

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2137187	<b>(X3) Date Survey Completed</b>  01/25/2022
<b>Name of Provider or Supplier</b>  Urgent Care For Children-280	<b>Street Address, City, State</b>  500 Cahaba Park Circle Ste 100, Birmingham, AL	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter AcT Diff 2 Quality Control (QC) records and an interviews with the Laboratory Manager, the laboratory failed to retain QC records and patient test records for at least 2 years. This was noted for two out of five months reviewed by the surveyor. The findings include: 1. A review of Beckman Coulter AcT Diff 2 QC records revealed the November 2019, March 2020, July 2020, September 2020 and December 2020 records were not available for review by the surveyor during the on-site visit. During an interview on 01/25/2022 at 1:00 PM, the Laboratory Manager stated she would email the QC records to the surveyor by Friday 01/28/2022. 2. During a phone interview on 01/28/2022 at 9:10 AM, the Laboratory Manager stated she had forwarded all the required documents she had. The surveyor explained she had not received all the needed Hematology QC records for Beckman Coulter. 3. During a second phone interview on 02/04/2022 at 9:00 AM, the Laboratory Manager stated she had located all the QC records for the Beckman Coulter and the surveyor stated she would review the data if it was received by 12:00 PM today (02/04/2022). 4. The November 2019, March 2020, and July 2020 Hematology QC records were emailed to the surveyor on 02/04/2022. A review of the QC data revealed no quality control was run on 03/16/2022; there was no information on whether patients were performed this date. The surveyor further noted seven days (the 6th, 12th, 13th, 14th, 17th, 21st, and 22nd) in July 2020 when at least two levels of QC were not acceptable, or were not run; there was no information on whether patient tests were performed on these dates. After review of the records on 02/04/2022, the surveyor emailed the Laboratory Manager and asked if patient testing was</p>

performed on the above dates when QC was not acceptable or was not run. The Laboratory Manager emailed the following statement, "...I have contacted billing department to make sure no CBCs were billed for that time period."

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on a review of Proficiency Testing Records for American Academy of Family Physicians (AAFP) and an interview with the Laboratory Manager, the laboratory failed to retain all proficiency testing records for at least 2 years. This was noted on one out of seven Proficiency Testing Events reviewed by the surveyor. The findings include: 1. A review of AAFP Proficiency Testing Records revealed the 2020 Event-C results evaluation was not retained. 2. During an interview on 01/25/2022 at 1:00 PM, the Laboratory Manager stated she would email the results evaluation due to not having it on-site during the survey. 3. During an email interview on 02/04/2022 at 1:15 PM, the Laboratory Manager provided a summary of results from AAFP for all labs, and stated this was all she could provide since the laboratory no longer used AAFP as their Proficiency Testing provider.

**D5447**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Sight OLO Hematology quality control records, the patient logs for the Sight OLO, and an interview with the Laboratory Manager and the Technical Consultant, the laboratory failed run controls at least once a day patient specimens are performed or follow the Individualized Quality Control Plan (IQCP) when implemented for the Sight OLO Complete Blood Count (CBC) analyzer. This was noted from February 2021 (when patient testing started) to December 2021. The findings include: 1. A review of the quality control records for the Sight OLO (in use from February 2021 to August 2021) revealed quality control (QC) documented on Levey-Jennings chart from the manufacturer with only the month and the year; the actual dates when the QC was run were not specified. QC appeared to only be run in January 2021, February 2021, and March 2021. Patients were performed on the following dates: 02/16/2021, 04/18/2021, 05/02/2021, 05/23/2021, 06/14/2021, 06/22/2021, 07/01/2021, 07/07/2021, 07/14/2021 (2 patients), 07/15/2021, 08/14/2021, and 08/30/2021 2. A review of the electronic QC records on the Sight OLO (in use from September 2021 to December 2021) revealed no QC was run on the following dates when patient testing was performed: 11-15-2021 (2 patients performed), and 11/20/2021. 3. A review of the of the Hematology records revealed an IQCP for the Sight OLO was implemented on 12/01/2021; per CLIA regulations QC should have been run each day of patient testing until the IQCP implementation (12/02/2021). 4. During

an interview on 01/25/2022 at 12:45 PM, the Technical Consultant confirmed QC was not performed before patient testing when using the second Sight OLO from September 2021 to December 2021 and the IQCP was not put into place until 12/01/2021. On 02/04/2022 at 9:00 AM the Laboratory Manager confirmed the only QC they had for the first Sight OLO (used from February 2021 to August 2021) was the Levey-Jennings and she felt that QC was not done on each day of patient testing during this time period.