Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2123329	09/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hermann Surgery Center Pinecroft	9305 Pinecroft Dr Suite 200, The Woodlands, 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 survey of the laboratory was conducted on 09/18/2023. The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories. STANDARD LEVEL DEFICIENCIES were cited.
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 surveyor's observations, review of laboratory's test system verification studies, instrument's Operators Manual, patient test records and staff interview, the laboratory failed to document verification of accuracy, reportable range and reference intervals prior to patient testing for one of one Hemochron instrument in use for testing activated clotting time (ACT). Findings included: 1. Surveyors observations on 09/18/2023 at 09:20 hours at the instrument's charging station revealed the laboratory used only one Hemochron Signature Elite instrument (serial number SE23778). 2. Review of laboratory's test system verification studies for the above instrument revealed the laboratory performed verification studies for precision on 02/08/2023. The laboratory did not document verification of accuracy, reportable range and reference intervals for the ACT test. 3. Review of the provided instrument's "Hemochron Signature Elite Whole Blood Microcoagulation System Operator's Manual" revealed the operator's manual did not specify protocols for verification studies. 4. Review of patient test records for 2023 revealed one patient was tested

	from February to September of 2023: Test accession number: 35991 Tested: 06/20 /2023 5. In an interview on 09/18/2023 at 1135 hours in the patient room, the facility's Technical Consultant (as indicated on submitted form CMS-209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of Hemochron instrument's operator's manual, laboratory's patient test and quality control (QC) records, and staff interview, the laboratory failed to document testing of required 2 levels of control material every 8 hours each day of patient testing for one of one test performed by the laboratory in 2023, activated clotting time. Findings included: 1. Review of the provided instrument's "Hemochron Signature Elite Whole Blood Microcoagulation System Operator's Manual" revealed: "QC of Instrument Performance The instrument should be tested at two levels once every eight hours of operation. Automatic internal Electronic Quality Control (EQC) can be used to provide a two level electronic verification of the of instrument performance, or liquid quality control products can be used." Note: EQC is an internal function check of the instrument, as opposed to performance of external (liquid) control material testing. 2. Review of the laboratory's patient test and QC records revealed the laboratory performed patient testing on 06/20/2023 on patient sample accession number 35991 without performing QC with two levels of external control material. Only Electronic Quality Control (EQC) was documented for that day. 3. Further review of the QC records revealed the following instructions to operators: "Perform two levels of liquid (external control material) QC every 30 days." The laboratory did not have documentation of completion of an Individualized Quality Control Plan (IQCP) with Risk Assessment to justify the validity of the 30-day interval between liquid QC performance, as opposed to the required every 8 hours of patient testing. 4. In an interview on 09/18/2023 at 1135 hours in the patient room, the facility's Technical Consultant (as indicated on submitted form CMS-209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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 surveyor's observations, review of laboratory's test system verification studies, instrument's Operators Manual, patient test records and staff interview, the Laboratory Director failed to ensure test verification procedures were complete for one of one test performed by the laboratory, activated clotting time (ACT). 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 Hemochron instrument's operator's manual, laboratory's patient test and quality control (QC) records, and staff interview, the Laboratory Director failed to ensure laboratory's quality control was maintained for one of one test performed by the laboratory, activated clotting time (ACT). Refer to D5545.
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: Based on surveyor's observations, review of laboratory's test system verification studies, instrument's Operators Manual, patient test records and staff interview, the Technical Consultant failed to ensure test verification procedures were complete for one of one test performed by the laboratory, activated clotting time (ACT). Refer to D5421.