Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0054055	10/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Medical Center	815 Virginia N 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
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 policies, personnel records, and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency. The findings included: 1. The laboratory failed to have written policies and procedures on performing competency in a moderate complexity laboratory. 2. Based on review of personnel records the following employees' competency assessments were being performed by the general supervisor: Testing Person 2 Testing Person 3 Testing Person 4 Testing Person 11 Testing Person 20 3. An interview with the technical consultant on November 1, 2018 at 10:30 hours in the laboratory confirmed the findings. She confirmed the laboratory did not have a policy for competency assessments and agreed some of the assessments were being done by the general supervisor for moderate complexity testing.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: A. Based on review of patient test records from 2017 and 2018, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual

	accuracy assessments for multiple analytes in 2017. The findings were: 1. A review of patient test records from 2017 revealed the laboratory performed the following testing in 2017: Bleeding Time Legionella pneumophilia Urinary Antigen Streptococcus pneumoniae Urinary Antigen Fetal Stain 2. The laboratory was asked to provide documentation of being enrolled in proficiency testing or of performing twice annual accuracy assessment for each of the missing analytes in 2017. No documentation was provided. 3. An interview with the technical consultant on October 30, 2018 at 12:00 hours in the laboratory confirmed the findings. B. Based on review of proficiency testing records from 2017 and confirmed in interview of facility personnel, the laboratory failed to perform twice annual accuracy for body fluid analysis in 2017. The findings were: 1. Review of the laboratory's proficiency testing records from WSLH for 2017 revealed the laboratory received the following scores: Body Fluid Analysis (RBC) 2017 Event 1 Score: 66% Body Fluid Analysis (RBC) 2017 Event 2 Score 33% 2. Because the laboratory failed to achieve an 80% or higher twice annually in 2017, the laboratory did not perform twice annual accuracy. 3. An interview with the technical consultant on October 30, 2018 at 12:00 hours in the laboratory confirmed the findings. Key: RBC - red blood cell
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the CLIA Form 116, surveyor observations, 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 tubes are maintained in a vertical position at all times. The findings were: 1. Review of the laboratory's submitted Form CMS 116 signed by the laboratory director on October 30, 2018 revealed the laboratory's Chemistry-14 Panel and Lipid Panel consists of the following analytes: CHEM-14 LIPID PROFILE Sodium Cholesterol Potassium High Density Lipoprotein Chloride Triglycerides Carbon Dioxide Low Density Lipoprotein Calcium Glucose Albumin Alkaline Phosphatase Alkaline Aminotransferase Aspartate Aminotransferase BUN Creatinine Total Bilirubin Total Protein 2. Surveyor observation in the laboratory on October 30, 2018 and November 1, 2018 revealed patient samples brought in by courier service. The two times samples arrived, they were brought in a cooler with an ice pack. Each of the specimens was in an individual biohazard bag and laying down in the cooler. 3. Review of the manufacturer's instructions for the Beckman Coulter reagent "Glucose" (Chemistry Information Sheet A18496 AG, July 2011) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 4. Review of the manufacturer's instructions for the Beckman Coulter reagent "Cholesterol" (Chemistry Information Sheet A18476 AH, May 2011) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 5. Review of the manufacturer's instructions for the Beckman Coulter reagent "LDLD" (Chemistry Information Sheet A18513 AK, December 2010) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 6. Review of

