

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0219508	(X3) Date Survey Completed 02/26/2019
Name of Provider or Supplier Roger W Marcus Md Pa	Street Address, City, State 1814 Belair Road, Fallston, MD	
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
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that quality control (QC) and quality assessment (QA) records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented (D6022) (This is a repeat deficiency and was cited during the re-certification survey performed on 03/01/17).</p>
D6022	<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 director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 03/01/2017 for not ensuring that quality control (QC) and quality assessment (QA) records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented. The plan of correction stated that</p>

the QC would be reviewed and the QA would be documented as required. Based on review of the quality control (QC) and quality assessment (QA) records and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that QC and QA records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented. Findings: 1. The "Quarterly Quality Assessment Review" worksheets for 2017 and 2018 were reviewed. 2. Review of the "Quarterly Quality Assessment Review" worksheets for 2017 showed that the quarterly reviews for the 2nd, 3rd, and 4th quarter were missing. The TC confirmed that the worksheets were missing. 3. Review of the "Quarterly Quality Assessment Review" worksheets for 2018 showed that the quarterly reviews for the 1st, 2nd, and 3rd quarter were signed by the LD on 10/24/18. The TC confirmed that all the QC records were not reviewed until 10/24/18 and then given to the LD for review. 4. The duties and responsibilities of the LD states: "Ensures that quality control and quality assurance programs are established and maintained, and all remedial actions are taken and documented." The monthly QC records were not reviewed for at least 10 months in 2018 and there is no documentation showing that the QC records had been reviewed for 9 months (three quarters) in 2017. 5. During the exit interview on 02/26 /19 at 11:30 AM the TC confirmed that QC and QA documentation was not being performed as required.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
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:
Based on record review and interview with the technical consultant (TC), the TC failed to ensure that QC and QA records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented (D6042) (This is a repeat deficiency and was cited during the re-certification survey performed on 03/01 /17); and failed to evaluate the competency of the testing personnel by reviewing the laboratory records (D6049) (This is a repeat deficiency and was cited during the re-certification survey performed on 03/01/17); and failed to ensure that all testing personnel received an annual competency review (D6054).

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 03/01/2017 for not ensuring that quality control (QC) and quality assessment (QA) records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented. The plan of correction stated that

the QC would be reviewed and the QA would be documented as required. The technical consultant failed to ensure that QC and QA records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented. Cross refer to D6022 for details.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 03/01/2017 for not ensuring that the testing personnel were evaluated annually. The plan of correction stated that the testing personnel would be evaluated annually. Based on review of the annual evaluations of the testing personnel and interview with the technical consultant (TC), the TC failed to evaluate the competency of the testing personnel in a timely manner. Findings: 1. The TC failed to review the quality control (QC) records in a timely manner to ensure that the testing personnel were performing QC, evaluating QC, and documenting remedial actions when QC was unacceptable. Cross refer to D6022 for details. 2. The annual evaluations for 2016 for testing person (TP) #1 and #2 were performed on 02/01/2017. The annual evaluations for 2017 for TP #1 and #2 were performed on 10/24/2018. The annual evaluations for 2018 for TP #1 and #2 were performed on 12/20/2018. 3. The annual evaluations were not performed routinely in the same month and the evaluations for 2017 and 2018 were performed within two months of each other in the same year. 4. During the exit interview on 02/26/19 at 11:30 AM the TC confirmed that annual evaluations of the testing personnel were not being performed in a timely manner to ensure that problems were identified and corrective actions implemented.

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:

The technical consultant failed to ensure that all testing personnel received an annual competency review. Cross refer to D6049 for details.