

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2004759	<b>(X3) Date Survey Completed</b>  10/08/2020
<b>Name of Provider or Supplier</b>  D Conrad Harper Md, Llc	<b>Street Address, City, State</b>  101 Nw Bowens Mill Rd, Suite D, Douglas, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on October 8, 2020. 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:
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) Procedure, and staff interview, the Laboratory Director (LD) failed to ensure that quality assessment programs were monitored and maintained to assure the quality of laboratory services provided. Findings: 1. Review of the QA procedure, the LD failed to maintain and monitor the quality of the laboratory services that were being provided. There was no QA monitors, to monitor Quality Control, the corrective action for Proficiency scores of less than 100%, for performance of weekly and monthly maintenance on the instruments, for competency evaluations for all teting personnel, and for overall operation and administration of the laboratory. 2. Interview with staff #1 (CMS 209 form), on October 8, 2020, at approximately 12:50 pm in the break room, confirmed that there was no QA documentation as stated in the aforementioned statement.</p>
<b>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of the documents for the Competency of Testing Personnel (TP), and staff interview, the Laboratory Director failed to perform competencies on TP to monitor their preanalytical, analytical, and postanalytical phases of testing. Findings: 1. Review of the Competency documents for the TP in the lab, was performed in 2016, when the TP worked at the facility at that time. The current TP, left and returned, and is currently working in the laboratory. No new competencies have been performed. 2. Staff interview with staff #1 (CMS 209 form), in the breakroom on October 8, 2020 at approximately 10:15 am, confirmed that the only competency that was documented for the TP was dated 2016.

**D6072**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of the maintenance logs for the Siemens Dimension Chemistry Analyzer (Dimension), and staff interview, the laboratory failed to document performance of the manufacturer's required maintenance on the maintenance log. Findings: 1. Review of the maintenance logs for the Dimension showed the following: 2019 There were no logs before May 2019 May, June, July and August - logs were blank September - weekly maintenance was performed twice October and November - logs were blank 2020 January - weekly not performed February-weekly not performed April - form was blank The instrument has been down since May 2020 2. Interview with staff #1 (CMS 209 form), in the breakroom, on October 8, 2020, at approximately 10:30 am, confirmed that the maintenance documentation was not performed as required.