

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0721322	(X3) Date Survey Completed 06/07/2023
Name of Provider or Supplier Pediatric Choice Clinic, Dayton	Street Address, City, State 149 Walnut Grove Church Road, Dayton, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the lab supervisor, it was determined that the laboratory director failed to sign the attestation sheets for the 2nd and 3rd events for 2022. The findings include: 1. Review of the laboratory's PT records revealed the following: -Attestation pages not signed by the lab director for the following: Hematology 2022 event two -Attestation pages not signed by the lab director for the following: Hematology 2022 event three 2. Interview with the lab supervisor on June 7, 2023 at 12:30pm confirmed the above findings.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, review of laboratory records and interview with the lab supervisor, the laboratory failed to follow their policy for documentation of temperature and humidity in June 2023. The findings include: 1.</p>

Review of the laboratory's procedure titled "Reagent Management" stated the following: "Document all temperatures daily" and "Document humidity daily". Additionally, review of the "Laboratory temperature/humidity log" stated "This log must be completed each day of patient testing. Record all temperatures and humidity as indicated with the initials of the individual recording". 2. Review of the "Temperature/humidity log" for June 2023 revealed the following: -June 1, 2023: No documentation of refrigerator temperature recorded -June 2 and June 5, 2023: No documentation of room temperature, refrigerator temperature or humidity recorded 3. Interview with the lab supervisor at approximately 9:35 a.m. on June 7, 2023 confirmed the laboratory failed to ensure that the procedure for temperature and humidity documentation was followed for three of seven days in June 2023.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of manufacturer complete blood count (CBC) quality control package insert and interview with the lab supervisor, the laboratory failed to label CBC quality control vials with corrected expiration date on the date of the survey (06.07.2023). The findings include: 1. Observation of the laboratory on June 7, 2023 at 9:35 a.m. revealed a Horiba ABX Micros-60 CBC instrument (serial #512CS95442) in use for patient testing. Also observed were three levels of Horiba Minotrol controls (Lot number MX441) that were not labeled with corrected expiration date. 2. Review of the manufacturer quality control package insert revealed the following statement: "Open tubes are stable for 16 days provided they are handled properly". 3. Interview with the lab supervisor on June 7, 2023 at 9:35a.m. confirmed the laboratory had not labeled CBC quality control vials with corrected expiration date on the date of the survey (06.07.2023).