Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2099521	**(X3) Date Survey Completed** 09/16/2020
Name of Provider or Supplier Memorial Medical Clinic Laboratory	**Street Address, City, State** 1016 N Virginia Street, Port Lavaca, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
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, it was revealed the laboratory failed to have documentation of performing a competency assessment on Technical Consultant 2 (as listed on Form CMS-209). The findings were: 1. A review of the laboratory's submitted Form CMS-209 (signed and dated by the laboratory director on September 17, 2020 revealed the laboratory identified two technical consultants. 2. A review of the personnel records for Technical Consultant #2 (as listed on Form CMS-209) revealed the records did not contain documentation of a competency assessment. 3. The laboratory was asked to provide documentation of the required competency

	assessment. No documentation was provided. 4. An interview with Technical Consultant #2 (as listed on Form CMS-209) on September 16, 2020 at 10:00 hours in the break room revealed she had never had a competency assessment performed on her for her duties as technical consultant. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 laboratory's IQCP (Individualized Quality Control Plan), review of laboratory policies, and confirmed in interview with facility personnel, the laboratory failed to have a policy for ongoing review of its IQCP for Serum hCG. The findings included: 1. An IQCP is composed of three parts: a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) Plan. 2. Review of the laboratory's IQCP for Serum hCG (human chorionic gonadotropin) found the laboratory director had reapproved the plan on April 26, 2018. 3. Review of laboratory records found the laboratory failed to establish written policies and procedures for the ongoing effectiveness of its IQCP for Serum hCG. 4. The findings were confirmed in interview with the Laboratory Manager, Technical Consultant #2 (as listed on Form CMS-209), and Testing Personnel #1 (as listed on Form CMS-209) on September 16, 2020 at 10:44 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of patient test reports from May 2019 and July 2020, and confirmed in interview of facility personnel, it was revealed the laboratory failed to include reference intervals or normal values for KOH (Potassium Hydroxide) and Wet Prep patient test reports. The findings were: 1. A review of patient test reports from May 2019 and July 2020 revealed the laboratory failed to include reference intervals or normal values on 4 of 4 patient test reports reviewed for KOH and Wet Prep. 2. The laboratory was asked to provide documentation of providing reference intervals or normal values to healthcare providers for KOH and Wet Preps. No documentation was provided. 3. An interview with the Laboratory Manager on September 16, 2020 at 11:45 hours in the break room confirmed the findings.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)

	The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to have procedures for evaluation of the competency of 3 of 3 testing personnel that include review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. The findings include: 1. Based on review of testing personnel records, 2019 annual competency assessments for Testing Personnel #1, Testing Personnel #2, and Testing Personnel # 4 (as listed on Form CMS-209) failed to include procedures for evaluating review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. 2. The laboratory was asked to provide documentation of competency assessments that include procedures to evaluate testing personnel performing review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. No documentation was provided. 3. During interview at 10:30 hours on September 16, 2020 in the breakroom, Technical Consultant #2 (as listed for Form CMS-209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to have procedures for evaluation of the competency of 3 of 3 testing personnel that include direct observation of performance of instrument maintenance and function checks. The findings include: 1. Based on review of testing personnel records, 2019 annual competency assessments for Testing Personnel #1, Testing Personnel #2, and Testing Personnel # 4 (as listed on Form CMS-209) failed to include procedures for direct observation of performance of instrument maintenance and function checks. 2. The laboratory was asked to provide documentation of competency assessments that include direct observation of performance of instrument maintenance and function checks. No documentation was provided. 3. During interview at 10:30 hours on September 16, 2020 in the breakroom, Technical Consultant #2 (as listed for Form CMS-209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

	This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to have procedures for evaluation of the competency of 3 of 3 testing personnel that include assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. The findings include: 1. Based on review of testing personnel records, 2019 annual competency assessments for Testing Personnel #1, Testing Personnel #2, and Testing Personnel # 4 (as listed on Form CMS-209) failed to include procedures for assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. The laboratory was asked to provide documentation of competency assessments that include assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. No documentation was provided. 3. During interview at 10:30 hours on September 16, 2020 in the breakroom, Technical Consultant #2 (as listed for Form CMS-209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to have procedures for evaluation of the competency of 3 of 3 testing personnel that include assessment of problem solving skills. The findings include: 1. Based on review of testing personnel records, 2019 annual competency assessments for Testing Personnel #1, Testing Personnel #2, and Testing Personnel # 4 (as listed on Form CMS-209) failed to include procedures for assessment of problem solving skills. 2. The laboratory was asked to provide documentation of competency assessments that include assessment of problem solving skills. No documentation was provided. 3. During interview at 10:30 hours on September 16, 2020 in the breakroom, Technical Consultant #2 (as listed for Form CMS-209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION 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, it was revealed the laboratory failed to have documentation of training prior to patient testing to qualify 1 of 8 testing personnel to perform moderate complexity testing (refer to 6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and 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, it was revealed the laboratory failed to have documentation of training records prior to patient testing to qualify 1 of 8 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS-209 revealed the laboratory identified 8 testing personnel who perform moderate complexity testing. 2. A review of the laboratory's personnel records found Testing Personnel #5 (as listed on Form CMS-209) had documentation of high school equivalency but failed to have documentation of training prior to patient testing. 3. The laboratory was asked to provide documentation of training prior to patient testing for Testing Personnel #5 (as listed on Form CMS-209). No documentation was provided. 4. An interview with the Laboratory Manager and Technical Consultant #2 (as listed on Form CMS-209) on September 16, 2020 at 10:30 hours in the break room confirmed the findings. They revealed the records were not onsite. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services