Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2130192	05/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Grace Er	1851 Pearland Parkway, Pearland, 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 laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory records, review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2017 to 2019, and confirmed in interview revealed the laboratory failed to have documentation of rotating proficiency testing among all testing personnel for hematology and chemistry. Findings were: 1. Review of the laboratory's CMS 209 signed by the laboratory director on 5/21/19 revealed 19 testing personnel for the laboratory. 2. A review of the laboratory's API proficiency testing records from 2018 revealed testing person #14 (TP#14) performed 3 of 3 testing events for hematology and 3 of 3 testing events for chemistry. 2018 Hematology 1st event 2018 Hematology 2nd event 2018 Hematology

	3rd event 2018 Chemistry Core 1st event 2018 Chemistry Core 2nd event 2018 Chemistry Core 3rd event 3. An interview with the technical consultant on 5/21/19 at 1010 hours in the patient room confirmed the above findings.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of records and confirmed in interview, the laboratory failed to retain the linearity (reportable range study) for the Cell-Dyn Emerald hematology analyzer. Findings included: 1. In review of records, the laboratory could not provide linearity (reportable range study) for the Cell-Dyn Emerald hematology analyzer performed in 09/2013. 2. In an interview with the technical consultant on 5/21/19 at 1110 hours in the patient room he stated, "It was done." The laboratory could not provide the reportable range studies at the time of the survey.
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 laboratory records and interview of laboratory personnel, it was revealed that the laboratory did not meet the applicable preanalytic system(s) requirements. Refer to D5311, D5317
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: Based on review of the manufacturer's instructions, laboratory patient test records, laboratory policies, and confirmed in interview, the laboratory failed to follow the preanalytical procedures for blood specimen acceptability and rejection, and conditions for specimen transportation for CBC (complete blood count) for the Cell-

	Dyn Emerald hematology analyzer. Findings were: 1. Review of the Cell-Dyn Emerald Operator's manual (9140851C, December 2009) under requirements for collecting, preparing and storing specimens revealed "maximum suggested elapsed time and storage temperatures after collection of venous whole blood: Four hours at room temperature." 2. Review of the laboratory records from the sister laboratory located at 10900 Gulf Freeway B102 revealed 1 specimen (refer to patient alias list) was collected on 2/28/19 at 1150 hours. Review of the instrument printouts from the sister laboratory revealed the specimen was analyzed for CBC (complete blood count) at 2/28/19 at 1158 hours; then again at 1205 hours; then again 1729 hours. All 3 runs had differential flags (L1, P1). 3. An interview with the testing person 12 (who is also a testing person at the sister laboratory) on 5/21/19 at 1005 hours confirmed that he ran the above specimen at the sister laboratory. He stated that per the physician's request to analyze the specimen at the sister laboratory, he transported the specimen at ambient temperature to this laboratory and performed the CBC on 2/28/19 at 2028; 8 hours, 38 minutes after the collection time. 4. Review of the laboratory policy Specimen Rejection (effective 10/28/17) revealed "specimen storage of transport was inappropriate for testing." 5. An interview with the technical consultant on 5/21/19 at 1015 hours in the patient room confirmed the above findings. He acknowledged that the testing person was "not following policy [for specimen rejection]."
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory records and policies, and confirmed in interview, the laboratory failed to document written instructions to laboratory clients for the preanalytical requirements for CBC (complete blood count) patient testing for the Cell-Dyn Emerald hematology analyzer. Findings were: 1. Review of the laboratory policy Procedures for specimen submission and handling revealed "this laboratory will have written policies and procedures for methods used for the preparation of patient specimen sollection, specimen preservation, and conditions of transportation. 2. Review of the laboratory records and policies available revealed no documentation of the above mentioned policy for CBC patient testing for the Cell-Dyn Emerald hematology analyzer. 3. An interview with the technical consultant on 5/21/19 at 1010 hours in the patient room confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5407, D5421, D5425, D5445
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedures, verification records, patient test reports, and confirmed in interview, the laboratory failed to have an approved procedure prior to start of CBC (complete blood count) patient testing for the Cell-Dyn Emerald hematology analyzer and Cardiac and DDimer testing on the Alere Triage Meter. Findings were: 1. Review of the laboratory policies and procedures revealed the laboratory director approved them on 10/23/17. 2. Review of the laboratory records revealed the laboratory began patient testing on 05/25/17. 3. An interview with the technical consultant on 5/21/19 at 1130 hours in the patient room confirmed the above findings. He acknowledged that the laboratory director should have signed them prior to patient testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on review of the laboratory policy, laboratory verification records, and confirmed in interview, the laboratory failed to document complete verification studies for the Cell-Dyn Emerald hematology analyzer. (accuracy, precision, and normal reference range) Findings were: 1. Review of the laboratory policy Validation of a New Test System revealed "it is the policy of this lab to validate a new test system prior to using it to report patient results...accuracy, precision, reportable ranges, and verification of manufacturer's normal values studies that meet the acceptance criteria validate the performance of the test system." 2. Review of the laboratory's verification studies revealed no documentation of the laboratory assessing the accuracy, precision, and normal reference range of CBC testing on the Cell-Dyn Emerald hematology analyzer. 3. An interview with the technical consultant on 5/21 /19 at 1105 hours in the empty patient room confirmed the above findings. B. Based on review of the laboratory policy, laboratory verification records, and confirmed in interview, the laboratory failed to document complete verification studies for CKMB, Troponin, Myoglobin, and DDimer testing on the Alere Triage meter. Findings were: 1. Review of the laboratory policy Validation of a New Test System revealed "it is the

