# Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	04D0642295	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Methodist Medical Center	4000 Linwood Drive, Suite D, Paragould, AR	

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	This is the validation survey of the laboratory conducted on 1/15/2019.
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: Through observations made during a tour of the laboratory, a review of the "Daily Temperature Checks" for January through December 2018, and interviews with staff, it was determined the laboratory criteria for storage of Becton Dickinson (BD) Vacutainers was not consistent with the manufacturer's instructions. Survey findings include: A. During a tour of the laboratory at 11:15 a.m. on 1/15/2019 the surveyor observed K2 EDTA BD Vacutainers (lot #8276782), PST Gel BD Vacutainers (lot #8099812), and Serum Blood Collection Tube BD Vacutainers (lot #8262609) stored at room temperature in the laboratory cabinets. The manufacturers storage instructions on the packages states that the BD Vacutainers are to be stored at 4 to 25 degrees Celsius. B. Through a review of the "Daily Temperature Checks" for January through December 2018 it was revealed the acceptable range for room temperature was listed as "18 to 30 degrees Celsius". C. A review of the "Daily Temperature Checks" for January through December 2018 revealed that the temperature in the laboratory was documented higher than the manufacturer's required storage range (4 to 25 degrees Celsius) on nine of twenty-two days in January, sixteen of twenty days in February, twenty-two of twenty-two days in March, twenty-one of twenty-one days in April,

	twenty-two of twenty-two days in May, twenty-one of twenty-one days in June, twenty-one of twenty-one days in July, twenty-three of twenty-three days in August, nineteen of nineteen days in September, twenty-three of twenty-three days in October, nineteen of twenty days in November, and eighteen of twenty days in December. D. In an interview, at 11:15 on 1/15/2019, laboratory employee #2 (as listed on the CMS-209 form) confirmed the acceptable temperature range on the log did not match the manufacturer's storage requirements for the BD Vacutainers and that temperatures had been above the acceptable storage requirements.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through a review of the AMMC Chemistry Policy and Procedure Manual, a review of June, September, and December 2018 monthly "QC Individual Reports" for the Vitros 350 chemistry analyzer, a review of the Patient Laboratory Reports, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions taken when control materials failed to meet the laboratory's criteria for acceptability. Failure to take corrective actions for quality control failures has the potential to affect all chemistry testing performed. Survey findings follow: A. Policy #CM.011 Quality Control states, "Control values are not acceptable if: The rule is violated across runs when the previous value for a particular control level exceeds the "same" (mean + 2s) or (mean -2s) limit" which means if there are two failures in a row outside of 2 standard deviations (SD). The policy further states, "If controls are out of range the following steps should be taken as applicable: 1. Rerun using fresh sample of control 2. Reconstitute new vial of control (s). 3. Recalibrate with current calibrators. 4. Recalibrate with new calibrators. 5. If reagent deterioration is suspected, repeat testing with fresh reagent pack following calibration. 6. If control results are still out of range, notify the department supervisor for further instructions. 7. Document all remedial action. If the problem has not been resolved, results cannot be released." B. Through a review of June, September, and December 2018 monthly "QC Individual Reports" for sixteen different analytes (Sodium, Glucose, Total Protein, AST (aspartate aminotransferase), Alkaline Phosphatase, Triglycerides, Potassium, BUN (blood urea nitrogen), Cholesterol, Calcium, Chloride, Total Bilirubin, Amylase, HDL(high density lipoprotein) Cholesterol, Uric Acid, and Lipase) performed on the Vitros 350 chemistry analyzer, the surveyor identified three instances when quality control was not acceptable (two failures in a row outside of 2 standard deviations) and the problem was not resolved (the corrective actions listed above were not documented) before patients were reported. C. On 6/22/2018 Liquichek Level 1 Control was unacceptable for Sodium and Chloride. The 2 SD acceptable range listed for Sodium on the QC Individual Report was 124.70 to 130.30. The control was reported as 132.7 at 6:59 a.m. and reported as 130.8 when rerun at 7:21 a.m. (two in a row outside of 2 standard deviations) The 2 SD acceptable range listed for Chloride on the QC Individual

	Report was 88.10 to 91.70. The control was reported as 93.5 at 6:59 a.m. and reported as 92.6 when rerun at 7:21 (two in a row outside of 2 standard deviations) There were no other corrective actions documented and patients were reported. D. On 6/22/2018 the following 18 patient samples had Sodium and Chloride results reported when the quality control was not acceptable: #31204, #31228, #31248, #31266, #31294, #31307, #31308, #31403, #31383, #31406, #31416, #31493, #31504, #31568, #31588, #31747, #31757, and #31907. E. On 9/17/2018 Liquichek Level 1 Control was unacceptable for Calcium. The 2 SD acceptable range listed for Calcium on the QC Individual Report was 8.35 to 8.87. The control was reported as 9.00 at 7:00 a.m., 9.12 at 7:26 a.m., and reported as 8.30 when rerun at 7:57 a.m. (three in a row outside of 2 standard deviations) There were no other corrective actions documented and patients were reported. F. The following 29 patient samples had Calcium reported on 9 /17/2018 when quality control was not acceptable: #48726, #48714, #48788, #48826, #48843, #48838, #48892, #48901, #48895, #48917, #48938, #48948, #48969, #49009, #49095, #49097, #49157, #49179, #49203, #49211, #49299, #49303, #49338, #49413, #49423, #49478, #49523, #49709, and #49777. G. In an interview, at 2:10 on 1/15/2019, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of corrective actions on the failures listed above and stated that she didn't understand the quality control policy as failure in two consecutive runs on the same day but that she thought it only applied to two consecutive days of testing.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel records for three of three laboratory testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director did not give written authorization for testing personnel to perform testing without direct supervision. Survey findings include: A. Through a review of personnel records for the three laboratory testing personnel (labeled number 2, 3, and 4 on the form CMS-209) it was determined that the written authorization to test which was a part of each competency assessment was signed by the laboratory manager (listed as #2 on the form CMS-209) and not the laboratory director. There were no other written authorizations in the personnel records. B. In an interview, at 10:07 on 1 /15/2019, laboratory personnel #2 (as listed on the form CMS-209) confirmed the laboratory director had not signed written authorizations stating the tests each employee was approved to perform or whether direct supervision was required.