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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0935390 | (X3) Date Survey Completed 07/30/2018 |
| Name of Provider or Supplier National Genetics Institute | Street Address, City, State 2311 Pontius Ave, Los Angeles, CA | |
| 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 |
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| D6079 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of personnel and patient testing records, lack of appropriate licensed testing personnel, and interview with the laboratory Technical Supervisor and testing personnel on July 30, 2018 at 3:05 pm, the laboratory Director failed to assure compliance with the high complexity testing personnel certification. The laboratory used testing personnel to perform high complexity test that are not within the scope of their state licensure. The findings include: See D6168 and D6170.</p> |
| D6168 | <p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> |

This CONDITION is not met as evidenced by:
Based on the severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing, testing personnel was not met. Almost all of the licensed testing personnel performing testing in virology subspecialty which is outside of their scope of practice. See D6170.

D6170

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:
Based on Surveyor review of testing personnel and patient testing records, and interview with the laboratory Technical Supervisor and testing personnel on July 30, 2018 at 3:05 pm, the laboratory failed to ensure the testing personnel performing the tests in virology possess an appropriate current license issued by the State of California. Division 2, Chapter 3, Article 1, 1206.5(c)(3) of the California Business and Professions Code (BPC) requires performance of laboratory testing by a licensed scientist if the test is within a specialty or subspecialty authorized by the person's licensure. The findings include: a. The laboratory performs high complexity testing in virology using molecular biology methods, and employs 7 full-time and 1 part-time testing personnel. Six out of 7 testing personnel possess the Clinical Genetic Molecular Biologist Scientist (CGMBS) license issued by Laboratory Field Services of California Department of Public Health. BPC 1210(b)(4) limits the CGMBS licensure to the subspecialty of molecular biology related to the diagnosis of human genetic abnormalities. b. On July 30, 2018 at 3:05 pm laboratory Technical Supervisor affirmed that most of the testing personnel possess CGMBS licensure. c. The laboratory testing declaration form, signed by the laboratory Director on July 27, 2018, indicates that the laboratory performs about 16,266 tests in virology, annually.