Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0896121	03/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ghyass Rizk, Md	200 La Rue France, Lafayette, 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 Recertification survey was conducted at Ghyass Rizk, MD-CLIA ID # 19D0896121 on March 28, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
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 room temperature and humidity where testing and supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on March 28, 2019 revealed the laboratory did not monitor the room temperature and humidity where the following supplies and instruments are located: a) BD Vacutainer Lithium Heparin blood collection tubes, Lot # 8187659, Quantity: 177 tubes b) BD Vacutainer Serum blood collection tubes, Lot # 8334742, Quantity: 155 tubes c) DCA Systems Microalbumin. Creatinine Cartridge, Lot # 0190118, Quantity: five (5) kits d) DCA Systems Hgb A1C, Lot # 0913088, Quantity: seven (7) kits e) DCA Vantage Instrument f) TOSOH AIA 360 Instrument 2. Review of the manufacturer requirements for the identified items revealed the following temperature and/or humidity requirements: a) BD Vacutainer Lithium Heparin blood collection tubes: temperature requirement 4-25 degrees Celsius b) BD Vacutainer Serum blood collection tubes: temperature requirement 4-25 degrees Celsius c) DCA

	Systems Microalbumin. Creatinine Cartridge: room temperature requirement 15-30 degrees Celsius d) DCA Systems Hgb A1C: room temperature requirement 15-30 degrees Celsius e) DCA Vantage Instrument: Microalbumin/Creatinine ambient temperature 18-30 degrees Celsius, non condensing humidity 10-90% f) TOSOH AIA 360 Instrument: temperature requirement 15-30 degrees Celsius, humidity 40-80 % 3. In interview on March 28, 2019 at approximately 9:20 am , Personnel 4 stated the laboratory's room temperature and humidity are not monitored.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: ***Repeat deficiency from survey conducted on May 30, 2017*** Based on record review and interview with personnel, the laboratory failed to ensure weekly maintenance for the TOSOH AIA 360 was performed and documented for five (5) of thirteen (13) weeks reviewed in 2019. Findings: 1. Review of the "TOSOH AIA-360 Maintenance Schedule" revealed the following weekly task: "Flush substrate line." 2. Review of the TOSOH AIA-360 maintenance log for 2019 (January 2019 through March 2019) revealed the laboratory did not have documentation of weekly maintenance performance for the following five (5 weeks): a) Week of February 25, 2019 b) Week of March 4, 2019 c) Week of March 11, 2019 d) Week of March 18, 2019 e) Week of March 25, 2019 3. In interview on March 28, 2019 at 11:20 am, Personnel 4 stated she was unaware that weekly maintenance was not documented for the identified weeks. Personnel 4 confirmed the laboratory did not have documentation of weekly maintenance performance for the TOSOH for the identified weeks.
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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D5413.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: ***Repeat deficiency from survey conducted on May 30, 2017*** Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. In interview on March 28, 2019, Personnel 4 stated Personnel 3 was no longer employed at the laboratory effective January 2019. 2. Review of personnel records revealed no documentation of competency assessment performance in 2018 for Personnel 3. 3. In interview on March 28, 2019 at 9:50 am, Personnel 4 stated the personnel records for Personnel 3 were not on-site. Personnel 4 confirmed the laboratory did not have documentation of competency assessment performance in 2018 for Personnel 3.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory did not have a written job description for the Laboratory Director. 2. In interview on March 28, 2019 Personnel 4 confirmed the laboratory did not have a written job description for the Laboratory Director.