the manufacturer's instructions for the Beckman Coulter reagent "Triglycerides" (Chemistry Information Sheet A18554 AG, September 2012) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 7. Review of the manufacturer's instructions for the Beckman Coulter reagent "BUN" (Chemistry Information Sheet A18467 AF, August 2010) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 8. Review of the manufacturer's instructions for the Beckman Coulter reagent "Creatinine" (Chemistry Information Sheet A44573 AG, September2012) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 9. Review of the manufacturer's instructions for the Beckman Coulter reagent "Alanine Aminotransferase (ALT)" (Chemistry Information Sheet A18452 AG, September 2012) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 10. Review of the manufacturer's instructions for the Beckman Coulter reagent "Aspartate Aminotransferase AST)" (Chemistry Information Sheet A18460 AH, September 2012) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 11. Review of the manufacturer's instructions for the Beckman Coulter reagent "Alkaline Phosphatase (ALP)" (Chemistry Information Sheet A18450 AG, August 2010) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 12. Review of the manufacturer's instructions for the Beckman Coulter reagent "Total Protein (TP)" (Chemistry Information Sheet A20656 AH, June 2012) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 13. Review of the manufacturer's instructions for the Beckman Coulter reagent "Total Bilirubin" (Chemistry Information Sheet A18553 AH, September 2012) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 14. Review of the manufacturer's instructions for the Beckman Coulter reagent "Potassium (K)" (Chemistry Information Sheet A18509 AF, August 2010) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 15. Review of the manufacturer's instructions for the Beckman Coulter reagent "Sodium (Na)" (Chemistry Information Sheet A18529 AF, August 2010) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 16. Review of the manufacturer's instructions for the Beckman Coulter reagent "Chloride (Cl)" (Chemistry Information Sheet A18480 AF, August 2010) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 17. Review of the manufacturer's instructions for the Beckman Coulter reagent "Carbon Dioxide (CO2)" (Chemistry Information Sheet A18481 AG) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 18. Review of the manufacturer's instructions for the Beckman Coulter reagent "High Density Lipoprotein (HDL) Cholesterol" (Chemistry Information Sheet B48208AB EN, 1/15) under, "Specimen" stated, "1. Tubes of blood are to be kept closed at all times and in a vertical position ..." 19. The following patient samples were tested when the manufacturer's instructions were not followed to maintain tubes in a vertical position (samples identified during the 2 of 2 direct observations). Sample ID: 12122 Date: 10/30/2018 Sodium: 137 mmol/L Potassium: 3.8 mmol/L Chloride: 98 mmol/L Carbon Dioxide: 30 mmol/L Calcium: 9.3 mg/dL Glucose: 108 mg/dL Albumin: 4.2 g/dL Alkaline Phosphatase: 63 IU/L Alanine Aminotransferase: 28 IU/L Aspartate Aminotransferase: 22 IU/L BUN: 16 mg/dL Creatinine: 0.87 mg/dL Total Bilirubin: 0.9 mg/dL Total Protein: 7.2 g/dL Cholesterol: 107 mg/dL HDL: 31 mg/dL Triglycerides: 110 m/dL LDL: 54 mg/dL Sample ID: 12230 Date: 10/30/2018 Sodium: 140 mmol/L Potassium: 3.6 mmol/L Chloride: 102 mmol/L Carbon Dioxide: 27 mmol/L Calcium: 9.2 mg/dL Glucose: 180 mg/dL Albumin: 3.8 g/dL Alkaline Phosphatase: 55 IU/L Alanine Aminotransferase:

	16 IU/L Aspartate Aminotransferase: 18 IU/L BUN: 24 mg/dL Creatinine: 1.74 mg /dL Total Bilirubin: 1.0 mg/dL Total Protein: g/dL Sample ID: 12888 Date: 11/01 /2018 Sodium: 140 mmol/L Potassium: 3.6 mmol/L Chloride: 104 mmol/L Carbon Dioxide: 23 mmol/L Calcium: 8.7 mg/dL Glucose: 155 mg/dL Albumin: 3.5 g/dL Alkaline Phosphatase: 34 IU/L Alanine Aminotransferase: 16 IU/L Aspartate Aminotransferase: 22 IU/L BUN: 52 mg/dL Creatinine: 0.80 mg/dL Total Bilirubin: 1.0 mg/dL Total Protein: 6.3 g/dL Sample ID: 12881 Date: 11/01/2018 Sodium: 140 mmol/L Potassium: 4.7 mmol/L Chloride: 100 mmol/L Carbon Dioxide: 30 mmol/L Calcium: 9.4 mg/dL Glucose: 92 mg/dL Albumin: 4.3 g/dL Alkaline Phosphatase: 55 IU/L Alanine Aminotransferase: 33 IU/L Aspartate Aminotransferase: 30 IU/L BUN: 18 mg/dL Creatinine: 0.88 mg/dL Total Bilirubin: 0.3 mg/dL Total Protein: 8.1 g/dL Sample ID: 12818 Date: 11/01/2018 Sodium: 140 mmol/L Potassium: 4.6 mmol/L Chloride: 102 mmol/L Carbon Dioxide: 29 mmol/L Calcium: 9.1 mg/dL Glucose: 115 mg/dL Albumin: 3.8 g/dL Alkaline Phosphatase: 75 IU/L Alanine Aminotransferase: 12 IU/L Aspartate Aminotransferase: 19 IU/L BUN: 16 mg/dL Creatinine: 0.73 mg /dL Total Bilirubin: 0.7 mg/dL Total Protein: 7.2 g/dL Sample ID: 12876 Date: 11/01 /2018 Sodium: 142 mmol/L Potassium: 4.3 mmol/L Chloride: 107 mmol/L Carbon Dioxide: 25 mmol/L Calcium: 9.4 mg/dL Glucose: 95 mg/dL Albumin: 3.9 g/dL Alkaline Phosphatase: 51 IU/L Alanine Aminotransferase: 11 IU/L Aspartate Aminotransferase: 21 IU/L BUN: 40 mg/dL Creatinine: 1.62 mg/dL Total Bilirubin: 0.6 mg/dL Total Protein: 6.9 g/dL 20. An interview with the Technical Consultant on November 1, 2018 at 09:15 hours in the laboratory confirmed the findings. Key: CLIA - Clinical Laboratory Improvement Amendments Mmol/L - millimols per liter Mg/dL - milligrams per deciliter g/dL - grams per deciliter IU/L - international units per liter
