

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1040166	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier Simedhealth Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Based on record review and staff interview, the laboratory failed to document annual competency assessment on four out of five testing personnel. The findings include: Review of the competency records showed that the laboratory failed to have documentation of annual competency assessments for four out of five testing personnel. Testing Person #2 last had a competency assessment on 2/10/16; Testing Person #3 last had a competency assessment on 5/19/14; Testing Person #4 last had a competency assessment on 7/8/09, and Testing Person #5 last had a competency assessment on 7/8/09. During an interview with the General Supervisor on 3/15/17 at 1:50 PM, it was confirmed that personal competency had not been performed annually for all testing personnel.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to assess and correct</p>

problems with verification of accuracy of C-reactive protein (CRP), 25-hydroxyvitamin D (25-OH Vit D), Human chorionic gonadotropin (HCG), erythrocyte sedimentation rate (ESR), and Microalbumin in 2016 and 2017. The findings include: The record review of the 2016-2017 American Proficiency Institute (API) testing results for the laboratory showed the following unsatisfactory grades: The API 2nd Event Immunology 2016 analyte CRP scored 50%. The correction action showed this was due to clerical error. The API 3rd Event Immunology 2016 analyte scored CRP 50% with no correction action documented. The API 1st Event Chemistry 2017 analyte 25-OH Vit D scored 67%. The correction action stated the failure was due to a reconstitution error. The API 1st Event Chemistry 2017 analyte HCG scored 40%. The correction action stated the failure was due to a dilution error. The API 2nd Event Chemistry 2017 analyte Microalbumin scored 0%. The correction action stated the failure was due to a clerical error. The API 3rd Event Hematology 2017 analyte ESR scored 50%. The correction action stated the failure was due to the sample being processed as a patient and not like a quality control sample. There was no documentation to show training of staff or changes in procedure to prevent the failures from occurring in the future. The interview with the General Supervisor on 3/15/18 at 2:00pm confirmed the lack of documentation to show training of staff or changes in procedure occurred as part of the correction action.