

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0512503	(X3) Date Survey Completed 04/03/2018
Name of Provider or Supplier St Anthony Hospital	Street Address, City, State 11600 W 2nd Pl, Lakewood, CO	
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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <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.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to ensure that 4 new technical consultants met the qualification requirements to provide technical oversight of the moderate complexity testing performed in the laboratory (Ref D6035).</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(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</p>

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 the review of personnel records, laboratory policies and staff interview, the laboratory failed to ensure that 4 of 11 point of care (POC) technical consultants listed on Form CMS-209 (#1,2,10, and 28) were qualified to perform the technical and scientific oversight of the POC laboratory where moderate complexity blood gas testing is performed. Findings include: a. The laboratory analyzes patient specimens for blood gases using the Abbott i-STAT portable clinical analyzer. b. The policy titled "POC Quality Program" states that competency and training will be observed by an educator qualified as a technical consultant under CLIA Subpart M. c. The policy titled "Authorization of Responsibilities and Job Duties" states that technical consultants must have at least a bachelor's degree in a chemical, physical, biological or clinical laboratory science with at least two years of experience in non-waived testing in the designated specialty/subspecialty area. d. Two technical consultants (#2 and 10 on Form CMS-209) had not earned a Bachelor's degree in a natural or clinical laboratory science. e. Two technical consultants (#1 and 28 on Form CMS-209) had earned a Bachelor's in a natural or clinical laboratory science but had not attained two years of experience in non-waived testing in the specialty/subspecialty of routine chemistry. f. Staff stated on 4-3-18 at about 2 p.m. that the POC technical consultants are designated as "super users" for the i-STAT and have performed competency assessments of testing personnel assigned to the nursing units in the hospital. g. The laboratory could not provide any documentation that these four technical consultants met the minimum qualifications required by the federal CLIA regulations.