

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0506774	(X3) Date Survey Completed 10/20/2021
Name of Provider or Supplier Regence Health Network, Inc	Street Address, City, State 410 Canyon Street, Plainview, TX	
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
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1409 Condition: Laboratories Performing Moderate Complexity Testing; Technical Consultant
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Review of the CMS 209 Laboratory Personnel Report, proficiency testing records and interview of facility personnel found the laboratory failed to ensure all testing personnel participated in five of five proficiency testing events for Hematology in 2020 and 2021. The findings included: 1. Review of the CMS report 209 Laboratory Personnel report found the laboratory designated three testing personnel performing non-waived testing. 2. Review of American Proficiency Institute (API) proficiency testing records for 2020 and 2021 found Five of five events tested by testing person one on the CMS Report 209 Laboratory Personnel Report. 3. Interview of the Lab Coordinator conducted October 20, 2021 at 1:58 PM confirmed that testing person one was the only person that participated in the proficiency testing events.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Observations, review of policies and procedures, manufacturers instructions, quality control records, patient test records, and interview of facility personnel found the laboratory director failed to establish and maintain a quality assessment program to assure the quality of laboratory services.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

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:

Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory failed to have a technical consultant to provide oversight of laboratory services that met the minimum education requirements. (see D 6035)

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:

Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory failed to have a technical consultant to provide oversight that met the minimum education requirements. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found one Technical Consultant identified. 2. Review of the Technical Consultant credentials provided for review found he had earned the following degrees: Associate in Applied Science for Medical Laboratory Technology Bachelor of Business Administration Master of Business Administration Management 3. Interview of the director of the Lab Coordinator conducted October 20, 2021 at 1:38 PM confirmed the individual identified as the Technical Consultant of the laboratory had not earned at least a bachelor degree in a chemical, physical or biological science or medical technology.