

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2010811	<b>(X3) Date Survey Completed</b>  11/01/2023
<b>Name of Provider or Supplier</b>  Allcare Medical Clinic, PLLC	<b>Street Address, City, State</b>  313 Cleveland St, Ripley, 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>D5893</b>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT 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 observation of the laboratory and staff interview during observations, review of the laboratory's quality assessment plan, patient test results and interview with the technical consultant, quality assessment reviews were ineffective in detecting and correcting problems with the final patient test report for three of three patients reviewed from 2022 and 2023, resulting in the reporting of Complete Blood Count (CBC) results without a laboratory address or units of measure, and incorrect reporting of both White Blood Cell (WBC) percent differential and WBC absolute counts. The findings include: 1. Observation of the laboratory on 11/01/23 at 12:30 pm revealed the CELL-DYN Emerald CBC instrument in use for patient testing for CBC. During observations the lead testing person was asked to describe the process for reporting patient test results. She stated that after the CBC is performed it is manually entered into the electronic medical record (EMR), the paper copy is taken to the provider for review, and the results from the instrument are scanned into the electronic medical record (EMR). She stated that if the patient needed a copy of their CBC results they would receive the clinic's EMR record/visit record. 2. Review of the laboratory's quality assessment plan revealed the following under the section for "POSTANALYTIC": The laboratory report for results must have the following information: Name and address of lab where testing was performed. Units of measure. "PATIENT TEST MANAGEMENT This process is a random review of a varied number of patient charts to check for proper ID by 2 identifiers, verify order request is</p>

in chart, completeness of all test results, potential adverse effect on the patient, successful QC, pm and correct and timely entrance into the chart or EMR. This process is a critical step in monitoring the quality assessment of the laboratory." 3. Review of patient test results revealed the following for three of three selected patients (patient #1 reported on 07/25/22, patient #2 reported on 05/04/23, patient #3 reported on 08/16/23): The electronic medical record did not include the address of the laboratory. The units of measure were not included for any of the reported CBC analytes. The results for the (WBC) percent differential were recorded as WBC absolute counts. The results for the WBC absolute count were recorded under the section for WBC % differential. 4. During an interview with the technical consultant on 11/01/23 at 3:45 pm the technical consultant stated that the CBC results that are manually entered from the laboratory copy to the laboratory section of the EMR are not included in the patient test management review. This confirmed the survey findings.