Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0484216	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Medical Center San Augustine	511 E Hospital Street, San Augustine, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: Based on review of the laboratory's policies, review of quality control (QC) records for the Sysmex XN 1000 hematology analyzer from March to October of 2021, review of the CMS Form 116 and staff interview it was determined the laboratory failed to follow its own procedure for documenting verification of acceptability of new controls with concurrent testing and determination of new standard deviation for 4 of 4 control lot changes reviewed. Findings included: 1. Review of the Laboratory's policy 11.0 "General QC Guidelines" (effective date 03/2020) under Procedure (page 1) revealed: "Whenever a new lot of control is put into use the consensus range will

	be used until at least 10 days are accumulated, at which time a standard deviation will be calculated. During this time the results should fall within the stated consensus range." 2. Review of the laboratory's QC records for the Sysmex XN 1000 hematology analyzer from March to October of 2021 revealed the following control lot changes: Lot 1090 placed in use on 04/26/2021 Lot 1146 placed in use on 06/21 /2021 Lot 1201 placed in use on 08/16/2021 Lot 1257 placed in use on 10/11/2021 2. Further review of the QC records revealed there was no documentation of concurrent testing of new lots and determination of new standard deviation prior to placing them in use for 4 of 4 control lot changes reviewed. 3. Review of the CMS Form 116 submitted by the laboratory at the time of the survey revealed the laboratory performed 40000 hematology tests annually. 4. In an interview on 12/16/2021 at 1505 hours in the conference room the Testing Person number 1 (as described on CMS Form 209 signed by laboratory director on 12/07/2021), after review of the records, confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's Sysmex XN 1000 hematology analyzer's operator's manual, review of the laboratory's policies and procedures, review of random sampling of hematology analyzer's patient result and patient final reports for December of 2021 and interview with the staff it was determined the laboratory failed to have protocols in place for addressing and reporting 4 of 20 test alert values reviewed. Findings included: 1. Review of the laboratory's Sysmex XN hematology analyzer's operator's manuals revealed: a. In section 10.1.4 Numerical Data of the Analysis Results under Notations: "If there is an abnormality in the analysis data, it is represented by the following masks and marks: Notation [*] Meaning Low reliability Description Indicates that the reliability of the data is low" b. In XN-Series Flagging Interpretation Guide (Document Number: 1166-LSS, Rev. 6, March 2021) section Abnormal, WBC Abn Scattergram: "Suggested Action Steps: ...2. Asterisk (*) next to results: Verify WBC, NRBC, PLT and differential results according to your laboratory's policy. Possible actions may include: - scanning the slide for abnormal cells or platelet clumping and to estimate the WBC, NRBC and PLT counts -

	performing a manual differential if abnormal cells are observed" Legend: WBC = White blood cells NRBC = Nucleated red blood cells PLT = Platelets 2. Review of the laboratory's policies and procedures revealed no mention of how to address low reliability results. 3. Review of a random sampling of hematology analyzer's patient result reports for December of 2021 revealed the following 4 of 20 reviewed samples had low reliability notation of [*]: Sample H2213440005 tested 12/10/2021 Sample H2213480005 tested 12/14/2021 Sample H2213470014 tested 12/14/2021 Sample H2213490030 tested 12/16/2021 4. Review of the patient final reports for the above samples revealed the test alert values (low reliability results) were reported to physician. 5. In an interview on 12/16/2021 at 1700 hours in the conference room the the Testing Person number 1 (as described on CMS Form 209 signed by laboratory director on 12/07/2021) confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Dimension EXL with LM chemistry analyzer's quality control (QC) for Alkaline Phosphatase (ALKP) for August to October of 2021, review of laboratory's policies, review of corrective action documentation, review of patient test records and staff interview it was determined the laboratory failed to document 2 levels of acceptable controls for ALKP QC for 3 consecutive days of 92 days reviewed. Findings included: 1. Review of the laboratory's Dimension EXL with LM chemistry analyzer's Levey-Jennings charts for Alkaline Phosphatase (ALKP) quality control (QC) for August to October of 2021 revealed: a. Two levels of controls were performed daily: Level 1 Level 3 b. On 3 consecutive days (of 92 days reviewed), only one of two controls was acceptable. Level 3 was out of acceptable range (268.39-300.39) on the following days: 10/01/2021 - result of 263.0 10/02/2021 - result of 263.0 10/03/2021 - result of 265.0 2. Review of laboratory's policy General QC Guidelines (effective 03/2020) revealed: "All technologists must document corrective action taken in the appropriate log. ... When one control is out of 2 SD - For random error - For occurrence of more than one day" Key: SD - Standard Deviation 3. Review of the laboratory's corrective action log revealed no documentation of corrective action for the above 3 consecutive days with ALKP QC results out of 2 SD. 4. Review of patient ALKP test records for the above days when only one control was within acceptable 2 SD revealed 16 patient samples were tested and reported to provider as follows: Samples tested on 10/01/2021: C2212740001 C2212740008 C2212740011 C2212740023 C2212470033 Samples tested on 10/02/2021: C2212750011 C2212750019 C2212750003 C2212750005 C2212750023 C2212750014 Samples tested on 10/03/2021: C2212760003 C2212760005 C2212760017 C2212760001 C2212760015 5. In an interview on 12/16/2021 at 1440 hours in the conference room the Testing Person number 1 (as described on CMS Form 209 signed by laboratory director on 12/07/2021), after review of the data, confirmed the findings.
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 random review of the laboratory's Quality Control (QC) records for coagulation Prothrombin Time (PT) for September to November of 2021, review of the laboratory's quality control policies, review of patient records and interview with the staff it was determined the laboratory failed to run quality controls every 8 hours as required for 2 of 91 days reviewed. Findings included: 1. Review of the laboratory's policy 10.0 Laboratory Quality Control (effective date 03/2020) revealed: "Coagulation Analyzer For all automated coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs." 2. Review of the laboratory's QC records for coagulation PT for September to November of 2021 revealed the laboratory failed to run quality controls every 8 hours for 2 of 91 reviewed days as follows: 10/12/2021 Controls performed at 22:58 Next QC performed on 10/13/2021 at 07:44 Time elapsed: 8 hours 46 minutes 10/13/2021 Controls performed at 22:40 Next QC performed on 10/14 /2021 at 08:05 Time elapsed: 9 hours 25 minutes 3. Review of the laboratory's patient records for the above dates revealed 2 samples where testing was performed past the required 8 hours QC interval as follows: Specimen H2212840048 Tested 10/13/2021 at 07:05 Last QC ran 10/12/2021 at 22:58 Elapsed time from QC: 8 hours 7 minutes Specimen H2212860029 Tested 10/14/2021 at 07:17 Last QC ran 10/13/2021 at 22:40 Elapsed time from QC: 8 hours 37 minutes 4. In an interview on 12/16/2021 at 1620 hours in the conference room the Testing Person number 1 (as described on CMS Form 209 signed by laboratory director on 12/07/2021), stated that the laboratory ran PT controls every 8 hours, and was not aware of patient sample testing beyond the required 8 hours QC interval. This confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the System Operator's Guide and maintenance logs (March to May of 2021) for the laboratory's Dimension EXL with LM chemistry analyzer, review of corrective action records, review of patient records for May of 2021 and staff interview it was determined the laboratory failed to document corrective action for 29 of 92 instances where cuvette temperature was out of manufacturer specified range. Findings included: 1. Review of the manufacturer's System Operator's Guide for the Dimension EXL with LM/EXL 200 (page 2-4) revealed: "Table 2-1:System

