Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2066463	03/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Grace Er	10900 Gulf Freeway, #B102, 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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: 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; 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory quality control records, patient test records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to perform at least one quality control prior to glucose patient testing for the Hemocue glucose analyzer. Findings were: 1. Review of the Hemocue package insert (150728 140908 US) revealed under Quality Control "the Hemocue Glucose 201 system must be verified on days of testing using at least one level of commercially available controls." 2. Random review of the patient Glucose test logs from July 2018 to February 2019 revealed 11 of 20 days the laboratory performed patient testing with no documentation of the quality control performed prior to patient testing. 7/27/18 8/10/18 8/13/18 9/9/18 10/10/18 10/30/18 11/3/18 11 /23/18 12/27/18 1/16/19 2/26/19 3. An interview with the technical consultant on 3/6 /19 at 1205 hours in the laboratory confirmed the above findings.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)

The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to test proficiency testing materials the same number of times as patient samples for CBC (complete blood count) on the Cell-Dyn Emerald hematology analyzer. Findings were: 1. Review of the policy Proficiency Testing revealed "PT specimens are to be treated the same as patient samples." 2. Review of the laboratory policy Policy for Handling Flagged CBC Differentials signed by the laboratory director on 2/9/19 revealed "it will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according to the procedures in the unit operator's manual...if the flags persist, then the laboratory will confirm the abnormal differential by sending out to a reference laboratory." 3. A review of the CELL-DYN Emerald Operators Manual (9140848E-June 2010) Section 3: Instrument Alarms, Operational Alerts and Measurand Data Flags revealed that: "An asterisk (*) for count invalidation or (s) suspect measurand flags are displayed with corresponding results." "These flags are generated after the instrument evaluates the measured data for a particular measurand or group of measurands. The result may be suspect due to interference substances or the inability of the instrument to measure a particular measurand due to sample abnormality." "s" (Suspect Measurand Flags) flags may indicate the presence of myelocytes, lymphoblasts, basophils, eosinophils or myelocytes. Differential "s" flag L2 May indicate the presence of myelocytes, lymphoblasts, or basophils. Differential "s" flag L3 May indicate the presence of eosinophils or myelocytes. Count Invalidation Flags (*) WBC and Differential "*" flag L1 May be due to platelet aggregates, NRBCs, giant platelets, cryoglobulins, incomplete lysis of RBC, small lymphocytes, fibrin clots, shift in WBC distribution due to EDTA anticoagulant equilibration. Differential "*" flag L5 Large-size cells present The actions indicated by the manufacturer for "s" flags was "check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." For "*" flags the actions indicated by the manufacturer was "check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required." 4. Review of the CBC instrument printout from the 2017 - 2018 API Hematology PT events revealed 6 of 6 events that the laboratory had flags for the following PT specimens with no documentation of the rerun result per the laboratory policy. 2017-1st event specimen flag Hem-01 L5 Hem-02 L5 Hem-03 L5 Hem-04 L5 Hem-05 L5 2017-2nd event specimen flag Hem-06 L5 Hem-07 L2, L5 Hem-08 L5 Hem-09 L5 Hem-10 L5 2017-3rd event specimen flag Hem-11 L5 Hem-12 L5 Hem-13 L5 Hem-14 L5 Hem-15 L5 2018-1st event specimen flag Hem-01 L5 Hem-02 L5 Hem-03 L5, P1 Hem-04 L5 Hem-05 L5 2018-2nd event specimen flag Hem -06 L1, L5 Hem-07 L5 Hem-08 L5 Hem-09 L2, L5 Hem-10 L5 2018-3rd event specimen flag Hem-11 L5 Hem-12 L2, L5 Hem-13 L5 Hem-14 L5 Hem-15 L5

	5. An interview with the technical consultant on 03/06/19 at 1045 hours in the exam room confirmed the above findings.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: A. Based on review of the 2017 - 2018 American Proficiency Institute (API) proficiency testing (PT) results and confirmed in interview, the laboratory failed to attain at least 80% for the analyte platelets for 2 of 6 Hematology events. Findings were: 1. Review of the 2017 - 2018 API Hematology PT results revealed the laboratory received the following scores for the analyte platelets. 2017 1st event (60% Platelets) Hem-02: lab result 81 (acceptable range 48-81) Hem-05: lab result 939 (acceptable range 267 - 446) 2018 1st event (40% Platelets) Hem-01: lab result 112 (acceptable range 50-85) Hem-03: lab result 971 (acceptable range 383 - 640) Hem-04: lab result 458 (acceptable range 257 - 429) 2. An interview with the technical consultant on 03/06/19 at 1030 hours in the exam room confirmed the above findings. B. Based on review of the 2017 - 2018 American Proficiency Institute (API) proficiency testing (PT) results and confirmed in interview, the laboratory failed to attain at least 80% for the analyte Red blood Cell for 1 of 6 Hematology events. Findings were: 1. Review of the 2017 - 2018 API Hematology PT results revealed the laboratory received the following scores for the analyte red blood cells (RBC). 2017 2nd event (60% RBC) Hem-07: lab result 5.54 (acceptable range 4.83 - 5.46) Hem-10: lab result 6.48 (acceptable range 5.68 - 6.41) 2. An interview with the technical consultant on 03/06/19 at 1030 hours in the exam room confirmed the above findings.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing records, PT corrective actions, and confirmed in interview, the laboratory failed to document the training and technical assistance to correct problems for 4 of 4 hematology testing events with PT failures. findings were: 1. Review of the laboratory policy Proficiency Testing revealed "use the 'Proficiency Testing Troubleshooting checklist' and the 'Proficiency Testing Remedial Action log Sheet' to help resolve and document failed proficiency testing." 2. Review of the 2017 -2018 API proficiency testing records revealed 4 of 6 Hematology events with PT failures for the following analytes. 2017 -1st event Platelets 60% 2017 - 2nd event RBC 60% 2017- 3rd event MCH 20% 2018 - 1st event Platelets 40%; MPV 20% 3. Review of

