10 of 10 patient test records from April 2021. The findings were: 1. Review of the laboratory's policy titled, "Test Records" no laboratory director approval date stated, "...Test Record Logs will provide the following information: the identity of the personnel who performed the tests." 2. Review of 10 patient final reports revealed that each of the 10 reports did not include the identity of the testing person who performed the test. 3. An interview with the primary testing person on April 27, 2021 at 15:00 hours in the patient exam room confirmed the findings. When asked if the laboratory documented the identification of the testing person performing the test any place else such as a testing log, she stated, "No."