

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1010322	(X3) Date Survey Completed 02/04/2019
Name of Provider or Supplier Eastern Reception Diagnostic & Correctional Center	Street Address, City, State 2727 Highway K, Bonne Terre, MO	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of troponin proficiency testing for 2017, 2018 and 2019 and interview with testing personnel #7 the laboratory failed to perform samples by personnel who routinely perform the testing in the laboratory. Findings: 1. Review of proficiency testing for 2017, 2018 and 2019 testing personnel # 9 performed all proficiency testing samples. 2. Interview with testing personnel #7 on February 4, 2019 at 11:45 AM confirmed testing personnel #9 performed all proficiency testing for 2017, 2018 and to date 2019.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature logs, troponin package and interview with testing</p>

	<p>personnel #7 the laboratory failed to document and monitor room temperature in one of two pharmacies that contain troponin tests. findings: 1. Review of temperature logs showed r & d pharmacy that contains troponin tests did not document or monitor room temperature. 2. Review of troponin package states store at "2 degrees Celsius to 30 degrees Celsius". 3. Interview with testing personnel #7 on February 4, 2019 at 12:30 PM confirmed the laboratory failed to document and monitor room temperature in r & d pharmacy that contains troponin tests.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2017, 2018 and to date 2019 and interview with testing personnel # 7 the laboratory director failed to ensure PT samples are tested by all of the individuals who test patient samples. Findings: 1. Review of 2017, 2018 and to date 2019 PT revealed that only one of twenty eight testing personnel performs all of the PT sample testing. 2. Interview with testing personnel #7 on February 4, 2019 at 12:15 PM confirmed all of the PT samples from 2017, 2018 and to date 2019 were tested by the same person.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of unregulated analyte troponin two times a year test accuracy for 2017 and 2018 and interview with testing personnel #7 on February 4, 2019 at 12:30 PM confirmed the laboratory director failed to ensure all proficiency testing reports are reviewed by the appropriate staff to evaluate the laboratory's performance.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p>

	<p>This CONDITION is not met as evidenced by: Based on review of competencies and interview with testing personnel #7 confirmed, the technical consultant failed to identify training needs (Refer to D6045), evaluate and document performance semiannually (Refer to D6053) and evaluate and document performance annually (Refer to 6054).</p>
<p>D6045</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on review of competencies and interview with testing personnel # 7 the technical consultant failed to identify training needs for four of twenty eight testing personnel in 2017 and 2018. Findings: 1. Review of competencies shows no initial training for testing personnel #12, #14, #16 and #17. 2. Interview with testing personnel #7 on February 4, 2019 at 12:30 PM confirmed the technical consultant failed to identify initial training needs for four testing personnel in 2017 and 2018.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competencies and interview with testing personnel #7 the technical consultant failed to evaluate and document the performance for one of twenty eight testing personnel for troponin semiannually during the first year the individual tests patient specimens. Findings: 1. Review of competencies showed testing personnel # 17 failed to have a semiannual competency documented. 2. Interview with testing personnel # 7 on February 4, 2019 at 12:30 PM confirmed the technical consultant failed to evaluate and document semiannual competency for one testing personnel.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competencies and interview with testing personnel #7 the technical consultant failed to evaluate and document annual competency for three of</p>

twenty eight testing personnel in 2018. Findings: 1. Review of competencies showed testing personnel # 13, #21 and #27 failed to have competency documented for 2018. 2. Interview with testing personnel #7 on February 4, 2019 at 12:30 PM confirmed the technical consultant failed to evaluate and document annual competency for three of twenty eight testing personnel in 2018.