Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2128748	05/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Village Emergency Room	14520 Memorial Drive Suite 4, 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	An announced validation survey of the laboratory was conducted on 05/22/2024. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] 42 C.F.R. 493.807 (a) - Reinstatement after failure 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to achieve successful performance for 3 of 3 consecutive testing

	events in 2022 and 2023 resulting in unsuccessful performance. The laboratory did not successfully participate in PT for the specialty of Hematology, White Blood Cell Differential. Refer to D2130.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records for 2022 and 2023, and staff interview, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program for 1 of 3 PT events from 2022, the 2022 Chemistry - Core - 3rd Event, resulting in an unsatisfactory performance for the event. Findings included: 1. Review of laboratory's American Proficiency Institute PT records for 2022 and 2023 revealed the laboratory received a score of 0% for the following analytes for 2022 Chemistry - Core - 3rd Event: Albumin Alcaline Phosphatase ALT/SGPT Amylase AST/SGOT Bilirubin, Total BNP (CM) Calcium, Total Chloride CO2 (Carbon Dioxide) Creatinine Kinase, CK Creatinine Kinase, Isoenzyme Creatinine D-Dimer Glucose Myoglobin Phosphorus Potassium Sodium Total Protein Troponin 1 (CM) Urea Nitrogen/BUN Uric Acid 2. In an interview on 05/22/2024 at 1100 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) stated that the score was a result of non-submission of results. This confirmed the findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records from 2022 and 2023, and staff interview, the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for 3 of 3 consecutive proficiency testing (PT) events for the specialty Hematology, White Blood Cell Differential. Two out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings included: 1. A review of the laboratory's American Proficiency Institute PT records from 2022 and 2023 revealed the following consecutive testing events with a score of less than 80% for the White Blood Cell Differential: 2022 Hematology/Coagulation - 2nd Event: Analyte: White Blood Cell Differential Score: 67% 2022 Hematology/Coagulation - 3rd Event: Analyte: White Blood Cell Differential Score: 27% 2023 Hematology/Coagulation - 1st Event: Analyte: White Blood Cell Differential Score: 20% 2. In an interview on 04/23/2024 at 1100 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)

	The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to document evaluation of "Not Graded" results for 2 of 30 reviewed Troponin results in 6 Chemistry - Core PT events from 2022 and 2023. Findings included: 1. Review of laboratory's PT records revealed the laboratory used American Proficiency Institute (API) as its PT provider. Review of API's instructions revealed: "Laboratories are responsible for documenting and performing corrective action for failures and must perform self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Review of the API PT records from 2022 and 2023 for 6 Chemistry - Core events revealed the following 2 "Not Graded" results of 30 Troponin results reviewed did not have documentation of self-evaluation: 2023 Chemistry - Core - 2nd Event: Analyte: Troponin I Performance: Not Graded Sample: CM-06 2023 Chemistry - Core - 2nd Event: Analyte: Troponin I Performance: Not Graded Sample: CM-09 3. In an interview on 05/22/2024 at 1100 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observations in the laboratory, review of manufacturer instructions/package inserts and staff interview, the laboratory failed to document open or amended expiration dates for 3 of 3 hematology controls in use observed. Findings included: 1. Surveyor's observations on 05/22/2024 at 1020 hours in the laboratory revealed the following 3 in use CELL-DYN 18 Plus Controls stored in the refrigerator: Control L Lot: L4092 Unopened vial expiration date: 2024-07-19 Control N Lot: N4092 Unopened vial expiration date: 2024-07-19 Control H Lot: H4092 Unopened vial expiration date: 2024-07-19 There was no open date or amended expiration date documented on either of the 3 control vials. 2. Review of the CELL-DYN 18 Plus Controls' manufacturer instructions (document 9231581A 350005-4 January 2015) revealed: "STORAGE AND STABILITY ... Once opened, containers can be used only for the number of days stated on the assay sheet..." 3. Review of the CELL-DYN 18 Plus Controls' assay sheet for Lot 4092 (document 9231582B 350006-5 August 2018) revealed: "8 Consecutive-Day Open-Tube Stability" 4. In an interview on 05/22/2024 at 1020 hours in the laboratory, the Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.
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: Based on review of laboratory's test verification records and staff interview, the laboratory failed to document verification of patient normal ranges for 1 of 1 new test platform implemented in 2023, the Abbott Cell-Dyn Emerald hematology analyzer. Findings included: 1. Review of laboratory's new test verification records revealed the Abbott Cell-Dyn Emerald hematology analyzer was implemented in February 2023. 2. Further review of the new test platform verification records revealed the Abbott Cell-Dyn Emerald hematology analyzer's verification studies did not include verification of patient normal ranges with representative samples from the laboratory's patient normal population. 3. In an interview on 05/22/2024 at 1210 hours in the breakroom, the Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.
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 manufacturer instructions, review of laboratory's quality control (QC) records, patient test records and staff interview, the laboratory failed to document daily external control testing on the Abbott Cell-Dyn Emerald hematology analyzer for 2 of 92 days reviewed from October to December 2023. Findings included: 1. Review of manufacturer instructions for use for the Abbott Cell-Dyn Emerald hematology analyzer (document 9140855D June 2010) revealed: "Quality Control specimens must be run, and results confirmed to be within acceptable limits before reporting patient results." 2. Review of laboratory's QC records revealed the laboratory did not document performance of QC on the Abbott Cell-Dyn Emerald hematology analyzer for the following 2 of 92 days reviewed from October to December 2023: 10/12/2023 10/14/2023 3. Review of laboratory's patient test records for the above days, revealed the laboratory tested the following patient samples on the Abbott Cell-Dyn Emerald hematology analyzer without documentation of QC for that day: Date:10/12/2023 Patient samples tested: 34758 34759 Date:10/14/2023 Patient samples tested: 34770 34772 34773 4. In an interview on 05/22/2024 at 1220 hours in the breakroom, the Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.
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 the laboratory's American Proficiency Institute (API) proficiency testing records and staff interview, the Laboratory Director failed to ensure successful participation in an HHS approved proficiency testing program for the White Blood Cell Differential for 3 of 3 consecutive events from 2022 and 2023. Rrefer to D6016.
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's American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the White Blood Cell Differential for 3 of 3 consecutive events from 2022 and 2023. Refer to D2130.