Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2186045	06/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Labrad Diagnostics, Llc	9690 Almeda Genoa Rd Suite 301, Houston, 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	Compliant Intake #: TX00365211 An unannounced complaint investigation was performed on June 8, 2021. The complaint was substantiated. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1240 Condition: Preanalytic systems
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the manufacturer's instructions, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems. (Refer to D5311-I, II)
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
I. Based on a review of the manufacturer's instructions for analytes run on the Beckman Coulter DxC 700 AU chemistry analyzer, a review of the laboratory's policies, surveyor observation of specimens received by the facility, a review of patient records, and staff interview, it was revealed the laboratory failed to have a mechanism in place to ensure patient samples were maintained at an acceptable temperature range during shipment to the laboratory for testing. Findings include: 1. A review of the manufacturer's instructions for assays performed on the Beckman Coulter DxC 700 AU chemistry analyzer revealed the following 4 analyte's storage requirements for patient samples being tested: a) AST (Aspartate Aminotransferase) - separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at 2C to 8C. b) CL (Chloride) - separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at 2C to 8C. c) BUN (Urea Nitrogen) - separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at 2C to 8C. d) CREA (Creatinine) - serum Creatinine is stable for 7 days at 2 - 8C and indefinitely when frozen (= -20C). 2. A review of the laboratory's policy titled 'Supply, Specimen and Shipment Handling Procedure' revealed the following: "Purpose: To ensure the successful completion and high quality of specimen integrity for laboratory testing on a national level. Proper handling of specimens: Specimens should be labeled and processed according to the SOP and kept in your cooler at all times. Coolers should ALWAYS have a minimum of two pre-frozen ice packs and if temperatures are above 100 degrees (with or without the heat index) then you need to have three ice packs minimum." 3. Surveyor observation of patient samples received by the laboratory on 6/8/21 at 11:00 a.m. revealed the samples were brought in by the courier in a large plastic bag. No cooler with ice packs was observed. All of the patient samples inside of the bag were warm to the touch. No temperature monitoring devices were observed. 4. A review of the patient results for the samples that were in the above mentioned plastic bag revealed the following 10 patient samples and the tests that were run and resulted by the laboratory: Sample ID: 211580000119 1 gold top tube, 1 lavender top tube, 1 pour-over tube Collection time on tubes: 06:50 Tests run by laboratory on 6/8/21: Basic Metabolic Panel (includes CREA, BUN, CL analytes) Sample ID: 211520000304 1 gold top tube Collection time on tube: 06:36 Tests run by laboratory on 6/8/21: Hepatic Function Panel (includes AST analyte) Sample ID: 211550000279 1 gold top tube Collection time on tube: 03:33 Tests run by laboratory on 6/8/21: Basic Metabolic Panel (includes CREA, BUN, CL analytes) Sample ID: 211520000308 1 gold top tube, 2 lavender top tubes Collection time on tubes: 06:24 Tests run by the laboratory on 6/8/21: Comprehensive Metabolic Panel (includes CREA, BUN, CL, AST analytes) Sample ID: 211380000216 1 gold top tube Collection time on tube: 06:35 Tests run by laboratory on 6/8/21: Basic Metabolic Panel (includes CREA, BUN, CL analytes) Sample ID: 211130000055 1 gold top tube, 2 lavender top tubes Collection time on tubes: 06:13 Tests run by laboratory on 6/8/21: Basic Metabolic Panel (includes CREA, BUN, CL analytes) Sample ID: 211520000327 1 gold top tube, 1 lavender top tube, 1 pour-over tube Collection time on tubes: 06:31 Tests run by laboratory on 6/8/21: Comprehensive Metabolic Panel (includes CREA, BUN, CL, AST analytes) Sample ID: 211550000263 1 gold top tube Collection time on tube: 03:20 Tests run by laboratory on 6/8/21: Comprehensive Metabolic Panel (includes CREA, BUN, CL, AST analytes) Sample ID: 211310000343 1 gold top tube Collection time on tube: 06:40 Tests run by laboratory on 6/8/21: Hepatic Function Panel (includes AST analyte) Sample ID: 211590000312

