Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2113375	01/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lindsay York, Md, Llc	1111 Medical Center Blvd N803, Marrero, LA	

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	A Certification Survey was performed on January 22, 2019 at Lindsay York, MD, LLC, CLIA ID # 19D1075504. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to retain proficiency records for one (1) of six (6) events reviewed for at least two (2) years. Findings: 1. Review of the laboratory's American Proficiency Institute (API) Proficiency Tests (PT) records for 2017 and 2018 revealed the laboratory did not maintain the following: a) 2018 3rd Event Hematology/Coagulation: results and Laboratory Director's evaluation 2. In interview on January 22, 2019 at 10:53 am, Personnel 2 stated she received an email from API on December 20, 2018 stating results for the identified event were available. Personnel 2 further stated she did not have the correct password information to access the results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by:

	I. Based on observation, record review, and interview with personnel, the laboratory failed to follow their established policy for Complete Blood Count flags. Findings: 1. Observation by the surveyor during the laboratory tour on January 22, 2019 revealed the laboratory utilizes the Medonic instrument for Complete Blood Count (CBC) testing. 2. Review of the laboratory's "Out-of-Range/Information Messages" policy revealed "Effective May 25, 2017, all CBC's containing a flag or error must be repeated in the office. If the flag is still present on repeat, the patient will be given an order to have a CBC repeated at the outpatient laboratory of West Jefferson Medical Center or Quest Diagnostics for specimen verification." 3. In interview on January 22, 2019, Personnel 2 stated for patients that refuse to have the CBC repeated at an outpatient laboratory, the laboratory places a sticker on the patient report that states" Unconfirmed/Void Specimen will not be used by the physician for patient treatment." 4. Review of random selection of eight (8) CBC final test reports from December 2018 and January 2019 revealed the following three (3) patients were not reported per laboratory policy: December 18, 2018: Patient 1: OM flag: Sample was not retested in the office or results voided due to inability to confirm result January 16, 2019: Patient 2: OM flag: Sample was not retested in the office January 18, 2019: Patient 3: BD flag: Sample was not retested in the office or results voided due to inability to confirm result 5. In interview on January 22, 2019 at 1:45 pm, Personnel 2 stated if the patient is under twelve months old then the CBC is retested in the office and if flag remains then the test is referred out. Personnel 2 further stated if the patient is older than one (1), then the parent is given the option to have CBC retested in the office or downstairs. Personnel 2 stated in both cases if the parent refuses, documentation of refusal and the order is placed in the patient's chart and the CBC results are voided. 6. In further interview on January 22, 2019, Personnel 2 confirmed the laboratory's actions for CBC flags did not follow the laboratory's policy. II. Based on record review and interview with personnel, the laboratory failed to follow their established manual review policy. Findings: 1. Review of the laboratory's "Policy and Procedure Manual" policy revealed "The policy & procedure manual will be reviewed by the laboratory director every six months and updated as needed." 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have documentation that the Laboratory Director reviewed the manual every six (6) months. 3. In interview on January 22, 2019 at 1:52 pm, Personnel 2 stated the laboratory does not have documentation that the Laboratory Director reviews the manual every six (6) months. 4. In interview on January 22, 2019, Personnel 1 stated she does not review the policy and procedure manual every six (6) months.
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 observation, record review, and interview with personnel, the laboratory failed to monitor the temperature of the closet where laboratory supplies are stored per manufacturer requirements. Findings: 1. Observation by the surveyor during the

	laboratory tour on January 22, 2019 revealed the laboratory did not monitor the temperature of the storage closet where laboratory supplies are stored. 2. Further observation by surveyor during the laboratory tour revealed the following items were stored without temperature monitoring: a) BD BBL Culture Swab Plus, Lot #172271516, Quantity: two (2) packs b) BD BBL Culture Swab, Lot # 180807509, Quantity: three (3) packs c) RSV Now, Lot # M103782, Quantity: five (5) boxes d) Urine BD Vacutainer, Lot # 8179602, Quantity: one (1) box 3. Review of the manufacturer's requirements for the identified items revealed the following: a) BD BBL Culture Swab Plus: storage requirement 5-25 degrees Celsius b) BD BBL Culture Swab, storage requirement 5-25 degrees Celsius c) RSV Now, storage requirement 2-30 degrees Celsius d) Urine BD Vacutainer, 4-25 degrees Celsius 4. In interview on January 22, 2019, Personnel 2 stated the laboratory does not monitor the temperature of the storage closet. Personnel 2 stated she was unaware of the temperature requirements for the identified supplies.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to follow their established policy for Complete Blood Count flags. Refer to D5401 I. 2. The laboratory failed to follow their established manual review policy. Refer to D5401 II. 3. The laboratory failed to monitor the temperature of the closet where laboratory supplies are stored per manufacturer requirements. Refer to D5413.