	the 2017 1st event Proficiency Testing Problem Resolution Form revealed no documentation of a resolution of the PT failure investigation. No documentation of appropriate training and/or technical assistance to correct problems for the PT failure was available for review. 4. Review of the laboratory API corrective actions for the above PT failures revealed no documentation of the Proficiency testing Troubleshooting checklist for 3 of the 4 testing events with PT failures per the laboratory policy. No documentation was provided of a resolutions of the PT failures. No documentation of appropriate training and/or technical assistance to correct problems for the PT failures were available for review. 5. An interview with the technical consultant on 03/06/19 at 1050 hours in the exam room confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records, quality control report records, and confirmed in interview,the laboratory failed to retain all quality control instrument records for at least 2 years. Findings were: 1. Random review of the QC report records from January to March 2019 for the CBC analysis on the Cell-Dyn hematology analyzer revealed no documentaion of all the printouts of the quality control reruns for the following dates. QC Level H, lot H8323, exp 3/8/19 1/14/19 (repeated 6x) 1/16/19 (repeated 5x) 2/22/19 (repeated 2x) QC Level N, Lot N8323, exp 3/8/19 1/14/19 (repeated 3x) 1/15/19 (repeated 2x) 3/1/19 (repeated 9x) 2/22/19 (repeated 2x) 2/22/19 (repeated 2x) QC Level L, Lot L8323, exp 3/8/19 1/19/19 (repeated 2x) 1/23/19 (repeated 17x) 2. An interview with testing person #1 on 3/6/19 at 1315 hours confirmed the above findings. He acknowledged that the testing personnel discarded all reruns and kept the acceptable quality control.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records, laboratory corrective actions, and confirmed in interview, the laboratory failed to ensure an effective QA (Quality Assessment) system was in place to monitor, assess and correct problems in the general laboratory systems. Findings were: 1. Review of the 2017 -2018 API proficiency testing records revealed 4 of 6 Hematology events with PT failures for the following analytes. 2017 -1st event Platelets 60% 2017 - 2nd event RBC 60% 2017- 3rd event MCH 20% 2018 - 1st event Platelets 40%; MPV 20% 2. Review of the laboratory QA records available for the above PT failures

	revealed no documentation of the effectiveness of corrective action taken to address PT failures. 3. An interview with the technical consultant on 03/06/19 at 1055 hours in the exam 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 D5401, D5447, D5461
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: A. Based on review of the laboratory policy, review of patient test records, and confirmed in interview, the laboratory failed to follow its policy for handling flagged cbc (complete blood count) differentials on the Cell Dyn Emerald hematology analyzer. Findings were: 1. Review of the laboratory policy Flagged CBC Differentials (updated 8/2016) revealed "if the flags persist the lab personnel will remove the flagged portion of the results, then presenting the remaining unflagged portion to the clinician. The initial sample should be placed with flags in the binder labeled flagged results for laboratory director. The laboratory will send out for a peripheral slide review based on the manufacturer's instructions: either by our reference lab or by our in-house medical laboratory technician. After receiving the peripheral slide review, it will be presented to the clinician for whatever follow-up action the clinician requires." 2. Review of the laboratory policy Policy for Handling Flagged CBC Differentials signed by the laboratory director on 2/9/19 revealed "it will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according to the procedures in the unit operator's manual...if the flags persist, then the laboratory will confirm the abnormal differential by sending out to a reference laboratory." 3. Random review of the patient printouts from December 2018 to February 2019 revealed 10 of 25 patients reported with flags prior to the peripheral slide review. Refer to CBC patient alias list. 4. An interview with the primary testing person on 3/6 /19 at 1445 hours in the exam room confirmed the above findings. He stated that the laboratory used to remove the flagged portion of the results but then "they physician started to complain about the incomplete results" so the laboratory provided the entire

