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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D2147454 | (X3) Date Survey Completed 04/15/2019 |
| 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 |
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| D5016 | <p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Chemistry as specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to ensure the procedure contained all the required information for reflex testing. Refer to D5403. 2. The laboratory failed to monitor and document the room temperature. Refer to D5413. 3. The laboratory failed to perform and evaluate the chemistry calibration verification. Refer to D5439. 4. The laboratory failed to perform valid quality control testing in chemistry. Refer to D5481. 5. The laboratory failed to provide accurate and reliable patient test results. Refer to D5801. 6. The laboratory failed to identify the name and address of the facility performing the sendout testing. Refer to D5805.</p> |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review and interview with the Technical Supervisor (TS), the</p> |

laboratory failed to perform and follow a written procedure for the "XN450 Procedure," for 5 of 5 (11/8/19 to 4/15/19) months. Findings include: 1. Procedure review of the "XN450 Procedure" section titled "Retained Patient Controls" revealed patient controls were not run as follows: a. "Within Day Precision" stated random patient bloods are run every 4 hours. b. "Day to Day Precision" stated the same random blood used for within day precision are kept and run the following morning after instrument start-up. 2. Interview with TS on 4/15/19 at 10:05 am acknowledged the laboratory does not perform "Within Day Precision" and "Day to Day Precision" according to the "XN450 Procedure."

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
. Based on patient results, procedure review, and interview with the Laboratory Director (LD), the laboratory failed to ensure the procedure contained all the required information for reflex testing for 5 of 5 months. Findings include: 1. Requisition review for 2 of 2 patients revealed reflex testing was performed as follows: a. Patient 1645, collected 12/5/19, had "Urinalysis (micro if IND)" ordered, macroscopic results were normal and reflex to microscopic testing was performed. b. Patient 1250, collected 11/7/18, had "TSH w/ reflex to Free T4" ordered, Thyroid Stimulating Hormone (TSH) results were normal and reflex testing to Free Thyroxine (Free T4) was performed. 2. The "Urine Microscopic Examination" policy lacked criteria for reflex testing. 3. Interview with LD on 4/15/19 at approximately 3:30 pm acknowledged the laboratory procedures did not contain criteria for reflex testing.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to monitor and document the room temperature for 5 of 5 months for hematology, urinalysis, and chemistry testing areas. Findings include: 1. Record review of temperature monitoring logs revealed a lack of documentation for room temperature for the hematology, urinalysis, and chemistry testing areas from 11/8/19 to 4/15/19. 2. Interview with TS on 4/15/19 at 2:40 pm, confirmed the laboratory failed to perform room temperature monitoring for the hematology, urinalysis, and chemistry testing areas.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to perform and evaluate the chemistry calibration verification at least once every 6 months as required for 1 (March 2019) of 2 events. Findings include: 1. Record review of the calibration verification data revealed a lack of documentation for the chemistry comprehensive panel and endocrinology Thyroid Stimulating Hormone (TSH) and Free Thyroxine (Free T4) for March 2019. 2. Phone interview with the TS on 4/18/19 at 11:50 am acknowledged the calibration verification was not completed at least every 6 months.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test

results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
. Based on quality control record review and interview with the Technical Supervisor (TS), the laboratory failed to perform valid quality control testing in chemistry for 3 of 5 months reviewed. Findings include: 1. Quality control record review of the Dimension EXL 200 analyzer revealed two levels of failed quality control on the day of patient testing as follows: a. 11/8/18 Total Protein (TP) b. 12/4/18 1. Bicarbonate (ECO2) 2. TP 3. High Density Lipoprotein (AHDLD) c. 1/15/19 1. Triglycerides (TGL) 2. Creatinine (EZCR) 3. Cholesterol (CHOL) 4. Calcium (CA) d. 3/13/19, 3/19/19, and 3/20/19 1. EZCR e. 3/25/19 1. Glucose 2. Albumin 2. Interview with TS on 4/15 /19 at 2:15 pm acknowledged valid quality control was not completed and documented prior to performing patient testing.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
. Based on record review, lack of documentation, and interview with the Technical Supervisor (TS), the laboratory failed to provide accurate and reliable patient test reports for 5 of 5 months (11/8/19 to 4/15/19) of patient testing. Findings include: 1. Record review of patient final test reports revealed the laboratory had reported a complete blood count (CBC) with multiple results for the same test for patient #1383 collected on 12/4/18. 2. On 4/15/19 at approximately 3:30 pm when queried, the Laboratory Director (LD) stated the computer system versus the interface was validated. The LD was not able to provide documentation of that process. 3. Interview on 4/15/19 at approximately 3:30 pm, the LD and TS acknowledged the validation of the interface was not properly performed and documented.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Laboratory Director (LD), the laboratory failed to identify the name and address of the facility performing the sendout testing for 5 of 5 months of testing. Findings include: 1. Record review of patient final reports revealed testing sent out to a reference laboratory(s) did not have the name and address of the testing facility on the final report as follows: a. Specimen #1383 Collected 12/4/18 Prostate Specific Antigen. b. Specimen #1808 Collected 3/5 /19 Urine Microalbumin and Urine Creatinine. 2. Interview with LD on 4/15/19 at approximately 3:30 pm acknowledged all referenced testing did not include the name and address of the testing facility on the final patient report.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
. Based on record review and interview with Technical Supervisor (TS), the laboratory failed to provide educational requirements for one of three testing personnel (#3) who perform moderately complex chemistry and hematology testing. Refer for D6065

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to ensure all testing personnel (TP) met the educational requirements at 493.1423 for one of three (TP3) TP. Findings include: 1. Record review of TP credentials revealed the educational requirements for performing moderately complex laboratory testing was not met. 2. Interview with TS on April 15, 2019 at 9:45 am confirmed educational requirements for TP3 were not met. 3. The laboratory was given five additional days to supply the necessary educational documents. The documents were not received.