

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1002113	(X3) Date Survey Completed 05/09/2023
Name of Provider or Supplier Shults Pediatrics A Division Of Summit	Street Address, City, State 9142 S Northshore Dr, Knoxville, 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 Clinical Supervisor, the laboratory's quality assessment process was ineffective when it failed to correct problems in July 2022, August 2022, September 2022, October 2022, November 2022, and December 2022. The findings include: 1) Review of the laboratory's quality assessment plan revealed the laboratory quality assessment plan is designed to "Identify problems in our laboratory and follow up with corrective action". 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 2-8 degrees Celsius (35.6-46.4 degrees Fahrenheit) for five of 31 days in July 2022 (07/18, 07/23, 07/24, 07/27, 07/28), 16 of 31 days in August 2022 (08/08, 08/09, 08/10, 08/12, 08/15, 08/16, 08/17, 08/18, 08/19, 08/20, 08/22, 08/23, 08/24, 08/29, 08/30, 08/31), nine of 30 day in September 2022 (09/01, 09/02, 09/03, 09/07, 09/08, 09/14, 09/20, 09/22, 09/26), nine of 31 days in October 2022 (10/01, 10/04, 10/07, 10/08, 10/15, 10/21, 10/25, 10/28, 10/29), eight of 30 days in November 2022 (11/01, 11/08, 11/12, 11/16, 11/18, 11/22, 11/23, 11/29), and two of 31 days in December 2022 (12/02, 12/12). 3) Interview with the Clinical Supervisor on May 9, 2022 at approximately 10:45 a.m. confirmed the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with improper storage of</p>

complete blood count controls in July 2022, August 2022, September 2022, October 2022, November 2022, and December 2022.