	CBC results. B. Based on review of the laboratory policy, review of quality control (QC) records, and confirmed in interview, the laboratory failed to follow its policy for QC outside of acceptable range for CBC (complete blood count) testing on the Cell Dyn Emerald hematology analyzer. Findings were: 1. Review of the laboratory policy Control Policy revealed "Use the 'QC out of limits log sheet' to record controls and remedial actions when controls are outside the expected range. Additionally, use the 'Daily Control Sample Troubleshooting Checklist', found in this section to help you resolve daily control problems. All control records and remedial action sheets will be reviewed, signed/initialed, and dated monthly by the laboratory technical consultant... ensure all remedial action steps are documented" 2. Random review of the QC report records from January to March 2019 of the CBC Cell-Dyn Emerald hematology analyzer revealed no documentaion of the corrective actions when control was out of acceptable range per the laboratory policy. QC Level H, lot H8323, exp 3/8/19 1/14 /19 (repeated 6x) 1/16/19 (repeated 5x) 2/22/19 (repeated 2x) QC Level N, Lot N8323, exp 3/8/19 1/14/19 (repeated 3x) 1/15/19 (repeated 2x) 3/1/19 (repeated 9x) 2 /22/19 (repeated 2x) 2/22/19 (repeated 2x) QC Level L, Lot L8323, exp 3/8/19 1/19 /19 (repeated 2x) 1/23/19 (repeated 17x) 3. Review of the laboratory master log from January to March 2019 revealed the laboratory performed CBC patient testing for the above dates. See patient alias list. 4. An interview with the technical consultant on 3/6 /19 at 1315 hours in the exam room confirmed the above findings. He acknowledged that the testing personnel should document the corrective actions.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, quality control report records, laboratory patient logs, and confirmed in interview, the laboratory failed to document 2 acceptable levels of controls prior to reporting patient test results for CBC analysis on the Cell-Dyn Emerald hematology analyzer. Findings were: 1. Review of the laboratory policy Control Policy revealed "for quantitative testing, two levels of controls shall be run for every procedure on each day of use...patient testing must not be performed or reported when controls results are outside the expected range for tow of three controls per analyte." 2. Review of the laboratory quality control report from January 2019 - March 2019 for the Cell Dyn Emerald hematology analyzer revealed no quality control documented for the following dates: 1/28/19, 2/21/19, 2/28/19 3. Review of the laboratory patient logs from January - March 2019 revealed the laboratory performed 8 patient testing without documentation of 2 acceptable levels of quality control for the above dates. See patient alias list. 4. An interview with the testing person #12 on 03/06/19 at 1350 hours confirmed the above findings. He acknowledged that the QC should have been run prior to patient testing. This is a repeat deficiency from the 08/05/2015 survey.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, laboratory records and confirmed in interview, the laboratory failed to document the performance of controls after a change in reagents on Cell Dyn Emerald hematology analyzer. Findings were: 1. A review of the facility's Hematology quality control records and event logs revealed no documentation of the change in reagent and corresponding control testing for 7 documented reagent changes from November 2018 to March 2019. The laboratory performed complete blood count (CBC) testing on this analyzer throughout this time period. 2. A review of the facility's Hematology quality control records and event logs revealed no documentation that quality control had been performed when the following reagents were opened. (lot numbers were not recorded) 11/30/18 Lyse, Cleaner 12/04/18 Diluent 01/01/19 Diluent 01/04/19 Cleaner 01/24/19 Diluent 01/30 /19 Cleaner 02/21/19 Diluent 3. An interview with the primary testing person on 3/6 /19 at 1340 hours in the laboratory confirmed the above findings. This is a repeat deficiency from the 08/05/2015 survey.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory policies, review of the patient test records, and confirmed in interview, the laboratory failed to ensure the the accuracy and reliability of the patient demographics for laboratory results from outside referral laboratories were accurate. Findings were: 1. Random review of the laboratory records from February and March 2019 revealed 1 of 10 patients whose demographics were different from the laboratory results and the final result from the reference laboratory. 2. Review of the laboratory result (sample ID 00003) from 3/2/19 revealed the laboratory incorrectly transcribed manually the patient last name. Review of the final report from the reference laboratory revealed an incorrect date of birth for the same patient. 3. Review of the laboratory records including the patient driver's licence confirmed the name was misspelled on the laboratory result and confirmed that the date of birth was incorrect on the reference lab final report. 4. An interview with the testing person # 12 on 03/06/19 at 1335 hours confirmed the above findings. He acknowledged that the laboratory should have caught the mistake.

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:
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory director failed to ensure proficiency testing materials are analyzed the same number of times as patient samples for CBC (complete blood count) on the Cell-Dyn Emerald hematology analyzer. Refer to D2006
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records, laboratory records, and confirmed in interview, the laboratory director failed to ensure the laboratory performed an approved corrective action plan for PT test results with unacceptable (less than 80%) scores. Refer to D2121, D2128
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records, laboratory corrective actions, and confirmed in interview, the laboratory director failed to ensure the laboratory had an effective QA (Quality Assessment) system to monitor, assess and correct problems in the general laboratory systems. Refer to D5293