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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 32D0000011 | (X3) Date Survey Completed 01/09/2019 |
| Name of Provider or Supplier Atlantic Labs, Llc | Street Address, City, State 1329 W Walnut Hill Suite 116, Irving, TX | |
| 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 |
|---------------------------|---|
| D0000 | The following deficiencies were cited as the result of a recertification survey on 01/09 /2019 for 42 CFR part 493 Laboratory Requirements. |
| D3031 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review, observation and interview with the laboratory owner, the laboratory failed to maintain copies of the manufacturer's instructions for laboratory reagents used in the laboratory for at least 2 years. This deficient practice could result in the improper use, including storage, of reagents used in drug testing. Findings are: A. During observation of laboratory supplies in the refrigerator on 01/09/19 at 10:52 am the following reagents were found stored at 2 degrees Celsius: 1. DRI Gravity Detect Reagent Lot 73158117 expiration date 08/2021 Label indicated it was opened on 10/15 /18. Storage requirement 15-30 degrees Celsius (See D5413) 2. Immunalysis Extraction Buffer Lot E31833 expiration date 09/19 Storage requirement 2-30 degrees Celsius 3. Siemens Syva Emit II Phencyclidine Enzyme Reagent Lot 9J348UL-K2 expiration date 05/23/17 Labeled "11/20/17" 4. Emit II Plus Phencyclidine Antibody Substrate Reagent 1 Lot 9J318UL-K2 expiration date 05/23/2019 Labeled "11/26/17" Storage requirement 2-8 degrees Celsius 5. Barbiturate Enzyme Reagent 2 Lot 9D348UI -K4 expiration date 12/04/19 Storage requirement 2-8 degrees Celsius 6. Sciteck Specific Gravity Cal 1.030 Lot 033015 expiration date 03/19 Received 10/17 /16 Storage requirement 2-10 degrees Celsius B. Record review revealed there were no manufacturer instructions in the laboratory's procedure manuals. C. During</p> |

interview on 01/09/19 at 11:09 am, the laboratory owner stated that he did not have the package inserts/instructions because he usually threw out the package inserts for the reagents after he unpacks the bottles.

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 review, observation and interview with the laboratory owner, the laboratory failed to ensure that all reagents were stored at the correct temperature. Findings are:
A. During observation on 01/09/19 at 10:52 am, the DRI Gravity Detect Reagent was found in the refrigerator. Review of the label indicated that it should have been stored at 15-30 degrees Celsius. B. Review of 2018 temperature logs revealed the laboratory refrigerator was maintained at 2 +/- 1 degrees Celsius. C. During interview on 01/09/19 at 11:09 am, the laboratory owner stated that he unpacks and stores all of the reagent shipments in the refrigerator and hadn't noticed the different temperature requirement for the Gravity Detect Reagent. D. Review of the manufacturer's instructions printed by the laboratory owner from the manufacturer's website on the 01/09/19 at 11:30 am, confirmed the reagent should be stored at 15-30 degrees Celsius.