Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0498881	02/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lavaca Medical Center	1400 N Texana, Hallettsville, 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	A recertification survey was performed March 25-26, 2019. The laboratory was found to be IN COMPLIANCE with the CLIA regulations and recertification is recommended.
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 surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for monitoring revised expiration dates for glucometer controls. The findings were: 1. Surveyor observation made on February 26, 2019 in the Day Surgery Department revealed glucometer controls (lot #106201) with an unopened expiration date of March 31, 2020. The controls were located in the instrument's storage case. The controls were open, but there was no revised expiration date. 2. Review of the manufacturer's instructions for the Precision Xceed Pro glucometer (PRT14160, ART14160, Rev. A) on page 24, it stated, "Check that the bottles of control solutions have not been open for more than 90 days." 3. A phone interview with the Day Surgery nurse confirmed the findings. When asked if she documents the revised expiration date and if she was aware that the controls had a revised expiration date once they were opened, she stated, "No."
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

	following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to ensure that results provide only a preliminary analytical test result. The findings were: 1. Review of the manufacturer's instructions for use with the Abbott Architect for Amphetamine, Methamphetamine (307301/R11, B3L370), Barbiturates (307036/R07, B3L380), Benzodiazepines (307267R14, B3L390), Cannabinoids (307075/R09, B3L410), Cocaine (307302/R10, B3L400), Methadone (307083/R07, B3L350), Opiates (307047/R09, B3L340), and Phencyclidine (307019/R07, B6L960) under, "Intended Use" they stated, " ...This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method." 2. Random review of patient results from February 2019 revealed the following patient's urine drug screen was performed by the laboratory using the Abbott Architect. The patient's results were: U Amph Scrn: Positive * U Barb Scrn: Negative U Benzodia Scrn: Positive * U Cocaine Scrn: Negative U Opiates Scrn: Negative U PCP Scrn: Negative U Methadone Scrn: Negative U THC Scrn: Negative 3. The patient report did not indicate that the results would be sent out for confirmation. 4. The patient report did not state the results were preliminary positive. 5. Interview with the technical consultant on February 25, 2019 at 15:45 hours in the Board Room confirmed the findings. Key: U - urine Amph - amphetamine Barb - barbiturates Benzodia - benzodiazepines PCP - phencyclidine THC - cannabinoids Scrn - screen
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor the room temperature of the General Stores where laboratory supplies were located. The findings were: 1. Surveyor observation made on February 26, 2019 in the General Stores revealed no means to monitor the room temperature. 2. Further observations revealed the following laboratory items were stored in the Purchasing Department: Greiner Vacuette Pink Top Tubes Lot B18033AS Expiration date: 08-27-19 Quantity: 50 tubes BD Universal Transport Medium Lot 180915800 Expiration date: 10-31-2019 Quantity: 3 boxes 3. Review of the manufacturer's instructions for the Greiner Vacuette tubes located on the package labeling revealed the storage conditions were "4 - 25 degrees Celsius." 4. Review of the manufacturer's instructions for the BD

	Universal Viral Transport Medium located on the package labeling revealed the storage conditions were "2 - 25 degrees Celsius." 5. It is noted that the supplies were not currently in use for patient testing. 6. An interview with the Engineering Representative on February 26, 2019 in the General Stores confirmed the findings. He confirmed that the temperature of the room was not being documented. Key: BD - Becton Dickinson
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 quality control records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to ensure at least two levels of quality control were acceptable prior to patient testing. The findings were: 1. Review of quality control records from November 2018, December 2018, and January 2019 revealed that on December 21, 2018, there were not two levels of acceptable quantitative quality control for MAS Diabetes. MAS Diabetes Level 2 (Lot 19062) A1C Acceptable Range: 0.48 - 1.28 Laboratory Result: 1.31 (1) Note: (1) indicated a flag, "Greater than 2SD 2. Review of patient reports from December 21, 2018 revealed the following patients were tested when there were not at least two levels of acceptable quality control: FIN 2121760004 FIN 2256940005 FIN 1063320013 FIN 2101090011 FIN 2100660005 FIN 1046690038 FIN 3011990001 3. An interview with the technical consultant on February 25, 2019 at 16:10 hours in the Board Room confirmed the findings. After her review of the records, she agreed there was only one level of acceptable quality control on December 21, 2018 for MAS Diabetes Control. Key: SD - standard deviation
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 instrument verification records, review of the laboratory's data for establishing MNPT (mean normal prothrombin time), and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for performance of its MNPT. The findings were: 1. Review of the manufacturer's instructions retrieved from the instrument verification records for the ACL Top stated, "Donors should be equally divided between male/female." 2. Review of the laboratory's MNPT records for the current lot number revealed the laboratory performed testing on 8 males and 15 females. The laboratory failed to follow the manufacturer's instructions for ensuring that donors are equally divided between male

	and female. 3. An interview with the technical consultant on February 26, 2019 at 10: 30 hours in the Board Room confirmed the findings.