

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2122735	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Acorn To Oak Pediatrics	Street Address, City, State 1025 Hwy 80 E, Haughton, LA	
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	A Recertification Survey was performed at Acorn to Oaks Pediatrics-CLIA ID # 19D2122735 on March 14, 2019. Acorn to Oaks Pediatrics was found not in compliance with the following CONDITION LEVEL DEFICIENCIES : 42 CFR 493.1403 CONDITION : Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1421 CONDITION : Laboratories performing moderate complexity testing; Testing Personnel
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on March 14, 2019</p>

at 10:23 am, Personnel 2 stated she was unable to locate the policy for competency assessment. Personnel 2 confirmed the laboratory did not have a policy which includes the identified six (6) procedures.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure testing personnel performing moderate complexity testing met educational requirements. Refer to D6029. 2. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure testing personnel performing moderate complexity testing met educational requirements. Refer to D6065.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	<p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to establish complete written policies and procedures to assess competency for testing personnel. Refer to D5209. 2. The Technical Consultant failed to ensure that competency of testing personnel was assessed as required. Refer to D6046.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Consultant failed to ensure that competency of testing personnel was assessed as required. Findings: 1. Review of the Laboratory Personnel Report (Form CMS-209) revealed Personnel 1 serves as the Laboratory Director and Technical Consultant. 2. Review of personnel records revealed the laboratory did not maintain documentation for the 2018 competency assessments for the following personnel: Personnel 2-5 3. In interview on March 14, 2019 at 11:10 am, Personnel 2 stated she was unable to find the documentation of competency assessments for 2018. Personnel 2 confirmed the above competencies were not accurately accounted for.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide documentation all testing personnel met education requirements for moderate complexity. Refer to D6065.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p>

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 record review and interview with personnel, the laboratory failed to provide documentation that one (1) of four (4) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Findings: 1. Review of personnel records on March 14, 2019 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for the following personnel: Personnel 4 2. In interview on March 14, 2019 at 11:08 am, Personnel 2 confirmed the laboratory did not maintain documentation of education for Personnel 4.