Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0498881	11/14/2024
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of evaluating the competency of 1 of 2 Technical consultants and 1 of 2 Technical supervisors. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the facility identified 2 technical consultants and two technical supervisors. 2. A review of the laboratory's personnel records determined the facility failed to have documentation of assessing the competency of technical consultant number 2 and technical consultant number 2 (as listed on Form CMS 209). 3. Technical consultant number 2 confirmed the findings in an interview conducted on 11/13/2024 at 1124 hours in the conference room.
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 the laboratory's American Proficiency Institute's proficiency testing records from 2024 and staff interview, the laboratory failed to have

	documentation of evaluating proficiency results for 5 of 5 events where the results were not graded by the proficiency testing agency. The finding included: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 (Immunohematology events 1 and 2) and Microbiology (events 1, 2, and 3) identified results which were return 'not graded' by the proficiency testing agency. They were: a) Immunohematology event 1 Crossmatch Type Sample: SER 01 Sample: SER 02 Sample: SER 03 Sample: SER 04 Sample: SER 05 XMatch Reaction Type Sample: SER 01 Sample: SER 02 Sample: SER 03 Sample: SER 04 Sample: SER 05 b) Immunohematology event 2 Crossmatch Type Sample: SER 06 Sample: SER 07 Sample: SER 08 Sample: SER 09 Sample: SER 10 XMatch Reaction Type Sample: SER 06 Sample: SER 07 Sample: SER 08 Sample: SER 09 Sample: SER 10 c) Microbiology event 1 MIC Value Sample: BL 1 Susceptibility Testing Sample: BL 1 d) Microbiology event 2 MIC Value Sample: UR 06 e) Microbiology event 3 MIC Value Sample: UR 11 Susceptibility Testing Sample: UR 11 2. Technical consultant number 2 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 11/13/2024 at 1000 hours in the conference room.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, the laboratory failed to label one of one Coplin glass staining jar on November 12, 2024 with the content's identity. Findings include: 1. Surveyor observation of the laboratory on 11/13/24 at 11:00 a.m. revealed 1 Coplin glass staining jar that the laboratory failed to label with the content's identity. 2. Further review of the Coplin glass staining jar revealed the preparation date of 11/12/24. 3. In an interview on 11/14/24 at 11:20 a.m. in the conference room, the technical supervisor confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of the technical supervisor performing two competency assessments for immunohematology testing within the first year of employment for 3 of 3 testing personnel. The finding included: 1. A review of the laboratory's personnel records determined competency assessments for immunohematology were performed by someone other than the technical supervisor during the first year of employment for 3 of 3 testing personnel. They were (as listed on Form CMS 209) a) testing personnel number 4 assessments performed: January

	2022 June 2022 b) testing personnel number 5 assessments performed: September 2022 March 2023 c) testing personnel number 6 assessments performed: November 2022 March 2023 Each assessment was performed by someone who did not meet the qualification as a technical supervisor. 2. Technical supervisor number 2 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 11/13/2024 at 1100 hours in the conference room.