

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2147454	(X3) Date Survey Completed 06/26/2019
Name of Provider or Supplier Heritage Labs Db a Ion Diagnostics Laboratories	Street Address, City, State 4512 Breton Rd Se, Kentwood, MI	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure manual review and interview with General Supervisor #2 (GS2), the Laboratory Director (LD) failed to approve, sign, and date 3 ("Reflex Testing Policy, To Whom So Ever It May Concern, and Urinalysis Grading Chart") of 6 new polices before put into use. Findings include: 1. Review of the procedure manual revealed for 3 of 6 new polices submitted with the Allegation of Compliance (AoC) were not approved, signed, and dated by the LD. When queried on 6/26/19 at approximately 11:45 am, GS2 was unable to provide the surveyor with the newly adopted and signed policies. 3. During the interview on 6/26/19 at approximately 11:45 am, GS2 acknowledged the newly adopted polices were not accessible.</p>
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review and interview with General Supervisor #2 (GS2), the laboratory failed to provided 6 ("Proficiency Testing, Proficiency Testing Failures, Temperature & Humidity, Test Report, Calibration Verification, and CBC Calibration") of 6 newly adopted, signed, and dated procedures for the surveyor. Findings include: 1. Procedure manual review revealed for 6 of 6 new procedures</p>

submitted with the Allegation of Compliance (AoC) were not provided in the procedure manual as follows: a. "Proficiency Testing" b. "Proficiency Testing Failures" c. "Temperatures & Humidity" d. "Test Report" e. "Calibration Verification" f. "CBC Calibration" 2. On 06/26/19 at approximately 11:45 am when interviewed, GS2 was not able to provide the surveyor with a copy of the newly adopted procedures.