

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0941532	(X3) Date Survey Completed 02/14/2019
Name of Provider or Supplier Beckley Area Medical Clinic	Street Address, City, State 1842 Harper Road, Beckley, WV	
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
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 review of the Personnel Manual, employee competency checklist, personnel records, and interview with testing personnel, the laboratory failed to follow written policies and procedures to assess employee competency. Findings: 1. Review of one of the laboratory's personnel records, titled "Laboratory Director's Verification of Applicant's Competency," that was retrieved from the administrative office, demonstrated that an initial employee competency assessment had been performed for the testing personnel at hire in April of 2018. 2. Review of the binder titled "Personnel Manual" demonstrated a policy titled "Personnel Training and Competency" that states on page 2 the following: "Competency assessment will be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload. Formal documentation of the competency assessment will be compiled and noted as follows: completion of training, six months of employment, one year of employment, annually, with new instrumentation and/or test procedures, and remedial training." 3. No records could be located by the testing personnel or office manager for the required 6-month competency assessment. 4. Interview with testing personnel on 2/14/2019 at approximately 10:20AM confirmed that the six-month required personnel competency had not been completed.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Policies and Procedures Manual and interview with testing personnel, the laboratory failed to verify the accuracy of the urine toxicology analytes that are not subject to Subpart I of the regulations. Findings: 1. Review of the "Laboratory Policies and Procedures" manual found that a policy titled "Proficiency Testing" exists, where it states that "all non-regulated tests that are non-waived are enrolled in an approved PT program or split sample comparisons are performed at least twice per year. Recommended at least 5 samples twice per year." 2. No lab records were found that documented a split sample comparison program for the urine toxicology and creatinine analytes, which the laboratory began testing and reporting in January of 2018. 3. Interview with testing personnel on 2/14/2019 at approximately 10:15AM confirmed that no proficiency testing or split sample analysis had been performed as of February 2019.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Policies and Procedures Manual, Personnel Manual, and Quality Assessment Plan Manual, the director failed to approve, sign, and date the laboratory's procedure and policy manuals. Findings: 1. Review of the Laboratory Policies and Procedures Manual on 2/14/2019 at approximately 10:30AM found that no director signature was present in the manual or any of the procedures contained within the manual. 2. Review of the Personnel Manual on 2/14/2019 at approximately 11:00AM found that no director signature was present in the manual or any of the procedures contained within the manual. 3. Review of the Quality Assessment Plan Manual on 2/14/2019 at approximately 11:10AM found that no director signature was present in the manual or any of the procedures contained within the manual.

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 review of the laboratory's records and interview with testing personnel and the director, the laboratory director failed to provide overall management and direction in accordance with 493.1407. Findings: 1. Refer to citations under D6021, D6023, D6028, and D6031.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's QA manual and interview with testing personnel, the director failed to ensure the performance and maintenance of a quality assessment program from April of 2018 to February 14, 2019. Findings: 1. Review of a binder titled, "Quality Assessment Plan Manual," on 2/14/19 at approximately 11:10AM demonstrated an acceptable quality assessment plan, procedure, and forms for documentation had been written by a laboratory consultant. The plan was not dated or signed by the current director. 2. No evidence was found during review of the manual to support that the QA plan is being followed. All forms were blank, and no completed forms could be located. 3. Interview with testing personnel on 2/14/19 at approximately 11:10AM found that he was not aware of the QA plan. He had not taken part in any quality assessment since his hire in March of 2018.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's calibration and QC records and interview with the director and testing personnel, the laboratory director failed to prove the calibrations and QC results are acceptable, ensuring the analytical performance of the Medica EasyRA instrument. Findings: 1. Review of calibration records from December 2018 and January and February 2019 demonstrates that the acceptability of a calibration run is not stated on stored records. 2. Interview with testing personnel on 2/14/19 at approximately 10:18AM and review of calibration documents stored in computer's hard drive demonstrated nothing stating the calibrations were successful. There were no acceptable ranges for the calibration values, or statements saying "pass" or "fail." 3. Per the testing personnel, the instrument will flag upon run completion if the calibration was unsuccessful. However, there was no log of this upon inspection of the stored documents. 4. Per telephone conversation on 2/14/19 at approximately 11:45AM with a member of the instrument's technical support hotline, the instrument should maintain a cumulative report of quality control results that shows proof whether the results were acceptable or not acceptable. However, he was unable to walk me or the testing personnel through finding this report as he "has to be in front of the instrument" in order to find the report.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

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)(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 described in this subpart;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records and interview with the director and testing personnel, the director failed to employ a technical consultant. Findings: 1. Review of the laboratory's personnel binder demonstrated that no person employed by the laboratory is qualified to be the technical consultant. 2. Review of the director's education documents and interview with the director on 2/14/19 at approximately 11:40AM determined that she does not qualify to serve as the technical consultant due to having no prior experience in managing or performing testing in a moderate complexity laboratory. 3. Interview with the testing personnel on 2/14/19 at approximately 10:10AM determined that he does not qualify to serve as the technical consultant due to having no prior experience in performing testing in a moderate-complexity laboratory.

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 review of the Laboratory Policies and Procedures manual, the director failed to ensure that an approved procedure manual was available for use during the testing process. Findings: 1. Review of the binder titled "Laboratory Policies and Procedures Manual" demonstrated that it was last signed on 11/22/17 by the previous director. The current director had not signed the manual. 2. Interview with the office manager on 2/14/19 at approximately 11:40 demonstrated that the current director took her position in approximately April of 2018.

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 review of the laboratory's personnel records, education documents, and interview with the director and testing personnel , the laboratory failed to employ a technical consultant. Oversight in accordance with the regulation was not provided due to the lack of a technical consultant. Findings: 1. Based on personnel records and the CMS 209 that was filled out by the lab, there is no one currently serving as the technical consultant. 2. Review of the director's education documents and interview with the director on 2/14/19 at approximately 11:40AM determined that she does not qualify to serve as the technical consultant due to having no prior experience in managing or performing testing in a moderate complexity laboratory. 3. Interview with the testing personnel on 2/14/19 at approximately 10:10AM determined that he does not qualify to serve as the technical consultant due to having no prior experience in performing testing in a moderate-complexity laboratory.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's personnel records and interview with testing personnel and the director, the laboratory failed to employ a technical consultant. Findings: 1. Refer to citation at D6033.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's personnel competency records, a 6-month personnel competency assessment for the testing person was not performed as required due to the lack of a qualified technical consultant. Findings: 1. A partial initial competency assessment was produced, titled "Laboratory Director's Verification of Applicant's Competency"; it included only pages 6 through 8 and was signed by the testing person and director on April 20, 2018. 2. The laboratory was unable to locate records for the required 6-month competency assessment for the testing personnel, which would have been due in October of 2018. 3. Interview with the testing person on 2/14/19 at approximately 10:15AM confirmed that he was not evaluated for competency at the 6-month interval. No further competency assessment records were found past the initial training record. 4. Based on personnel records and the CMS 209 that was filled out by the lab, there is no one currently serving as the technical consultant.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records, a semiannual evaluation of the testing personnel was not performed due to the lack of a qualified technical consultant. Findings: 1. Refer to citation at D6046