

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2130449	<b>(X3) Date Survey Completed</b>  02/28/2018
<b>Name of Provider or Supplier</b>  Center For Health Education, Medicine	<b>Street Address, City, State</b>  108 Hillside Boulevard, Lakewood, NJ	
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 surveyor review of the Procedure Manual (PM) Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to establish a procedure for verifying new QC material used on Beckman Coulter Act diff2 hematology analyzer from January 2018 to the date of the survey. The TP #1 Listed on the CMS for 209 confirmed on 2/28/18 at 1:00 pm the laboratory did not have a procedure to verify new QC.</p>
<b>D5807</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), and interview with the Testing Personnel (TP), the laboratory failed to include the Normal Reference Intervals (NRI) for Throat Culture tests on FR from June 2017 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 2/28/18 at 12:45 pm that the laboratory failed to include the NRI on the FR.</p>

**D6013****LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Verification (PV) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that two out of four verification procedures performed on the Act 2 analyzer for complete blood count were adequate from January 2017 to the date of survey. The findings include: 1. The PV was not reviewed and approved by the current LD before performing patient samples. 2. The LD failed to ensure that the accuracy of analytes verified was adequate. 3. The LD failed to ensure that patient normal ranges were verified. 4. The TP #1 listed on CMS form 209 confirmed on 2/28/18 at 1:00 pm that verification studies were not adequate.