

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0310262	(X3) Date Survey Completed 03/14/2023
Name of Provider or Supplier Children's Diagnostic Center	Street Address, City, State 7550 Goodwin Road, Chattanooga, TN	
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
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of laboratory records and interview with the technical consultant, the laboratory's quality assessment process was ineffective when it failed to correct problems in October 2022, November 2022, and December 2022. The findings include: 1) Review of the laboratory's quality assessment plan revealed the laboratory quality assurance plan is designed to "identify, then correct problems as they occur". 2) Review of laboratory refrigerator temperature records revealed the following error that went undetected by review processes with no documented corrective action: The refrigerator used for storage of complete blood count (CBC) controls had temperatures documented outside the defined storage range of 3-8 degrees Celsius for three of 31 days in October 2022 (10/27, 10/28, and 10/31), 22 of 30 days in November 2022 (11/01, 11/02, 11/04-11/09, 11/11, 11/14-11/17, 11/19, 11/22, 11/23, 11/25-11/30), and 10 of 31 days in December 2022 (12/03-12/09, 12/12, 12/13, 12/16). 3) Interview with the technical consultant on March 14, 2023 at approximately 12:00 p.m. confirmed the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with improper storage of complete blood count controls in October 2022, November 2022, and December 2022.</p>