

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0937575	(X3) Date Survey Completed 07/10/2018
Name of Provider or Supplier Clinical Research Center Core Laboratory	Street Address, City, State 263 Farmington Ave, L-1098, Mc-3805, Farmington, CT	
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 have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's competency records on 7/10/18 revealed the following: a. The laboratory did not have a policy in place to assess the competency of the clinical consultant (CC), technical supervisor (TS), and general supervisor (GS). b. Competency documentation for the CC, TS and GS was not available. 2. Staff interview with the laboratory director (LD) on 7/10/18 at 10:35 AM confirmed the above findings.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document annual</p>

competency of testing personnel (TP) to assess the knowledge and skills necessary to perform high complexity laboratory testing. Findings include: 1. Review of the laboratory's 2017 competency assessment records on 7/10/18 revealed annual competency documentation for 3 of 3 TP was not available. 2. Staff interview with the laboratory director on 7/10/18 at 10:50 AM confirmed the above findings. 3. The laboratory performs 527 tests annually.