	policy of this lab to validate a new test system prior to using it to report patient results...accuracy, precision, reportable ranges, and verification of manufacturer's normal values studies that meet the acceptance criteria validate the performance of the test system." 2. Review of the laboratory's verification stuies revealed no documentation of the laboratory assessing the normal reference range for CKMB, Troponin, Myoglobin, and DDimer testing on the Alere Triage meter. 3. An interview with the technical consultant on 5/21/19 at 1105 hours in the empty patient room confirmed the above findings.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to document verification of control performance for CKMB, Troponin, Myoglobin, and DDimer testing on the Alere Triage meter. Findings were: 1. Review of the laboratory verfication records for CKMB, Troponin, Myoglobin, and DDimer testing on the Alere Triage meter revealed no documentation of the laboratory establishing the frequency of control performance to include test system instrument /reagent stability, including relocation; frequency with which the test is performed; technique dependence of the method; frequency of quality control failures; and training, experience, and competency of technical personnel. 2. An interview with the technical consultant on 5/21/19 at 1325 hours in the patient room confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of the laboratory test records, quality control records, manufacturer's instructions, and confirmed in interview, the laboratory failed to document a complete INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) for the CKMB, Troponin, Myoglobin, and DDimer testing on the Alere Triage meter. (risk assessment) Findings were: 1. Review of the laboratory IQCP for CKMB, Troponin, Myoglobin, and DDimer testing on the Alere Triage meter revealed no documentation of the risk assessment evaluation that included all five components (specimen, test system, reagent, environment, testing personnel) and all phases (preanalytical, analytical, postanalytical) of testing. a. Review of the IQCP E

	optimizer records under preanalytical phase of testing revealed "all staff will be trained in the preanalytic phase of testing." Review of the laboratory records available revealed no documentation of the training documents referenced in the IQCP. b. Review of the IQCP E optimer records under analytical phase of testing revealed "all storage temperatures are monitored and recorded daily." Review of the laboratory records available revealed no documentation of the temperature logs referenced in the IQCP. 2. An interview with the technical consultant on 5/21/19 at 1230 hours in the patient room confirmed the above findings. He acknowledged that the temperature logs and QC that were referenced in the IQCP were not maintained prior to establishing the IQCP; therefore, could not have been reviewed. Also, he was unaware the laboratory was required to document a 30 day QC study for the IQCP. B. Based on review of the laboratory records, quality control records, IQCP (Individualized Quality Control Plan) records, patient test logs and confirmed in interview, the laboratory failed to provide documentation of performing quality control each day of patient testing or complete documentation of an IQCP prior to modifying the frequency of quality control testing for CKMB, Troponin, Myoglobin, and DDimer testing on the Alere Triage meter. Findings were: 1. Random review of the laboratory quality control report from November 2018 - April 2019 for the Alere Triage meter revealed no quality control performed on the following days for the following analytes on the following days. Ddimer date 04/18/2019 04/04/2019 04/03/2019 03/06/2019 12 /17/2018 11/26/2018 Cardiac (CKMB, Troponin, Myoglobin) 04/04/2019 04/03/2019 03/22/2019 03/25/2019 01/19/2019 01/05/2019 12/17/2018 11/26/2018 2. Random review of the laboratory patient logs from November 2018 to April 2019 revealed the laboratory performed patient testing for the above days. Refer to patient alias list. 3. Review of the IQCP records revealed no documentation of the performance specifications for each analyte (CKMB, Troponin, Myoglobin, and DDimer) daily for 30 days to modify the QC to every 30 days. 4. An interview with the technical consultant on 5/21/19 at 1235 hours in the patient room confirmed the above findings. He was unaware the quality control study for the IQCP was insufficient. The laboratory only performed external quality control monthly.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007, D6013, and D6020)
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 laboratory preanalytic and analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Hematology and Chemistry. Refer to D5311, D5421, D5425.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory verification records and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete verification studies Alere Triage meter and Cell-Dyn Emerald hematology analyzer prior to start of patient testing. (Refer to D5421)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and confirmed in interview, the laboratory failed to ensure the laboratory established and maintained a quality control program. Refer to D5425, D5445
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by:

