Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1034225	06/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Clinical Laboratory	1405 Airline Drive, Metairie, 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 conducted on June 14, 2018 at Advanced Clinical Laboratory-CLIA ID # 19D1034225. 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 temperature of areas where laboratory supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on June 14, 2018 revealed the laboratory did not monitor the temperature for the following areas: Storage area near Hematology analyzer Storage area for blood collection tubes 2. Review of the manufacturer requirements listed on the packaging revealed the following temperature requirements: a) Sychron systems No foam; 8-30 degrees Celsius b) Premier Hb 9210 Premier Buffer A; 2-28 degrees Celsius c) CTS Auto-Gloss; 8-30 degrees Celsius d) Premier Hb 9210 Premier Buffer B; 2-28 degrees Celsius e) Premier Hb 9210 Premier Wash; 2-28 degrees Celsius f) Cartridge Chem Wash Solution (CCWA); 8-30 degrees Celsius g) Beckman Coulter ISE Electrolyte Buffer, 8-30 degrees Celsius h) Beckman Coulter Albumin Reagent; 8-30 degrees Celsius i) Beckman Coulter Creatinine Reagent; 8-30 degrees Celsius j) Beckman Coulter Sample Diluent 1; 8-30 degrees Celsius k) Beckman Coulter Direct

Bilirubin Reagent; 8-30 degrees Celsius l) Beckman Coulter Magnesium Reagent; 8-30 degrees Celsius m) Beckman Coulter Phosphorus Reagent; 2-28 degrees Celsius n) Beckman Coulter Total Bilirubin Reagent; 8-30 degrees Celsius o) Iron/TIBC Cal Kit; 8-30 degrees Celsius p) Anti Foam; 8-30 degrees Celsius q) Beckman Coulter DxH Cleaner; 2-25 degrees Celsius r) Beckman Coulter DxH Diff Pack; 2-25 degrees Celsius s) Beckman Coulter Cell Lyse; 2-40 degrees Celsius t) Roche Assay Cup; 2-32 degrees Celsius u) Roche Assay Tips, 2-32 degrees Celsius v) Beckman Coulter DxH Diluent; 2-40 degrees Celsius w) Monoject Covidien No Additive blood collection tubes; 0-40 degrees Celsius x) Covidien EDTA blood collection tubes; 0-40 degrees Celsius y) BD Vacutainer Sodium Heparin blood collection tubes; 4-25 degrees Celsius z) BD Vacutainer Sodium Fluoride/Potassium Oxalate blood collection tubes; 4-25 degrees Celsius aa) BD Vacutainer ACD Solution A blood collection tubes; 4-25 degrees Celsius bb) BD Vacutainer Buffered Sodium Citrate blood collection tubes; 4-25 degrees Celsius cc) BD Vacutainer EDTA blood collection tubes; 4-25 degrees Celsius dd) BD Vacutainer Serum blood collection tubes; 4-25 degrees Celsius ee) BD Vacutainer SST tubes; 4-25 degrees Celsius ff) BD Vacutainer Trace Element blood collection tubes; 4-25 degrees Celsius 3. Further observation during laboratory tour revealed the following items stored without room temperature monitoring: Storage area near Hematology analyzer: a) Sychron systems No foam, 1.0 L, Lot # M803221, Quantity 5; Lot # M801096, Quantity 2; Lot # M802198, Quantity 3; Lot # M712062, Quantity 4; Lot # M710058, Quantity 3; Lot # M71286, Quantity 2; Lot # M708160, Quantity 4; Lot # M70987, Quantity 5; Lot # M706049, Quantity 1 b) Premier Hb 9210 Premier Buffer A; 940 mL, Lot # 7855, Quantity 4; Lot # 8289, Quantity 7 c) CTS Auto-Gloss; 500 mL, Lot # M801022, Qty 1 d) Premier Hb 9210 Premier Buffer B; Lot # 7509, Quantity 1; Lot # 7864, Quantity 10 e) Premier Hb 9210 Premier Wash; Lot # 8133, Quantity 3; Lot # 8466, Quantity 2 f) Cartridge Chem Wash Solution (CCWA); Lot# M803016, Quantity 3 boxes g) Beckman Coulter ISE Electrolyte Buffer, Lot # M802707, Quantity 1 bottle; Lot # M803213, Quantity 2 boxes; Lot # M804058, Quantity 2 boxes; Lot # M804054, Quantity 1 box; Lot # M80404148, Quantity 1 box; Lot # 802200, Quantity 1 box h) Beckman Coulter Albumin Reagent; Lot # M803028, Quantity 2 boxes i) Beckman Coulter Creatinine Reagent; Lot M710007, Quantity 6 boxes, Lot # M709011, Quantity 1 box; Lot # M712020, Quantity 5 boxes; Lot # M712420, Quantity 3 boxes; Lot # M802021, Quantity 5 boxes; Lot # 801132, Quantity 6 boxes; Lot # M802481, Quantity 6 boxes; Lot # M803030, Quantity 6 boxes j) Beckman Coulter Sample Diluent 1; Lot # M803027, Quantity 8 boxes; Lot # M802015, Quantity 2 boxes k) Beckman Coulter Direct Bilirubin Reagent; Lot # M710016, Quantity 1 box; Lot # M612297, Quantity 2 boxes; Lot # M706075, Quantity 1 box; Lot # M710016, Quantity 1 box; Lot # 803019, Quantity 1 box; Lot # 704021, Quantity 2 boxes l) Beckman Coulter Magnesium Reagent; Lot # M803033, Quantity 2 boxes; Lot # M804038, Quantity 3 boxes m) Beckman Coulter Phosphorus Reagent; Lot # M70013, Quantity 1 box; Lot # M704027, Quantity 1 box n) Beckman Coulter Total Bilirubin Reagent; Lot # M801015, Quantity 16 boxes o) Iron/TIBC Cal Kit; Quantity 2 boxes p) Anti Foam; Quantity 8 q) Beckman Coulter DxH Cleaner; Quantity 3 boxes r) Beckman Coulter DxH Diff Pack; Quantity 6 boxes s) Beckman Coulter Cell Lyse; Quantity 3 boxes t) Roche Assay Cup; Quantity 3 boxes u) Roche Assay Tips, Quantity 5 boxes v) Beckman Coulter DxH Diluent; Quantity 36 boxes Storage area with blood collection tubes: a) Monoject Covidien No Additive blood collection tubes; Lot # 722825, Quantity 50 tubes b) Covidien EDTA blood collection tubes; Lot # 628646, Quantity 98 tubes c) BD Vacutainer Sodium Heparin blood collection tubes; Lot # 7279845, Quantity 80 tubes d) BD Vacutainer Sodium Fluoride /Potassium Oxalate blood collection tubes; Lot # 7100996, Quantity 50 tubes e) BD Vacutainer ACD Solution A blood collection tubes; Lot # 7255808, Quantity 120

	tubes f) BD Vacutainer Buffered Sodium Citrate blood collection tubes; Lot # 7346912, Quantity 90 tubes g) BD Vacutainer EDTA blood collection tubes; Lot # 8011928, Quantity 700 tubes h) BD Vacutainer Serum blood collection tubes;Lot # 7255765, Quantity 500 tubes i) BD Vacutainer SST tubes; Lot # 7321649, Quantity 300 tubes; Lot # 8047611, Quantity 100 tubes j) BD Vacutainer Trace Element blood collection tubes; Lot # 7340972, Quantity 80 tubes 4. In interview on June 14, 2018 at 9:15 am, Personnel 3 stated the temperature of the identified storage areas are not monitored.
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 laboratory personnel performed testing as required. Refer to D5413.