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: Review of verification studies found that the laboratory failed to ensure that each system introduced had been validated to ensure it met the manufacturer's specifications prior to testing patients. The findings were: 1. Validation studies for the Solana Trichomonas performed in May 2018 was incomplete. Missing documentation was as follows: a. Final review by laboratory director 2. The laboratory was asked to provide documentation of the missing verification records. No documentation was provided. 3. Interview with the technical consultant on 10/31/2018 at 10:21 hours in the laboratory confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--

	(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory Individualized Quality Control Plan (IQCP), review of quality control records, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to follow its IQCP for Group B Streptococcus testing on the Illumigene. The findings were: 1. Review of the laboratory's IQCP for Group B Streptococcus testing on the Illumigene approved by the laboratory director on May 14, 2018, stated, "2. External positive and negative controls are ran with each new lot, shipment, and every thirty days." 2. Review of quality control records for Group B Streptococcus testing on the Illumigene from October, November, and December 2017 revealed external quality control was performed as follows: October 3, 2017 November 12, 2017 (40 days later) 3. Review of patient results from October, November, and December 2017 revealed the following patient specimen was performed when quality control had not been performed: Account: 1356675 Date: November 10, 2017 4. An interview with the technical consultant on October 31, 2018 at 11:20 hours in the laboratory confirmed the findings. She stated that she had been working on identifying these types issues through QA (quality assurance) but had not had a chance to go back that far.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A) Based on review of the CLIA and FDA database, review of laboratory policy, review of manufacturer's instructions, review of quality control records, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to perform an external positive and negative quality control each day of patient testing for Legionella pneumophilia urinary antigen. 1. The laboratory did not perform an IQCP (Individualized Quality Control Plan) for Legionella pneumophilia urinary antigen. The laboratory must perform an external positive and negative quality control test each day of patient testing. 2. Review of the CLIA and FDA database revealed the BinaxNOW Legionella pneumophilia urinary antigen kit is a moderate complexity test kit. 3. Review of the laboratory's policy, "Alere BinaxNOW Legionella urinary Antigen Card Laboratory Procedure" reviewed and approved by the laboratory director on February 22, 2018 stated, " ...Alere kits contain Positive and Negative Control swabs. These swabs will monitor the entire assay. Test these swabs with each new shipment received. Other controls may be tested in order to conform with: local, state and/or federal regulations, accrediting groups and/or, your lab's standard Quality Control procedures." 4. Review of the manufacturer's instructions for the BinaxNOW