	Based on review of the laboratory policies, verification studies, calibration records, and confirmed in interview, the technical consultant failed to provide technical oversight of the laboratory. (Refer to D6040, D6042, and D6053)
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records, calibration records, and patient test records found that the technical consultant failed to ensure the laboratory documented complete verification studies for the Alere Triage meter and Celly-Dyn Emerald hematology analyzer. (See D5421)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the quality control program had been established and maintained for the Alere Triage meter. (See D5425, D5445)
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records and verified by interview, the Technical Consultant failed to perform the 2018 annual competency evaluations for 12 of 12 testing personnel for the moderately complex testing in the specialties of chemistry and hematology. Findings were: 1. Review of the laboratory's CMS 209 signed by the laboratory director on 5/21/19 revealed 19 testing personnel for the laboratory. 2. A random review of the facility's personnel files available revealed 12 of 12 testing personnel had no documentation of the 2018 annual competency for the moderately complex testing in the specialties of chemistry and hematology. The technical consultant provided documentation of competency assessments peformed at the sister laboratory located at 10900 Gulf Freeway B102. Date of hire Testing person 1 06/20/2014 Testing person 2 11/15/2016 Testing person 5 01/07/2017 Testing person 6 05/16/2014 Testing person 9 09/16/2017 Testing person 10 02/10/2016

	Testing person 11 09/06/2015 Testing person 12 02/08/2016 Testing person 13 10/19 /2017 Testing person 15 10/21/2015 Testing person 17 11/21/2017 Testing person 19 11/20/2017 Testing person 20 07/06/2017 3. An interview with the technical consultant on 5/21/19 at 1005 hours in the patient room confirmed the above findings. He was unaware the laboratory was required to document competency assessments separately for each laboratory.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records and verified by interview, the Technical Consultant failed to perform the initial and second competency evaluations in the first year for 19 of 19 testing personnel for the moderately complex testing in the specialties of chemistry and hematology. Findings were: 1. Review of the laboratory's CMS 209 signed by the laboratory director on 5/21/19 revealed 19 testing personnel for the laboratory. 2. A random review of the facility's personnel files available revealed 19 of 19 testing personnel had no documentation of the intial and second competency in the first year for the moderately complex testing in the specialties of chemistry and hematology. The technical consultant provided documentation of competency assessments peformed at the sister laboratory located at 10900 Gulf Freeway B102. Date of hire Testing person 1 06/20/2014 Testing person 2 11/15/2016 Testing person 3 08/02/2018 Testing person 4 07/04/2018 Testing person 5 01/07/2017 Testing person 6 05/16/2014 Testing person 7 06/19/2018 Testing person 8 06/06/2018 Testing person 9 09/16/2017 Testing person 10 02/10/2016 Testing person 11 09/06/2015 Testing person 12 02/08/2016 Testing person 13 10/19 /2017 Testing person 15 10/21/2015 Testing person 16 06/25/2018 Testing person 17 11/21/2017 Testing person 18 07/09/2018 Testing person 19 11/20/2017 Testing person 20 07/06/2017 3. An interview with the technical consultant on 5/21/19 at 1005 hours in the patient room confirmed the above findings. He was unaware the laboratory was required to document competency assessments separately for each laboratory.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education 2 of 19 testing personnel. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education to qualify 2 of 19 testing personnel for moderately complex testing for CBC (complete blood count) on the Cell-Dyn Emerald hematology analyzer. Findings were: 1. A review of personnel records available revealed no documentation of education for 2 of 19 testing personnel (TP#4, TP#14). 2. An interview with the technical consultant on 5/21/19 at 1030 hours in the patient room confirmed the above findings. CMS - Centers of Medicare and Medicaid Services