

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0468729	<b>(X3) Date Survey Completed</b> 06/19/2018
<b>Name of Provider or Supplier</b> Gentry Medical Center	<b>Street Address, City, State</b> 643 East Third Street, Gentry, AR	
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>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Through a review of the QC (quality control) file tabular reports for November 2017, a review of the Tabular report for 11/1/2017 and 11/2/2017, and interviews with laboratory staff, it was determined the laboratory failed to ensure control results were acceptable before reporting patient test results. Survey findings follow: A. The QC file tabular reports for November include all hematology quality controls tested and also include the time that each control was run. On 11/1/2017 the QC file tabular reports include the QC Low which was tested at 16:12 (4:12 p.m.), the QC Normal which was tested at 16:18 (4:18 p.m.), and the QC High which was tested at 16:22 (4:22 p.m.). B. The Tabular report (a list of patients tested with the time that they were tested) for 11/1/2017 includes eight patients. All eight patients were tested prior to the quality controls. Patient samples tested are as follows: 00916231 at 8:35 a.m.; 00916224 at 8:37 a.m.; 00916240 at 8:39 a.m.; 00916297 at 11:01 a.m.; 00916271 at 11:45 a.m.; 00916324 at 11:48 a.m.; 00916303 at 11:52 a.m.; and 00916265 at 11:59 a.m. C. The QC file tabular reports for November include all hematology quality controls tested and also include the time that each control was run. On 11/2/2017 the QC file tabular reports include the QC Low which was tested at 16:03 (4:12 p.m.), the QC Normal which was tested at 16:05 (4:18 p.m.), and the QC High which was tested at 16:07 (4:22 p.m.). D. The Tabular report for 11/2/2017 includes twelve patients. All twelve patients were tested prior to the quality controls. Patient samples tested are as follows: 00916446 at 8:52 a.m.; 00916481 at 9:31 a.m.; 00916492 at 9:49 a.m.; 00916460 at 10:13 a.m.; 00916465 at 10:32 a.m.; 00916446 at 10:35 a.m.; 00916511 at 10:41 a.m.; 00916549 at 11:18 a.m.; 00916558 at 11:42; 00916587 at 13:38; 00916614 at 14:53;</p>

and 00916617 at 15:03. E. In an interview at 3:12 p.m. on 6/19/2018, the technical (as listed on the form CMS-209) confirmed the laboratory reported patients prior to testing quality control.