

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0710170	<b>(X3) Date Survey Completed</b> 02/01/2018
<b>Name of Provider or Supplier</b> Covenant Medical Group Central Lab	<b>Street Address, City, State</b> 6600 Nightingale Ln, Lower Level, Knoxville, TN	
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>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:</p> <p>_____ Based on Quality Assurance Plan for Personnel Policy stating "employees are evaluated twice within the first year of employment for competency-may be done at the 6 month evaluation, lack of 6 month competency evaluation for testing person number 3 of 5, hired 3/21/16, and interview with the Laboratory Supervisor and Technical Consultant, determined the laboratory failed to follow policy to assess personnel competency twice within the first year of employment for testing person #3. The findings include: 1. Quality Assurance Plan for Personnel Policy states "employees are evaluated twice within the first year of employment for competency-may be done at the 6 month evaluation". 2. Lack of competency evaluation twice within the first year of employment for testing person number 3 of 5 hired 3/21/16. 3. Interview at approximately 11:00 a.m. February 1, 2018 with the Laboratory Supervisor and Technical Consultant confirmed the laboratory failed to follow policy to assess personnel competency twice within the first year of employment for testing person #3 hired 3/21/16.</p> <p>_____</p>
<b>D5469</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When</p>

control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

\_\_\_\_\_ Based on review of package insert and assay sheets for Chemistry Quality Control (QC ) Materials, lack of verification of statistical parameters for QC materials as recommended by manufacturer and interview with the Laboratory Supervisor and Technical Consultant, determined the laboratory failed to verify the criteria for acceptability of Chemistry Control Materials for 2016 and 2017. The findings include: 1. Review of package insert and assay sheets for Chemistry QC materials. 2. Lack of verification of statistical parameters to include mean and standard deviations for Chemistry QC materials as recommended by the manufacturer for 2016 adn 2017. 3. Interview at approximately 2:00 p.m. February 1, 2018 with the Laboratory Supervisor and Technical Consultant confirmed verification of statistical parameters for Chemistry QC materials had not been verified for the 2 year period. \_\_\_\_\_

**D5481**

**CONTROL PROCEDURES**

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

\_\_\_\_\_ Based on out of range Lipase Quality Control (QC) results on 1/30/18, laboratory's criteria for acceptable QC results, one patient test result reported on 1/30/18 and interview with the Laboratory Supervisor and Technical Consultant, determined the results of QC materials did not meet the laboratory's criteria for acceptability prior to reporting patient Lipase results on 1/30 /18. The findings include: 1. Out of range Lipase QC results for 2 of 3 quality control materials on 1/30/18. 2. Laboratory's criteria of at least 2 levels of acceptable QC results prior to reporting patient results. 3. One patient Lipase result reported on 1/30 /18. 4. Interview at approximately 2:00 p.m. February 1, 2018 with the Laboratory Supervisor and Technical Consultant confirmed the results of Lipase QC materials did not meet the laboratory's criteria for acceptability prior to reporting one patient test result on 1/30/18. \_\_\_\_\_