

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0677246	<b>(X3) Date Survey Completed</b>  01/24/2024
<b>Name of Provider or Supplier</b>  Memphis Childrens Clinic	<b>Street Address, City, State</b>  1129 Hale Road, Memphis, 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>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, review of the Centers for Medicare &amp; Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), and staff interview, the laboratory failed to ensure PT was performed by personnel who routinely perform patient testing for Complete Blood Count (CBC) in 2022 and 2023. The findings include: 1. Review of the laboratory's PT attestation statements from 2022 and 2023 revealed that three of five PT events were performed by testing person two (2022 event three, 2023 event two, and 2023 event three). 2. Review of the Form CMS-209 revealed five testing personnel who perform patient testing for CBC. 3. During an interview on 01/24/24 at 1:30 pm the lead testing person stated the laboratory doesn't have a process in place to ensure the PT is rotated among all testing personnel, and confirmed that PT was not rotated among all testing personnel who perform patient testing for CBC in 2022 and 2023.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory procedure manual, employee personnel records for 2022 and 2023, and interview with the laboratory lead, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency, resulting in competency assessments performed without including all six required criteria for four of five testing personnel, eight of nine competency assessments reviewed. The findings include: 1. Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure for assessing testing personnel competency: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2. Review of the 2022 and 2023 employee personnel records revealed the following: Testing person number two: Competency assessment dated 05/2022-no assessment of blind testing. Competency assessment dated 05/31/23-no assessment of blind testing. Testing person number three: Competency assessment dated 03/29/23-no assessment of blind testing. Competency assessment dated 09/19/23-no assessment of blind testing. Testing person number four: Competency assessment dated 08/25/22-no assessment of blind testing. Competency assessment dated November 2022-no assessment of blind testing. Competency dated 02/24/23-No assessment using blind testing. Competency dated 8/28/23-No assessment of blind testing. Testing person number five: Competency assessment dated 09/30/22-No assessment of blind testing. 3. Interview on 01/24/24 at 1:45 pm with the laboratory lead confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS), resulting in competency assessments performed that did not include all six required criteria for four of five testing personnel (eight of nine competency assessments reviewed).

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory procedure manual and interview with the laboratory lead, the laboratory failed to have policies or procedures that defined quality activities related to proficiency testing. The findings include: 1. Review of the laboratory procedure manual revealed no policy or procedure related to proficiency testing. 2. Interview with the laboratory lead on 01/24/24 at 1:45 pm confirmed the laboratory failed to have proficiency testing policies and procedures.

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, staff interview, review of the laboratory procedure manual, and interview with the laboratory lead, the laboratory failed to follow its' own policy for labeling of patient CBC samples. The findings include: 1. Observation of the laboratory on 01/24/24 at 9 am revealed the Sysmex XN 330 (serial # 14732) used for performing patient testing for Complete Blood Count with automated white blood cell differential (CBC w/Diff). 2. On 01/24/24 at 9 am, testing person number three was asked to describe how patient samples are labeled. She stated she did not label patient CBC samples at any point during the collection and testing of the sample. 3. Review of the laboratory procedure titled "LABELING, HANDLING AND STORAGE OF SPECIMENS POLICY" revealed the following statement: "Correct and timely labeling of each specimen is critical. The correct labeling system includes: patient's full name + last 4 digits of the SS# or DOB, date of collection (in some cases)." The procedure titled "SPECIMEN COLLECTION" revealed the following statement "Labeling of the collected specimen must take place immediately after collection and be legible, indelible, accurate, and firmly affixed to the specimen container." 4. During an interview on 01/24/24 at 1:45 pm, the laboratory lead confirmed the laboratory failed to follow its' own policy for labeling of patient specimens, when testing person three stated she did not label patient CBC samples.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, interview with testing person number three, review of the laboratory's quality assessment monitoring form and interview with the laboratory lead, the laboratory's quality assessment process did not include monitoring for pre-analytic laboratory activities. The findings include: 1. Observation of the laboratory on 01/24/24 at 9 am revealed the Sysmex XN 330 used for performing patient testing for CBC. 2. During an interview on 01/24/24 at 9 am, with testing person three, the testing person stated she never labels a patient CBC specimen. 3. Review of the laboratory's monthly quality assessment form revealed pre-analytic activities were not monitored. 4. Interview with the lead testing person on 01/24/24 at 1:45 pm confirmed the laboratory's quality assessment process did not include monitoring for pre-analytic activities.

**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 review of manufacturer basic operation manual, the laboratory procedure for the Sysmex XN 330 CBC instrument, and staff interview, the laboratory procedure for CBC failed to contain the following required procedure elements: specimen rejection criteria, reportable range as determined during validation, actions to take for results outside the reportable range, quality control protocol that was consistent with the manufacturer requirements, control corrective actions, panic/alert values, and actions to take if the instrument becomes inoperable. The findings include: 1. Review of the Sysmex basic operation manual revealed the following under section 3.2.2: QC is performed before sample analysis, after replacement/replenishment of reagents, after instrument maintenance, or when there is a concern about the accuracy of analysis values. 2. The laboratory procedure for the Sysmex XN 330 under the section for Quality Control revealed the follow under the section titled "Frequency of Control use and review": XN CHECK/XN-L CHECK control levels:   XXX   will be run on first shift. Additionally, the procedure for Sysmex XN 330 CBC instrument procedure did not include the following: Specimen rejection criteria, reportable range as determined during validation, actions to take for results outside the reportable range, quality control protocol that was consistent with manufacturer requirements, control corrective actions, panic/alert values, actions to take if the instrument becomes inoperable. 3. During an interview with the laboratory lead on 01/24/24 at 1:45 pm, the laboratory lead confirmed the Sysmex XN 330 CBC procedure did not include all required procedural elements, and was not consistent with manufacturer requirement for performance of quality control after reagent replacement, instrument maintenance, or instances when results are questioned.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(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.

This STANDARD is not met as evidenced by:

Based on a chart audit, review of the laboratory's QC records, and staff interview, the

laboratory's quality assessment process was ineffective in detecting problems with instrument date and time settings, and determining if quality control was performed prior to patient testing, in 2022 and 2023. The findings include: 1. During a chart audit, patient number 197527 was selected for audit of CBC results. The instrument printout had a date of 11/15/23 and a time of 00:02:20. The time on the QC records for the same date revealed a time of 20:28. It could not be determined from records whether the quality control was performed before patient testing as required by the instrument manufacturer, due to the incorrect times and potentially incorrect dates. 2. Review of the laboratory's QC records revealed the following months/days when the time of QC performance was inconsistent with the laboratory's hours of operation. December 2022-17 day of 23 days. January 2023-36 of 38 days. February 2023-20 of 24 days. November 2023-29 of 41 days. December 2023-27 of 31 days. 3. Review of the November 2023 laboratory's quality assessment records revealed QC record review documented on 12/21/23 with no corrective action performed for the incorrect instrument times. 4. During an interview on 01/24/24 at 1:45 pm the lab lead stated the laboratory did not have a review process in place to determine if QC was being performed before patients, or if instrument date/time was correct. This confirmed the survey findings.