	2 gold top tubes, 2 lavender top tubes Collection time on tubes: 03:03 Tests run by laboratory on 6/8/21: Basic Metabolic Panel (includes CREA, BUN, CL analytes) 5. An interview with testing person #2 (as indicated on the CMS 209 form) on 6/8/21 at 11:10 a.m. in the processing area, revealed the laboratory did not ensure the temperature of the patient samples were maintained at the required temperature for running on the Beckman Coulter DxC 700 AU chemistry analyzer. This confirmed the above followings. II. Based on a review of the laboratory's policies, surveyor observation, a review of patient test records, and staff interview, it was revealed that the laboratory failed to ensure samples remained in a vertical position during transportation to the laboratory for testing. Findings include: 1. A review of the laboratory's policy titled 'DxC-700 Procedure Chemistry Information Sheet' revealed the following analytes required "Tubes of blood are to be kept closed at all times and in a vertical position" : a) Albumin (ALB) b) Alkaline Phosphatase (ALP) c) Aspartate Aminotransferase (AST) d) Chloride (CL) e) Carbon Dioxide (CO2) 2. Surveyor observation of patient samples received by the laboratory on 6/8/21 at 11:00 a.m. revealed the samples were brought in by the courier in a large plastic bag. Samples were not kept in a vertical position. 3. A review of the patient results for the samples that were in the above mentioned plastic bag revealed the following 10 patient samples and the tests that were run and resulted by the laboratory: Sample ID: 211580000119 1 gold top tube, 1 lavender top tube, 1 pour-over tube Tests run by laboratory on 6/8/21: Basic Metabolic Panel (includes CL, CO2 analytes) Sample ID: 211520000304 1 gold top tube Tests run by laboratory on 6/8/21: Hepatic Function Panel (includes ALB, ALP, AST analyte) Sample ID: 211550000279 1 gold top tube Tests run by laboratory on 6/8/21: Basic Metabolic Panel (includes CL, CO2 analytes) Sample ID: 211520000308 1 gold top tube, 2 lavender top tubes Tests run by the laboratory on 6/8/21: Comprehensive Metabolic Panel (includes ALB, ALP, AST, CL, CO2 analytes) Sample ID: 211380000216 1 gold top tube Tests run by laboratory on 6/8/21: Basic Metabolic Panel (includes CL, CO2 analytes) Sample ID: 211130000055 1 gold top tube, 2 lavender top tubes Tests run by laboratory on 6/8 /21: Basic Metabolic Panel (includes CL, CO2 analytes) Sample ID: 211520000327 1 gold top tube, 1 lavender top tube, 1 pour-over tube Tests run by laboratory on 6/8/21: Comprehensive Metabolic Panel (includes ALB, ALP, AST, CL, CO2 analytes) Sample ID: 211550000263 1 gold top tube Collection time on tube: 03:20 Tests run by laboratory on 6/8/21: Comprehensive Metabolic Panel (includes ALB, ALP, AST, CL, CO2 analytes) Sample ID: 211310000343 1 gold top tube Tests run by laboratory on 6/8/21: Hepatic Function Panel (includes ALB, ALP, AST analyte) Sample ID: 211590000312 2 gold top tubes, 2 lavender top tubes Tests run by laboratory on 6/8 /21: Basic Metabolic Panel (includes CL, CO2 analytes) 4. An interview with testing person #2 (as indicated on the CMS 209 form) on 6/8/21 at 1:30 p.m. in the processing area, confirmed the above findings.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

	This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, a review of patient test records, and staff interview, it was revealed that the laboratory director failed to ensure the test system provided quality laboratory results (refer to D5311 I, II).