

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0993634	(X3) Date Survey Completed 11/25/2019
Name of Provider or Supplier Frix-Jennings Clinic Pc	Street Address, City, State 1314 Hwy 45 Bypass Suite D, Henderson, TN	
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
D6016	<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 the laboratory's proficiency testing records and the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), and interview with the lead testing personnel, the laboratory director failed to ensure proficiency testing was performed by personnel who perform patient testing in the laboratory in 2018 and 2019. The findings include: 1) Review of the laboratory's proficiency testing records and Form CMS-209 revealed attestation statements signed by personnel not listed on Form CMS-209 as follows: 2018 Event One-Microscopy-image numbers US 01, US 02, VA 01, VKP 01. 2019 Event One-Microscopy-image numbers US 01, US 02, VA 01, VKP 01. 2) Interview with the lead testing personnel on November 25, 2019 at 3:00 p.m. confirmed proficiency testing images for urine microscopy, wet prep and Potassium Hydroxide (KOH) were not performed by personnel that perform testing in the laboratory for proficiency testing events 2018 event one and 2019 event one. The laboratory director failed to ensure proficiency testing was performed by personnel who perform patient testing in the laboratory in 2018 and 2019.</p>