

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2113862	(X3) Date Survey Completed 07/18/2019
Name of Provider or Supplier Slma Comprehensive Healthcare Clinic	Street Address, City, State 605 Enterprise Drive, Suite B, Houma, 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 performed on July 18, 2019 at SLMA Comprehensive Healthcare Clinic, CLIA ID # 19D2113862. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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: Based on observation and interview with personnel, the laboratory failed to ensure laboratory supplies had not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on July 18, 2019 revealed the following expired items: BBL Culture Swab Plus, Lot # 170380616, Expiration date: 2018/11, Quantity: three (3) swabs 2. In interview on July 18, 2019 at 9:53 am, Personnel 5 confirmed the identified swabs were expired. Personnel 5 stated the laboratory did not use the identified swabs.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p>

	<p>This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5417.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(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> <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 for assessing personnel competency were maintained. Refer to D6046 and D6051.</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 with personnel, the Technical Consultant failed to perform competency assessments for testing personnel. Findings: 1. Review of the laboratory's "Staff Orientation, Training and Competency" policy under "Annual Orientation and Competency of Laboratory Staff" stated "The Technical Consultant (TC) for moderate complexity is responsible for performing and documenting competency assessments." 2. Review of personnel records revealed the Technical Consultant did not perform the competency assessments for the following testing personnel in 2019: Personnel 2 Personnel 3 Personnel 4 3. In interview on July 18, 2019 at 10:22 am, the Laboratory Director, who also serves as the Technical Consultant, stated he did not perform the competency assessments for the identified testing personnel. The Laboratory Director stated Personnel 5 performed the assessments.</p>
<p>D6051</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed</p>

specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples or external proficiency samples. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 2 Personnel 3 Personnel 4 Personnel 5 2. Review of the laboratory's "Staff Orientation, Training and Competency" policy stated "As defined by CLIA, the following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing: 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. Competency assessment, inclusive of the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform." 3. Review of the laboratory's "Competency Checklist" revealed the following task : "Assessment of Proficiency Testing Reporting: Achieves Accuracy, The employee can provide corrective action for failed proficiency events." 4. Review of the laboratory's American Proficiency Institute (API) proficiency records for 2018 revealed the following testing personnel did not perform proficiency testing: Personnel 3 Personnel 4 5. In interview on July 18, 2019, Personnel 5 confirmed the identified personnel did not perform proficiency testing, internal blind samples, or previously analyzed samples in 2018.