

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2064079	(X3) Date Survey Completed 11/15/2022
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory representative (A. P.) the laboratory failed to verify the accuracy for two ungraded proficiency testing (PT) samples reviewed for six of six hematology/coagulation PT events from 2020 through 2022. Findings Include: 1. American Proficiency Institute (API) PT documentation was reviewed for 2020 through 2022. 2. Review of API hematology /coagulation PT performance summary documentation revealed for event three of 2020 and event two of 2022 the following ungraded PT samples: Event 3 of 2020 Sample Reported Result Expected Result Performance US-06 Renal tubular epithelial See Data Summary Not Graded Event 2 of 2022 Sample Reported Result Expected Result Performance VA-02 No yeast, Trich. or clue cells See Data Summary Not Graded 3. Review of API PT performance evaluation documentation for hematology /coagulation events three of 2020 and two of 2022 the laboratory failed to identify the ungraded PT samples (US-06 and VA-02) and verify their accuracy. 4. On survey date 11-15-2022, at 1:56 pm, the laboratory representative A.P. confirmed the laboratory failed to evaluate the non-graded PT samples (US-06 and VA-02) for PT event three in 2020 and event two in 2022.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p>

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory records and interview with a laboratory representative (A.P.); the laboratory failed to have a technical consultant (TC) who meets the qualification requirements of 493.1411. Findings Include: 1. One of one technical consultants, as listed on the CMS-209 (Laboratory Personnel Report), failed to meet the educational requirements. See D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with a laboratory representative (A.P.) one of one technical consultants (TC), as identified on the CMS-209 (Laboratory Personnel Report), failed to meet the qualification requirements for the position. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report)

identified testing personnel (TP) #7 as the TC. 2. Review of personnel records for TP#7 revealed TP#7 had a bachelor of science in health care administration and not a qualifying bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution. 3. On survey date 11-15-2022, at 1:56 pm, the laboratory representative A.P. confirmed the above findings.