

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0674230	(X3) Date Survey Completed 10/18/2018
Name of Provider or Supplier Brookside Women's Medical Services	Street Address, City, State 1902 S Ih 35 Frontage Rd, Austin, 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	As a result of the CLIA recertification inspection, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, training documentation for testing personnel, and staff interview, the laboratory director failed to ensure that 1 of 11 testing personnel for the moderately complex test systems had documentation of qualifying education prior to performing patient testing. The findings included: 1. Based on review of laboratory policy "Laboratory Director", on page 4, the document states the following: "10. Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities;" 2. Based on review of personnel files, Testing Person 10 (1 of 11 Testing Persons) did not have documentation of credentials</p>

that met the requirements for moderate complexity testing at 42 CFR 493.1423. Refer to D6065. 3. In an interview at 10:53 hours on 10/18/2018, the Office Manager confirmed the findings.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a review of the CMS-209, laboratory policies and procedures, personnel records, and staff interview, the laboratory failed to ensure that 1 of 11 testing personnel met the qualification requirements at 42 CFR 493.1423 by having the appropriate education required to perform moderate complexity testing prior to analyzing patient specimens (refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, training documentation for testing personnel, and staff interview, the laboratory failed to ensure that 1 of 11 testing personnel for the moderately complex test systems had documentation of qualifying education prior to performing patient testing. The findings included: 1. Based on review of laboratory policy "Laboratory Director", on page 4, the document states the following: "10. Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities;" And; Based on review of the laboratory policy "Testing Personnel Qualifications and Responsibilities", the document states the following: "The testing personnel must meet one of the following qualification requirements regarding education, training, and experience: 1. M.D. or D.O. with a current medical license in the state of the laboratory's location. OR 2. Doctorate in laboratory science or chemical, physical, or biological science. OR 3. Masters in medical technology or chemical, physical, or biological science. OR 4. Bachelors in medical technology or chemical, physical, or biological science. OR 5. Associate degree in chemical, physical, or biological science or medical laboratory

technology. OR 6. High school graduate or equivalent and successfully completed military training or 50 or more weeks and served as a medical laboratory scientist. OR 7. Academic high school diploma or equivalent and appropriate training/experience for the test performed prior to analyzing client specimens. (See Training Section for specific requirements)." 2. Based on review of personnel files, Testing Person 10 (1 of 11 Testing Persons) did not have documentation of credentials that met the requirements for moderate complexity testing at 42 CFR 493.1423. The documentation for review indicated Testing Person 10 had a Bachelor of Arts with Distinction in German. 3. In an interview at 10:53 hours on 10/18/2018, the Office Manager confirmed the findings.