

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0685723	<b>(X3) Date Survey Completed</b>  12/13/2023
<b>Name of Provider or Supplier</b>  Children's Clinic Of Nashville Plc The	<b>Street Address, City, State</b>  4322 Harding Road Suite #313, Nashville, TN	
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>D0000</b>	During a recertification survey that was completed on 12/13/2023, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
<b>D2009</b>	<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 staff interview, the laboratory failed to ensure the laboratory director signed the attestation statements for events two and three in 2023 (two of seven reviewed). The findings include: 1. Review of the laboratory's API PT records revealed the attestation statements for 2023 events two and three lacked the laboratory director's signature. 2. Interview on 12/13/2023 at 3:30 pm with the office manager, office supervisor, testing person two, and the laboratory director, confirmed the laboratory failed to ensure the laboratory director signed the API PT attestation statements for 2023 events two and three.</p>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) 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</p>

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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's API PT records, and staff interview the laboratory failed to retain PT documents for a period of two years for two events (two of seven reviewed) in 2022 and 2023. The findings include: 1. Review of the laboratory's API PT records revealed the following were not retained for a period of two years: 2022 Event one- Performance evaluation documents provided by API 2023 Event two- Instrument printouts for the samples that were performed on the Medonic hematology analyzer 2. Interview on 12/13/2023 at 3:30 pm with the office manager, office supervisor, laboratory director, and TP two confirmed the laboratory failed to ensure the PT documents were retained for a period of two years when the performance evaluation documents were not retained in 2022 and the Medonic instrument printouts were not retained in 2023 .

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:  
Based on review of the Form CMS-209, laboratory policy, personnel records, and staff interview, the laboratory failed to follow it's own policy for competency assessments for personnel that perform CBC patient testing in 2021 and 2022. The findings include: 1. Review of the Form CMS-209 revealed TP three (new since last survey) listed as performing moderately complex CBC patient testing. 2. Review of the laboratory policy titled "Personnel" section one "Competency Assessment" revealed "New hires will be assessed at their 6 month anniversary the first year of employment and yearly thereafter." 3. Review of the laboratory's personnel records revealed TP three was hired on 09/07/2021 and completed competency assessments on 07/22/2022 and 11/27/2023. The competency assessment was not completed at six months and annually according to the laboratory policy. 4. Interview on 12/13/2023 at 3:30 pm with the office manager, office supervisor, TP two, and laboratory director, confirmed the laboratory failed to follow it's own personnel policy when TP three did not have completed competency assessments according to the policy in 2021 and 2022.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:  
 Based on observation of the laboratory, review of laboratory's policy, operator's manual review, and staff interviews, the testing personnel (TP) failed to follow the laboratory's procedures for labeling patient samples for complete blood count (CBC) testing in 2023. The findings include: 1. Observation of the laboratory on 12/13/2023 at 10:35 am revealed a Medonic hematology instrument (Serial 49409) in use for patient CBC testing. Specimens were observed and were not labeled with any identifiers. TP two stated at 11:05 am the patient samples are not labeled during the collection or testing process. 2. Review of the laboratory policy titled "Specimen Labeling and Rejection Policy" revealed specimens submitted to the laboratory for testing must be accurately labeled with the patient's name and collection information at the time of collection. 3. Review of the Medonic Operator's manual section "Specimen Identification/Causes for Specimen Rejection" revealed "specimens must be labeled with both first and last name of patient as well as one more unique identifier (Medical Record Number, Date of Birth, social security number (SSN), etc.)". 4. Interview with the office manager, office supervisor, laboratory director, and TP two on 12/13/2023 at 3:30 pm confirmed the laboratory TP failed to follow the laboratory's procedures for specimen labeling in 2023.

**D5403**

PROCEDURE MANUAL  
 CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
 Based on observation of the laboratory, review of the laboratory's procedure and staff interviews the laboratory failed to ensure the Medonic CBC instrument procedure included panic or alert values on the date of the survey (12/13/2023). The findings include: 1. Observation of the laboratory on 12/13/2023 at 10:35 am revealed a Medonic (Serial 49409) CBC instrument in use for patient testing. 2. Review of the laboratory's procedure for the Medonic CBC instrument revealed the procedure lacked panic or alert values. 3. Interview on 12/13/2023 at 3:30 pm with the office manager, office supervisor, TP two, and the laboratory director confirmed the laboratory did not have defined panic or alert values included in the Medonic procedure for CBC patient testing on the date of the survey (12/13/2023).

<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure and staff interviews, the laboratory failed to ensure the procedure in use for the Medonic CBC instrument was approved by the laboratory director. The findings include: 1. Observation of the laboratory on 12/13 /2023 at 10:35 am revealed a Medonic (Serial 49409) hematology instrument in use for CBC patient testing. 2. Review of the procedure for the Medonic CBC instrument revealed it had not been approved by the laboratory director. 3. Interview on 12/13 /2023 at 3:30 pm with the office manager, office supervisor, TP two, and laboratory director confirmed the laboratory director had not approved the procedure for the Medonic CBC instrument.</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's procedure for use, lack of records, and staff interviews, the laboratory failed to ensure instrument maintenance was performed on the CBC analyzer used for patient testing according to the manufacturer's requirements in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 12/13/2023 at 10:35 am revealed a Medonic (Serial 49409) instrument in use for CBC patient testing. 2. Review of the Medonic procedure manual sections 8.2- 8.3 revealed cleaning procedures that were to be completed monthly (8.2) and every six (6) months (8.3). 3. No documentation of equipment maintenance was available on the date of the survey. 4. Interview on 12/13/2023 at 3:00 pm with the office manager, office supervisor, TP two, and laboratory director confirmed the laboratory failed to perform instrument maintenance according to the manufacturer requirements in 2021, 2022 or 2023.</p>
<p><b>D5893</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(b)(c)</p> <p>(b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient report review, and staff interviews the laboratory failed to have an effective quality assessment to identify and correct errors</p>

