

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2054928	<b>(X3) Date Survey Completed</b> 07/03/2019
<b>Name of Provider or Supplier</b> Citizens Of Lake County For Healthcare	<b>Street Address, City, State</b> 317 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>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the quality assessment (QA) plan, the QA records and interview with the laboratory liaison, the laboratory failed to follow the QA plan for complete blood count (CBC) quality control (QC) review process, in 2018 and 2019. The findings include: 1) Observation of the laboratory on July 3, 2019 at 9:50 a.m. revealed the Medonic CBC instrument, serial number 22514, in use for patient CBC testing. 2) Review of the QA plan revealed, "At the end of each month the clinic will email the monthly quality control summary page for that month to include all three levels of controls and the kit insert containing the limits and ranges to the technical consultant. The TC will review the quality control records, noting any problems or issues that may need corrective action or follow up and report back to the clinic via email with one week of receipt." 3) Review of the QA records revealed there was no monthly documentation from the technical consultant for reviewing the monthly CBC QC for the following: February, April, May, November, and December of 2018; January and April of 2019. 4) Interview on July 3, 2019 at 10:30 a.m. with the laboratory liaison confirmed the QA plan is not followed when the monthly CBC QA reviews are not returned within one week.</p>