	Legionella pneumophilia urinary antigen kit (IN8520050 Rev. 9, 2017/02) under "Quality Control" stated, "Alere BinaxNOW Legionella kits contain Positive and Negative control Swabs. These swabs will monitor the entire assay. Test these swabs with each new shipment received. Other controls may be tested in order to conform with: local state, and/or federal regulations, accrediting groups, and/or, your lab's standard Quality Control procedures." 5. Review of quality control records in conjunction with patient results from January 1, 2018 to October 30, 2018 revealed the following patients were tested when an external positive and negative quality control had not been performed: Account Number: 1381870 Date: 07-31-2018 6. An interview with the technical consultant on October 31, 2018 at 15:00 hours in the laboratory confirmed the findings. B) Based on review of the CLIA and FDA database, review of manufacturer's instructions, review of quality control records, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to perform an external positive and negative quality control each day of patient testing for Streptococcus pneumoniae urinary antigen. 1. The laboratory did not perform an IQCP (Individualized Quality Control Plan) for Streptococcus pneumoniae urinary antigen. The laboratory must perform an external positive and negative quality control test each day of patient testing. 2. Review of the CLIA and FDA database revealed the BinaxNOW Streptococcus pneumoniae urinary antigen kit is a moderate complexity test kit. 3. Review of the laboratory's policy, "Alere BinaxNOW Legionella urinary Antigen Card Laboratory Procedure" reviewed and approved by the laboratory director on February 22, 2018 stated, " ...Alere kits contain Positive and Negative Control swabs. These swabs will monitor the entire assay. Test these swabs with each new shipment received. Other controls may be tested in order to conform with: local, state and/or federal regulations, accrediting groups and/or, your lab's standard Quality Control procedures." 4. Review of the manufacturer's instructions for the BinaxNOW Streptococcus pneumoniae urinary antigen kit (IN710050 Rev. 10, 2018/07) under "Quality Control" stated, "Alere BinaxNOW Legionella kits contain Positive and Negative control Swabs. These swabs will monitor the entire assay. Test these swabs with each new shipment received. Other controls may be tested in order to conform with: local state, and/or federal regulations, accrediting groups, and/or, your lab's standard Quality Control procedures." 5. Review of quality control records in conjunction with patient results from January 1, 2018 to October 30, 2018 revealed the following patients were tested when an external positive and negative quality control had not been performed: Account Number: 1370411 Date: 04-02-2018 Account Number: 1370851 Date: 04-06-2018 Account Number: 1381870 Date: 07-31-2018 6. An interview with the technical consultant on October 31, 2018 at 15:00 hours in the laboratory 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 manufacturer's instructions for the Dade Behring WalkAway analyzer, review of the laboratory's diagnostics reports for the Dade Behring WalkAway analyzer, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when instrument temperatures were not documented within the manufacturer's specifications. The findings were: 1. This is a repeat deficiency. 2. A review of the manufacturer's instructions for the Dade Behring WalkAway analyzer (9020-7223, Rev A) under the section titled "Monitor the Temperature" revealed: "The WalkAway instrument displays the internal temperature on the control panel; however, you musts also check the temperature on the thermometer located on the top left corner of the instrument. The temperature must be 35C +/-1C The temperatures displayed on the control panel and the external thermometer must agree within +/- 0.5C.... If agreement between the internal and external temperature readings is not within +/- 0.5C, call the Technical Assistance Center. 3. A review of the laboratory's diagnostics reports from September and October 2018 identified the following days where the internal temperature and external thermometer were not within 0.5C of each other or the 2nd reading was not performed. If the second reading was not performed the laboratory could not determine if the internal and external temperature reading is acceptable: Date Temperature 09/09 Internal: not recorded External: 35.2 09/12 Internal: not recorded External: 35.7 09/18 Internal: not recorded External: 35.0 09/25 Internal: not recorded External: 34.9 09/27 Internal: not recorded External: not recorded 10/07 Internal: not recorded External: not recorded 10/08 Internal: not recorded External: not recorded 10 /13 Internal: not recorded External: 35.4 10/14 Internal: not recorded External: not recorded 10/17 Internal: not recorded External: 34.3 4. The laboratory was asked to provide documentation of performing corrective actions as required by the manufacturer. No documentation was provided. 5. An interview with the technical consultant on 10/31/2018 at 11:00 hours in the laboratory confirmed the findings.