

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1040166	<b>(X3) Date Survey Completed</b>  02/21/2020
<b>Name of Provider or Supplier</b>  Simedhealth Llc	<b>Street Address, City, State</b>  4343 W Newberry Rd Suite 5, Gainesville, FL	
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 recertification survey conducted on 2-21-2020, found the SimedHealth L.L.C clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were not met: D5200- General Laboratory Systems
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Cross Reference D5209 - Personnel Competency Assessment Policies</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: This is a repeated deficiency from last survey on 3/15/2018. Based on record review and interview the laboratory failed to perform initial and 6-month competency assessments for 2 (TP#F and TP# G) out of 7 testing personnel (TP). Annual competency</p>

assessment for 4(TP#A-D) out of 7 TP, 2 general supervisors (GS), 2 technical supervisors (TS), clinical consultant (CC) and technical Consultant (TC). Findings Include: A review of the CMS 209 Laboratory personnel record displays that TP# A-G are Testing personnel. GS# A and B are general supervisors. TS# A and B are technical supervisors. CC#A is a clinical consultant. TC#A is a technical consultant. A review of 2019 Employee Competency Assessment record is revealed that initial and six-month competencies were not preformed for 2 (TP#F and TP# G) out of 7 TP in 2019. Annual competency assessments were not performed for 4 (TP#A -D) out of 7 TP ,GS#A , GS#B , CC#A ,TS#A , TS#B and TC#A. During an interview on 2-21-2020 at 3:30pm, The general supervisor A confirmed that initial and 6-month competency assessment were not done for 2 TP and the annual competency assessments were not performed for 2 GS, 2 TS , 4 TP, CC and TC .

**D5413**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on observation, record review and staff interview, the laboratory failed to monitor room humidity for Beckman Coulter Unicell DXH 800 and Dynex DSX Best 2000 Analyzer for 2018 and 2019 . Finding Include: An observation of the Chemistry and Hematology areas revealed a thermometer in each room with a humidity gauge. A review of Beckman Coulter Unicell DXH 800 manual record displayed the required humidity range of 70 -85% for Beckman Coulter Unicell DXH 800. A review of Dynex DSX Best 2000 Analyzer manual record states a required humidity range 15 -85% for DSX Best 2000 Analyzer . A review of Temperature Log Manual Record displayed that humidity was not recorded from 2018 to 2019. During an interview on 2-21-2020 at 3:30pm, the general supervisor A confirmed that humidity was not recorded for 2018 and 2019.

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on observation and staff Interview, the laboratory failed to properly label reagents with name, open date, expiration date and remove expired reagents from refrigerators located in Chemistry and Hematology areas. Findings Include: An observation of the Hematology area revealed a Beckman coulter refrigerator. The

refrigerator contained small bottles of diluents, A1C linearity, A1A alcohol and Stock wash solution that were missing expiration and open dates. Two small sample diluents bottles had expiration dates of October 2019 . An observation of the Chemistry area reveled a Dynex refrigerator. The refrigerator contained immunology stock wash and auto antibodies reagent in two bottles without an open date, expiration date and no proper label to identify chemical. During interview on 2-21 -2020 at 3:30 pm , The general supervisor A and testing personnel E confirmed that reagents were not labeled with name, open date, expiration date and expired reagents were not thrown away in Dynex and Beckman coulter refrigerators.

**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 record review and staff interview, the laboratory director failed to sign and validate the Beckman Coulter DxH800 and Au680 in 2018. Findings Include: A review of the CMS 209 Laboratory Personnel record displays Employee B as a general supervisor (GS). Employee A is the laboratory director (LD) and technical consultant (TC). A review of Beckman Coulter DxH800 validation record revealed the GS signed on the method approval line on 5-25-2018 . A review of Beckman Coulter Au680 validation record showed the GS signed on the method approval line in 4-16-2018 . During an interview on 12-21-2020 at 3:30pm, the GS confirmed that he had signed the validations for Beckman Coulter DxH800 and Au680 in 2018.