

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0674920	(X3) Date Survey Completed 04/17/2018
Name of Provider or Supplier Oak Grove Medical Clinic	Street Address, City, State 708 East Main Street, Oak Grove, 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 Certification Survey was conducted on April 17, 2018 at Oak Grove Medical Clinic - CLIA # 19D0674920. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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:</p> <p>I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 7 and 8 serves as Technical Consultants. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Consultant. 3. Review of personnel records revealed competency assessments for the duties of Technical Consultant on Personnel 7 and 8 were not documented. 4. In interview on April 17, 2018 at 9:30 am, Personnel 8 stated that competency assessments were not performed for the Technical Consultants. II. Based on record review and interview with personnel, the laboratory failed to ensure detailed written policies and procedures were established to assess competency for testing personnel. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did have a policy to address competency; however, it did not include the following six (6) procedures as a minimal requirement for assessing the competency of the testing personnel: 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</p>

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 April 17, 2018 at 9:30 am, Personnel 8 confirmed the laboratory did not have detailed policies and procedures for personnel competency assessments.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: * Performance specifications for Laboratory Instrumentation to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges. b) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges. c) Policies and procedures for when data from the studies for precision, accuracy, reportable and reference ranges fail to meet acceptability criteria. * Detailed policies and procedure for an Individualized Quality Control Plan (IQCP): detailing who is going to perform, what is going to be performed, when it is going to be performed, where it is going to be performed and how it will be performed. What data is needed to support the IQCP and how that data will be retained. Also what will be the acceptability criteria, and who needs to review and sign off on the IQCP and when to implement the outcome. 2. Interview with personnel 7 and 8 on April 17, 2018 confirmed the laboratory did not have a complete policy and procedure manual.

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;

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 maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were complete. Refer to D5209 I. 2. The laboratory failed to ensure detailed written policies and procedures were established to assess competency for testing personnel. Refer to D5209 II.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5403.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Consultants failed to evaluate and document personnel annually for five (5) of five (5) testing personnel reviewed. Findings: 1. Review of personnel records revealed the Technical Consultants did not perform competency assessments annually in 2017 for the following personnel: Personnel 2 - 6 2. Further review of personnel records revealed the Technical Consultants did not perform a competency assessment in 2018 for Personnel 6. 3. In interview on April 17, 2018 at 9:30 am, Personnel 8 stated the

previous Technical Consultant retired in 2017. Personnel 8 stated that she was hired for the position in late 2017 and was unaware that competency assessments had not been performed. 4. In further interview on April 17, 2018, Personnel 8 stated that Personnel 6 was a "floater nurse" and that she did not perform a competency assessment. 5. Interview with Personnel 7 and 8 confirmed that competency assessments were not documented for testing personnel in 2017.