	Temperature System Temperature Specifications Cuvette 36.8C - 37.2C" 2. Review of the daily maintenance records for March to May of 2021 for the Dimension EXL analyzer revealed the following out of range cuvette temperatures: March: 03/13 /2021: 36.5C 03/19/2021: 36.5C 03/14/2021: 36.4C 03/20/2021: 36.6C 03/15/2021: 36.4C 03/21/2021: 36.6C 03/16/2021: 36.5C 03/22/2021: 36.7C 03/17/2021: 36.5C 03 /23/2021: 36.7C 03/18/2021: 36.5C 03/24/2021: 36.7C April: 04/07/2021: 36.7C 04/18 /2021: 36.7C 04/10/2021: 36.7C 04/23/2021: 36.7C 04/11/2021: 36.7C 04/24/2021: 36.6C 04/17/2021: 36.7C May: 05/01/2021: 36.7C 05/08/2021: 36.7C 05/02/2021: 36.7C 05/10/2021: 36.7C 05/03/2021: 36.6C 05/11/2021: 36.7C 05/06/2021: 36.7C 05 /19/2021: 36.7C 05/07/2021: 36.7C 05/20/2021: 36.7C 3. Review of corrective action documentation for March to May of 2021 revealed no corrective action documented for the 29 of 29 instances cuvette temperature was out of specified range. 4. A review of the patient records for May 1st through the 3rd of 2021 revealed the following patient samples were tested on the days cuvette temperature was outside manufacturer's specifications: On 05/01/2021: C2211210001 C2211210002 C2211210004 C2211210007 C2211210009 On 05/02/2021: C2211220001 C2211220003 C2211220006 C2211220010 On 05/03/2021: C2211230014 C2211230018 C2211230025 C2211230030 C2211230033 C2211230041 C2211230044 C2211230051 C2211230058 C2211230059 C2211230071 5. In an interview on 12/16/2021 at 1545 hours in the conference room the Testing Person number 1 (as described on CMS Form 209 signed by laboratory director on 12/07 /2021) stated that corrective action should have been documented. This confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of quality control and maintenance logs and staff interview it was determined the laboratory's Quality Assurance assessment failed to identify and correct issues with maintenance, quality control and testing requirements for the laboratory's analyzers. Findings included: 1. The laboratory's quality assessment plan failed to ensure laboratory's quality control policy for new control lot verification and standard deviation calculation is followed (refer to D5401). 2. The laboratory's quality assessment plan failed to ensure Sysmex XN hematology analyzer's test alert values were addressed (refer to D5403). 3. The laboratory's quality assessment plan failed to ensure coagulation quality controls (QC) were run every 8 hours as required (refer to D5545). 4. The laboratory's quality assessment plan failed to ensure 2 levels of acceptable Alkaline Phosphatase QC were documented on each day of patient testing (refer to D5481). 5. The laboratory's quality assessment plan failed to ensure documentation of corrective actions for out of limit cuvette temperature results for Dimension EXL chemistry analyzer was performed (refer to D5781).
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of quality control and maintenance logs for the hematology and chemistry analyzers and staff interview it was determined the laboratory director failed to ensure the laboratory's Quality Assurance assessments identified and corrected instrument/test performance issues (refer to D5791).