

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2074713	(X3) Date Survey Completed 06/03/2021
Name of Provider or Supplier Accordia Healthcare, Llc	Street Address, City, State 3193 East First St, Vidalia, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on June 3, 2021. Condition and Standard level Citations were found. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the daily Quality Control (QC) for the Horiba Hematology Analyzer, (Horiba), the laboratory failed to verify the QC performed in January 2021 thru April 2021, met the acceptable guidelines before patient sample results were released. The laboratory released 78 patient results, when the QC was out of range on 17 days from January 2021 thru April 2021. Reference :D6020, D6024</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:
 Based on the review of the Quality Control (QC), for the Horiba Hematology Analyzer (Horiba), the Laboratory Director (LD) failed to ensure the quality control program is established and maintained to assure the quality of laboratory services being provided. Findings: 1. Review of the QC documents for the Horiba, for the month of January showed that the QC was out of range for the analyte White Blood Cell (WBC) for the High, Normal and Low for the following days, and patient results were reported out: 1-9-2021 the High and Normal levels for WBC were out of range, 5 patients had WBCs reported 1-10-2021 the High and Normal levels for WBC were out of range, 6 patients had WBCs reported 1-14-2021 the High and Normal levels for WBC were both out of range, 5 patients had WBCs reported 1-22-2021 the High, and Low levels for WBC were out of range, 4 patients had WBCs reported 1-24-2021 the High, Normal and Low levels for WBC were out of range, 4 patients had WBCs reported 2-01-2021 the High, and Normal levels for Red Blood Cell (RBC) QC were out of range, 8 patients had RBC's reported 2-02-2021 the High and Low levels for RBC were out of range, 4 patients had RBC's reported 2-03-2021 the High and Normal levels for RBC were out of range, 2 patients had RBC's reported 3-09-2021 the High and Normal levels for WBC were out of range, 3 patients had WBCs reported 3-13-2021 the High and Normal levels for WBC were out of range, 2 patients had WBCs reported 3-17-2021 the High and Normal levels for WBC were out of range, 5 patients had WBCs reported 3-21-2021 the High and Normal levels for WBC were out of range, 1 patient had WBCs reported 3-23-2021 the High and Normal levels for WBC were out of range, 4 patients had WBCs reported 3-24-2021 the High and Normal levels for WBC were out of range, 2 patients had WBCs reported 3-25-2021 the High and Normal levels for WBC were out of range, 6 patients had WBCs reported 3-31-2021 the High and Normal levels for RBC were out of range, 11 patients had RBCs reported 4-5-2021 the High and Normal levels for WBC were out of range, 6 patients had WBCs reported. 2. Review of the QC for the Horiba, for the months of January thru April 2021 confirmed the analyte WBC was out of range for the following consecutive days for each month as follows: January 2021 - The WBC was out of range for 23 consecutive days, with no corrective action documented. February 2021 - The WBC was out of range for 25 consecutive days, with no correction action documented March 2021 - The WBC was out of range for 20 consultative days, with no correction action documented April 2021 - The WBC was out of range for 11 consecutive days, with no correction action documented. 3. Interview with staff # 5 (CMS form 209) on June 3, 2021, at approximately 4pm in the breakroom, confirmed the above findings for the months of January 2021 thru April 2021, and that there was no corrective action documented.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:
 Based on the review of the Quality Control (QC) documents for the Horiba

Hematology Analyzer (Horiba), the Laboratory Director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified. QC documents for January 2021 thru April 2021 were not followed up and corrective action performed on the 78 patients that were reported out, when on 17 days the QC was not acceptable, due to the QC was out of range for two levels of QC for the Horiba. Findings: 1. Review of the QC documents for the Horiba, for the month of January showed that the QC was out of range for the analyte White Blood Cell (WBC) for the High, Normal and Low for the following days, and patient results were reported out: 1-9-2021 the High and Normal levels for WBC was both out of range, 5 patients had WBCs reported 1-10-2021 the High and Normal levels for WBC was both out of range, 6 patients had WBCs reported 1-14-2021 the High and Normal levels for WBC was both out of range, 5 patients had WBCs reported 1-22-2021 the High, and Low levels for WBC was both out of range, 4 patients had WBCs reported 1-24-2021 the High, Normal and Low levels for WBC was all three out of range, 4 patients had WBCs reported 2-01-2021 the High, and Normal levels for Red Blood Cell (RBC) QC was both out of range, 8 patients had RBC's reported 2-02-2021 the High and Low levels for RBC was both out of range, 4 patients had RBC's reported 2-03-2021 the High and Normal levels for RBC was both out of range, 2 patients had RBC's reported 3-09-2021 the High and Normal levels for WBC was both out of range, 3 patients had WBCs reported 3-13-2021 the High and Normal levels for WBC was both out of range, 2 patients had WBCs reported 3-17-2021 the High and Normal levels for WBC was both out of range, 5 patients had WBCs reported 3-21-2021 the High and Normal levels for WBC was both out of range, 1 patient had WBCs reported 3-23-2021 the High and Normal levels for WBC was both out of range, 4 patients had WBCs reported 3-24-2021 the High and Normal levels for WBC was both out of range, 2 patients had WBCs reported 3-25-2021 the High and Normal levels for WBC was both out of range, 6 patients had WBCs reported 3-31-2021 the High and Normal levels for RBC was both out of range, 11 patients had RBCs reported 4-5-2021 the High and Normal levels for WBC was both out of range, 6 patients had WBCs reported. 2. Review of the QC for the Horiba, for the months of January thru April for 2021 shows that for the analyte WBC, was out of range for the following consecutive days for each month as follows: January 2021 - The WBC was out of range for 23 consecutive days, with no corrective action documented. February 2021 - The WBC was out of range for 25 consecutive days, with no correction action documented. March 2021 - The WBC was out of range for 20 consultative days, with no correction action documented. April 2021 - The WBC was out of range for 11 consecutive days, with no correction action documented. 3. Interview with staff # 5 (CMS form 209) on June 3, 2021, at approximately 4pm in the breakroom, confirmed the above findings for the months of January 2021 thru April 2021, and that there was no remedial action documented.