

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D1026068	(X3) Date Survey Completed 09/17/2018
Name of Provider or Supplier Heartland Diagnostic Services Llc	Street Address, City, State 3290 20th St S, Fargo, ND	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to twice annually verify the accuracy of 4 of 4 non-regulated microscopy analytes (vaginal wet preparation [wet prep], potassium hydroxide preparation [KOH], sperm absence/presence, and urine sediment) in 2017. The laboratory performed approximately 580 microscopy patient tests in 2017. Findings include: 1. Reviewed at approximately 10:30 a.m. on 09/17/18, the laboratory's test menu listed wet prep, KOH, post vas semen analysis (sperm absence/presence), and urinalysis microscopic examination (urine sediment) available for patient testing. 2. Reviewed at approximately 10:40 a.m. on 09/17/18, the 2017 proficiency testing records indicated the laboratory did not participate in proficiency testing for wet prep, KOH, sperm absence/presence, and urine sediment. 3. Upon request on 09/17/18, the laboratory failed to provide evidence of twice annual accuracy verification for wet prep, KOH, sperm absence/presence, and urine sediment in 2017. 4. During interview at approximately 12:00 p.m. on 09/17/18, a technical consultant (#1) confirmed the laboratory did not twice annually verify the accuracy of wet prep, KOH, sperm absence/presence, and urine sediment in 2017. 5. Reviewed at 1:15 p.m. on 09/17/18 the policy "Laboratory Quality Assurance (Assessment) Plan," approved 05/27/15, stated, ". . . V. Monitoring of Standards as Defined by CLIA [Clinical Laboratory Improvement Amendment] '88: . . . D. Comparison of Test Results . . . 2. Any test done that is not included in a proficiency testing program is verified for accuracy and reliability twice a year. . . ."</p>