

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0672706	<b>(X3) Date Survey Completed</b>  07/03/2018
<b>Name of Provider or Supplier</b>  Fulton Reception & Diagnostic Center	<b>Street Address, City, State</b>  1393 Highway O, Po Box 190, Fulton, MO	
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>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the general supervisor, the laboratory failed to retain syphilis serology and general immunology (anti-HIV) scores obtained for five of five PT samples for two of three testing events in 2017 and one of one testing events through July 3, 2018. Findings: 1. The laboratory did not have documentation for PT scores obtained for five of five syphilis serology samples for the first and second testing events of 2017 and the first testing event of 2018. 2. The laboratory did not have documentation for PT scores obtained for five of five anti-HIV samples for the first and second testing events of 2017 and the first testing event of 2018. 3. Interview with the general supervisor on July 3, 2018 at 11:30 AM confirmed, the laboratory failed to retain all proficiency testing records for at least two years.</p>
<b>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of verification procedures for the Bioplex analyzer and two of two Evolis analyzers, and interview with the laboratory director, the laboratory director failed to ensure the verification procedures were adequate to determine accuracy,</p>

precision, reportable range and reference intervals (normal values) prior to patient testing for syphilis serology, anti-HIV and hepatitis markers. Findings: 1. Review of verification procedures for the Bioplex analyzer revealed no documentation the laboratory director reviewed and approved the procedures prior to implementing patient testing April 2017. 2. Review of verification procedures for two of two Evolis analyzers revealed no documentation the laboratory director reviewed and approved the procedures prior in implementing patient testing April 2018. 3. Interview with the laboratory director on July 3, 2018 at 11:30 AM confirmed, the laboratory director failed to review and approve verification procedures prior to patient testing.