

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2059877	(X3) Date Survey Completed 03/12/2024
Name of Provider or Supplier Family Care Walk-In Clinic, Inc	Street Address, City, State 400 Us Hwy 45w, Humboldt, 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 observation of the laboratory, review of the laboratory's temperature logs, Quality Assessment records, and staff interview, the laboratory's quality assessment review failed to identify and correct errors for refrigerator temperatures that were recorded below the acceptable range in 2023 and 2024 (eleven of eleven months reviewed) for the refrigerator used to store materials for the complete blood count (CBC) instrument used for patient testing. The findings include: 1. Observation of the laboratory on 03/12/2024 at 9:00 am revealed a Cell-Dyn Emerald (Serial #030520-008302) CBC instrument used for patient testing and a refrigerator used to store quality control, proficiency testing, and calibrator materials for the CBC instrument. 2. A review of the laboratory temperature logs for 2023 and 2024 revealed acceptable refrigerator temperature ranges of 2-8 degrees Celsius (C). Refrigerator temperatures were recorded below 2C as follows: April 2023 12 of 20 days May 2023 seven of 22 days June 2023 seven of 22 days July 2023 seven of 19 days August 2023 six of 23 days September 2023 six of 20 days October 2023 six of 20 days November 2023 three of 21 days December 2023 five of 19 days January 2024 nine of 17 days February 2024 11 of 20 days 3. A review of the quality assessment records for 2023 and 2024 (01/13/2023, 03/22/2023, 07/21/2023, 09/12/2023, 11/29/2023, 02/20/2024) revealed no documentation of corrective action for the recorded refrigerator temperatures that were below the acceptable range. 4. An interview with the technical consultant on 03/12/2024 at 11:30 am confirmed the laboratory's quality assessment</p>

review failed to identify and correct errors with recorded refrigerator temperatures in 2023 and 2024.