in the final patient test report for the normal ranges for the hematocrit (Hct), hemoglobin (Hgb), and white blood cell (WBC) analytes in 2022 and 2023. The findings include: 1. Review of the laboratory policy titled "Quality Assurance Plan" revealed patient chart reviews were conducted annually to "address potential failure and errors during the testing process." 2. Review of final patient test reports revealed the following discrepancies for normal ranges between the Medonic CBC instrument used for patient testing and the final patient test report in the electronic chart (four of four charts reviewed): Patient 1-22 reported 01/12/2022 Electronic Chart Hct 33.0-50.0 % WBC 4.5-17.0 10<sup>3</sup>/uL Hgb 12-16 g/dL Medonic Printout Hct 33-39% WBC 6.0-17.0 10<sup>3</sup>/uL Hgb 10.5-13.5 g/dL Patient 2-22 reported 12/08/2022 Electronic Chart Hct 33.0-50.0 % WBC 4.5-17.0 10<sup>3</sup>/uL Medonic Printout Hct 36-50% WBC 4.5-13.5 10<sup>3</sup>/uL Patient 3-23 reported 03/23/2023 Electronic Chart WBC 4.5-17.0 10<sup>3</sup>/uL Hgb NONE Medonic Printout WBC 4.5-13.5 10<sup>3</sup>/uL Hgb 11.5-15.5 g/dL Patient 4-23 reported 11/30/2023 Electronic Chart WBC 4.5-17.0 10<sup>3</sup>/uL Hgb NONE Medonic Printout WBC 5.0-15.5 10<sup>3</sup>/uL Hgb 11.5-13.5 g/dL 3. Interview on 12/13/2023 at 4:00 pm with the office manager, office supervisor, TP two, and laboratory director confirmed the laboratory quality assessment review failed to recognize the discrepancy between the Medonic CBC instrument printout and the electronic record in 2022 or 2023 with no corrective action performed. Word Key: uL=microliter g/dL=grams/deciliter %= percent

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's API PT records, and staff interview, the laboratory director failed to ensure the performance evaluations were reviewed for three events (three of seven reviewed) in 2021 and 2022. The findings include: 1. Review of the laboratory's API PT records revealed the following performance evaluations lacked the laboratory director's signature: 2021 Event three, 2022 Event two, 2022 Event three 2. Interview on 12/13/2023 at 3:30 pm with the office manager, office supervisor, laboratory director, and TP two confirmed the laboratory director failed to ensure the performance evaluations were reviewed in 2021 and 2022.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can

perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), personnel records, lack of records, and staff interview, the laboratory director failed to ensure the TP had documentation of highest level of education, documentation of training, and demonstrated accuracy prior to patient CBC testing. (Refer to D6065 and D6066). The findings include: 1. Review of the Form CMS-209 revealed four new testing personnel since the last survey that perform moderately complex CBC patient testing. 2. Review of the laboratory's personnel records revealed the following: TP three hired 09/07/2021 TP four hired 02/06/2023 TP five hired 10/30/2023 TP six hired 02/14/2023 The records did not contain evidence of the highest level of education, training, or demonstration of accuracy. 3. Interview on 12/13/2023 at 12:27 pm with the office manager, TP six, and the laboratory director confirmed there was no documentation in the testing personnel records of highest level of education, training, or demonstration of accuracy for performance of CBC testing on the Medonic instrument prior to patient testing.

**D6063**

LABORATORY TESTING PERSONNEL  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the Form CMS-209, TP personnel record review, and staff interview, TP three through six did not qualify as TP for moderately complex patient testing due to lack of documentation of highest level of education, training, or documentation of accuracy prior to patient testing. (Refer to D6065 and D6066)

**D6065**

TESTING PERSONNEL QUALIFICATIONS  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Form CMS-209, personnel record review, and staff interviews the laboratory failed to ensure the TP had documentation of highest level of education

on the date of the survey (12/13/2023). The findings include: 1. Review of the Form CMS-209 revealed TP three through six (four of six) listed as performing moderately complex patient testing. 2. Review of the TP personnel records revealed there was no documentation of the highest level of education for TP three through six. 3. Interview on 12/13/2023 at 12:27 pm with the office manager, office supervisor, laboratory director, and TP two confirmed that TP three through six did not have evidence of highest level of education for performing moderately complex patient testing in 2021 or 2023.

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of the Form CMS-209, personnel record review, and staff interviews the laboratory failed to ensure the TP had documentation of training prior to analyzing patient CBC samples in 2021 and 2023. The findings include: 1. Review of the Form CMS-209 revealed four new testing personnel (four of six) since the last survey that perform moderately complex CBC patient testing. 2. Review of the laboratory's personnel records revealed there was no documentation of training for TP three through six prior to patient testing CBC samples. 3. Interview on 12/13/2023 at 12:27 pm with the office manager, office supervisor, TP two, and the laboratory director confirmed that TP three through six did not have documented training for performing moderately complex CBC patient testing in 2021 and 2023.