

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2283054	(X3) Date Survey Completed 09/22/2025
Name of Provider or Supplier Constant Care Pediatrics Llc	Street Address, City, State 7700 N Kendall Drive Suite 710, Miami, FL	
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
D0000	An announced CLIA recertification survey was conducted at CONSTANT CARE PEDIATRICS LLC from 09/04/2025 to 09/22/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: -D3000 CFR 493.1100 Facility Administration. -D6000 CFR 493.1403 Moderate Complexity Laboratory Director
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to keep records of the testing of Proficiency Testing (PT) in the Specialty of Hematology for three out of four events in 2024 and 2025. Findings included: 1-Review of American Proficiency Institute (API) PT records for Hematology 5H second and third event of 2024 and for first and second event of 2025, revealed that the laboratory did not maintain instrument testing records as follows: a) Second event 2024: No analyzer results. b) Third event 2024: No analyzer results. c) First event 2025: No analyzer results. 2- During an interview on 09/04/2025 at 2:30 PM, the Laboratory Director confirmed that the laboratory failed to have the records for PT listed above.</p>
D2121	HEMATOLOGY CFR(s): 493.851(a)

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory failed to score at least 80 % on Red Blood Cells (RBC) on 2nd event 2024 and Hematocrit on 1st event 2025. Findings included: 1-Review of API PT records revealed a score of 60% for RBC in second event 2024 and 60% in the first event of 2025. 2-During an interview on 09/04/2025 at 02:45 PM, the Laboratory Director confirmed the proficiency testing failures listed above.

D3000

FACILITY ADMINISTRATION
CFR(s): 493.1100

Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

This CONDITION is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to keep Quality Control records for the Hematology Analyzer DXH 520 from July 2024 to February 2025. Refer to D3031.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

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. In addition, retain the following:

This STANDARD is not met as evidenced by:
Based on record review and interview with Laboratory Director (LD), the laboratory failed to retain daily Quality Control (QC) records from 07/01/2024 to 02/28/2025 for the Beckman Coulter DXH 520. This is a repeat deficiency from the Initial Certification survey conducted 04/17/2024. Findings included: 1-Review of the Allegation of Compliance signed by the LD on 07/17/2024, revealed that on page 2 under D3031 stated "Data lost cannot be retrieved. Moving forward all QC records are being backed up on an external hard drive." 2-Review of QC records stored in the Beckman Coulter Complete Blood Cell Count DxH520 and in the external hard drive, revealed that the laboratory failed to have the records from 07/01/2024 to 02/28/2025. In this period the laboratory tested 32 patients. 3-During an interview on 09/04/2025 at 03:35 PM, the LD confirmed that the laboratory failed to have the QC records for the period of 07/01/2024 to 02/28/2025.

D5417

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

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and staff interview, the laboratory failed to stop using complete blood count (CBC) Hematology controls after the open expiration as per manufacturer's instructions. Findings included: 1-During the laboratory tour on 09/04/2025 at approximately 10:10 AM, the surveyor observed that the laboratory was using DxH500 Control with Lot number 352517411 for Abnormal Low level, 362517412 for Normal level and 372517413 for Abnormal High level; the vials had no open date and no expiration date. 2-Review of the DxH500 Table of Expected Result revealed that used controls had an expiration date of 16 days after first use on the following days: 07/24/2025 (2 patients tested), 07/25/2025 (1 patient tested), 07/29/2025 (1 patient tested), 08/04/2025 (1 patient tested), 08/13/2025 (1 patient tested), 08/14/2025 (1 patient tested), 08/15/2025 (1 patient tested), 08/18/2025 (2 patient tested), 08/19/2025 (1 patient tested), 08/25/2025 (1 patient tested), 08/27/2025 (1 patient tested), 08/29/2025 (1 patient tested), 09/03/2025 (1 patient tested). The laboratory tested 15 patients with the expired controls. 3-During an interview on 09/04/2025 at 10:25 AM the laboratory testing person admitted that the vials were used passed the 16 days and up to 30 calendar days for each level of controls.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform maintenance for Hematology analyzer DxH 520 as specified by the manufacturer for period reviewed August through December of 2024 and January through August of 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 09/04/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant and Technical Consultant (TC) for Hematology specialty, and one Testing Personnel (TP). 2- Review of maintenance records obtained from the LOG_ALL downloaded file from the DxH520 Serial number BG030141 from 8-18-2024 to 09-04-2025 at 2:54 PM revealed that the laboratory did not follow manufacturer instructions for the following events: a) Bleach Cycle for the months of November 2024 and June 2025. b) Cleaning of the WBC Bath Filter for the months of August, September, October, and November of 2024, and January, February, March, April, May, June, July and August of 2025. 3- Review of the instrument manual PN C41838AA Chapter 12, stated the frequency for the a) Bleach Cycle - Monthly b) Cleaning of the WBC Bath Filter - Monthly 4- During phone interview on 09/11/2025 at 1:32 PM the LD stated that the records were accessed by the manufacturer to email the missing documentation. On 09/22/2025 emailed received from the laboratory did not provide documents for missing monthly maintenance.

D5447

CONTROL PROCEDURES

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

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform at least two levels of quality control (QC) each day of patient testing on the Complete Blood Cell Counter (CBC) DXH 520 for 4 out of 21 testing dates from June to August 2025. Findings included: 1-Review of procedure manual signed by the Laboratory Director on 01/03/2025 revealed that the laboratory will run daily Quality Controls. 2-Review of QC records and patients log revealed that the following dates of patients testing the laboratory had no documentation that QC were run for the DXH 520 analyzer the following dates: 06/09/2025 (1 patient tested), 06/10/2025 (1 patient tested), 07/25/2025 (1 patient tested), and 08/04/2025 (1 patient tested). 3-During an interview on 09/04/2025 at 2:45 PM, the Laboratory Director confirmed that the laboratory failed to have documentation that ran QC the days of reference.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to effectively oversee the laboratory. Findings included: -The Laboratory Director (LD) failed to ensure that the laboratory maintained the Quality Control records in 2024 and 2025. Refer to D6004.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on observation, record review and staff interview, the Laboratory Director failed to effectively oversee the laboratory. Findings included: 1-The LD failed to ensure the laboratory had all Proficiency Testing records. Refer to D2014. 2-The LD failed to ensure the laboratory maintained all Quality Controls records for the Beckman Coulter DXH 520 Complete blood Analyzer. Refer to 3131.