

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0891080	<b>(X3) Date Survey Completed</b>  04/06/2018
<b>Name of Provider or Supplier</b>  Community Clinic Springdale Medical	<b>Street Address, City, State</b>  614 E Emma Ave, Ste 300, Springdale, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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: Through review of personnel records, lack of documentation, and interview it was determined that the laboratory failed to perform competency evaluations on two of seven personnel identified on the CMS 209 form. Findings follow: A. Review of personnel records revealed that no competency evaluations were provided for the testing personnel identified as number six on the CMS 209 form, who has been testing since 9/1/16, and number seven on the CMS 209 form, who has been testing since 3/21/17. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 4/6/18 at approximately 01:30 pm, the laboratory director identified as number one on the CMS 209 form confirmed that competency evaluations had not been performed on the personnel identified above.</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Through observation and interview it was determined that the laboratory failed to assure that supplies were not used when they have exceeded their expiration date.</p>

Findings follow: A. During a tour of the laboratory on 4/6/18 at approximately 0835, five of five bottles of Potassium Hydroxide Solution ( one bottle Lot # 5315803 with an expiration date of 2016//11/09, and four bottles lot # 1703015 with an expiration date of 2018/01/30) were observed in the microscopy area and no unexpired Potassium Hydroxide was observed in the area at that time . B. In an interview on 4/6 /18 at approximately 0835, the laboratory director identified as number one on the CMS 209 form confirmed that the bottles were available for use, and had exceeded the expiration date.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Through review of personnel records, lack of documentation, and interview it was determined that the laboratory failed to have written authorization to perform testing for three of seven testing personnel listed on the CMS 209 form. Findings follow: A. Upon review of personnel records, no written authorization to test was found for testing personnel identified as numbers six, seven and nine on the CMS 209 form. B. Upon request, the laboratory could not produce a written authorization to test for the personnel mentioned above. C. In an interview on 4/6/18 at approximately 1245 the laboratory director identified as number one on the CMS 209 form confirmed that no written authorization to test was available for the testing personnel identified above and that those personnel did perform moderate complexity testing.