

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2064079	(X3) Date Survey Completed 08/28/2019
Name of Provider or Supplier Genesis Health Group - Moline	Street Address, City, State 3900 28th Ave Dr Suite 100, Moline, IL	
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 an interview with the technical consultant (TC1); the laboratory failed to establish and follow written procedures that meet the requirement to assess employees performing technical consultant responsibilities in a moderately complex laboratory, affecting 1 out of 1 TC. Findings include: 1. The procedures manual and personnel records were reviewed. 2. The laboratory's personnel policy failed to include a written competency procedure that assesses the TC's performance of the following responsibilities: *Providing technical and scientific oversight of the laboratory; *Availability *Selection of test methodology appropriate for the clinical use of the test results; *Verification of the test procedures performed and the establishment of the laboratory ' s test performance characteristics, including the precision and accuracy of each test and test system; *Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; *Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; *Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory ' s established performance specifications; *Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; *Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the</p>

laboratory services performed; and *Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. 3. The personnel file of TC1 did not include a performance review of their TC responsibility. 4. On an Recertification survey conducted on 08/28/19 at 3:00 PM, TC1 and staff confirmed the above findings and stated that they were unaware the TC's competency had to be assessed.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on record review, the Laboratory Personnel Report (CMS 209), and an interview with the technical consultant (TC); the laboratory director (LD) failed to ensure that prior to testing patients' specimens, all personnel have demonstrated that they can perform the testing reliably to provide and report accurate results, affecting 5 out of 5 testing personnel (TP). Findings: 1. The CMS 209, personnel records for the years of 2018 and 2019, and manuals were reviewed. 2. Review of the competency files revealed the following: *TP1, TP2, TP3, TP4 and TP5 meet the education criteria required to perform moderately complex testing. *The competencies of 5 out of 5 TP were performed by laboratory manager (LM1) for the years of 2018 and 2019. *LM1 failed to meet the education criteria required to perform the responsibilities of a technical consultant (TC) to assess TP. 3. The LD failed to ensure the competencies performed by LM1 were reviewed, approved and the TP authorized to perform the moderately complex tests the laboratory provides. 4. On an Recertification survey conducted on 08/28/19 at 3:00 PM, the TC and staff confirmed the above findings.