Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2130192	07/25/2023
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 a review of the CMS 209 form, personnel records, the laboratory's API (American Proficiency Institute) proficiency testing results, and staff interview, it was revealed that the laboratory failed to ensure that proficiency testing samples were analyzed by personnel who routinely performed patient testing in the laboratory for four of four proficiency testing events in 2023. Findings include: 1. A review of the laboratory's CMS 209 form revealed 21 testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed 12 of 21 testing personnel were hired prior to 2023: Testing person #1 Hire date: 4/2022 Testing person #2 Hire date: 12/2022 Testing person #3 Hire date: 12/2022 Testing person #5 Hire date: 1/2014 Testing person #6 Hire date: 9/2015 Testing person #7 Hire date: 12/2017 Testing person #8 Hire date: 1/2022 Testing person #9 Hire date: 1 /2021 Testing person #10 Hire date: 7/2020 Testing person #11 Hire date: 7/2020 Testing person #12 Hire date: 5/2021 Testing person #19 Hire date: 7/2022 3. A review of the laboratory's API proficiency testing records from 2023 revealed the laboratory participated in the following 4 testing events: - Chemistry 2023 first event - Hematology/Coagulation 2023 first event - Chemistry 2023 second event - Hematology/Coagulation 2023 second event 4. Further review of the proficiency testing events from 2023 revealed all 4 events were tested by Testing person #3. 5. An

	interview with the technical consultant (as indicated on the CMS 209 form) on 7/25 /23 at 12:55 p.m. in the break room, after review of the records, confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's validation records, QC records from March 2023 to May 2023, and confirmed in an interview, the laboratory failed to have documentation of monitoring quality control values over time for one of three months reviewed for Medonic M-series hematology analyzer. The findings were: 1. Review of the laboratory's validation records revealed the laboratory validated Medonic M-series hematology analyzer (SN: 62138) on March 9, 2023. 2. Review of the laboratory's QC records from March 2023 to May 2023 revealed the laboratory failed to have documentation of monitoring quality control values over time for one of three months reviewed for Medonic M-series hematology analyzer. April 2023 3. An interview with the technical consultant on 7/25/2023 at 12:29 pm in the breakroom confimed the above findings. Key: QC=Quality Control
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, the laborartory's validation records, QC records from March 2023 to July 2023, and confirmed in an interview, the laboratory filaed to follow its own policy to verify the criteria for acceptilibility for

	two of two lot numbers for Medonic M-series hematology analyzer. The findings were: 1. Review of the laboratory's validation records revealed the laboratory validated Medonic M-series hematology analyzer (SN: 62138) on March 9, 2023. 2. Review of the laboratory's policy titled QUANTITATIVE CONTROL VALIDATIONS revealed "Method: New controls shall be run at least once a day for 5 days along with current controls." 3. Review of the laboratory's QC records from March 2023 to July 2023 revealed no documentation of verifying the criteria for acceptilibility for two of two lot numbers on Medonic M-series hematology analyzer. Lot# 22303 Exp. 2023-07-27 From 3/9/2023 to 7/20/2023 Lot# 22306 Exp. 2023-10-30 From 7/21/2023 to 7/25/2023 (current) 4. An interview with the TP#3 and the tecniclal consultant on 7/25/2023 at 10:42 am in the breakroom confirmed the above findings. Key: QC=Quality Control TP=Testing personnel
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on a review of the laboratory's annual competency assessments performed in 2022, proficiency testing records, and staff interview, it was revealed that the technical consultant failed to include the testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 10 of 12 annual competency assessments performed in 2022. Findings include: 1. A review of the annual competency assessments forms revealed the technical consultant noted the following for all testing personnel competency assessments performed in 2022: "Assessment of test performance: A. through testing previously analyzed specimens-NO B. internal blind testing specimens-NO C. or external proficiency testing samples-YES" 2. A review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2022 revealed no documentation of the following 10 testing personnel performing any of the proficiency testing samples in 2022: - Testing person #1 - Testing person #4 - Testing person #5 - Testing person #6 - Testing person #7 - Testing person #8 - Testing person #9 - Testing person #10 - Testing person #11 - Testing person #12 3. Further review of the laboratory's competency assessments performed in 2022 on the above listed testing personnel revealed no documentation of testing previous analyzed samples or internal blind testing. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 7/25/23 at 12:55 p.m. in the break room, after review of the records, confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that thirteen of twenty one testing personnel failed to have documentation of training prior to performing patient

	testing on the Medonic M Series hematology analyzer. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 21 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed that the following 13 testing personnel failed to have documentation of training on the Medonic M Series hematology analyzer: - Testing person #1 - Testing person #2 - Testing person #5 - Testing person #6 - Testing person #7 - Testing person #8 - Testing person #9 - Testing person #10 - Testing person #11 - Testing person #12 - Testing person #13 - Testing person #18 - Testing person #21 3. An interview with the technical consultant on 7/25/23 at 12:55 p.m. in the break room, after review of the records, confirmed the above findings.