Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1080428	08/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Vincent Medical Group Hot Springs (Pcb)	1662 Higdon Ferry Rd,Ste 110, Hot Springs, 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
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: Through a review of manufacturer ' s instructions (package inserts), the "Geometric Mean Calculation" form, and the instrument printout, and through interviews with laboratory staff it was determined the laboratory failed to follow manufacturer's instructions for changing lot numbers of coagulation reagent which has the potential to affect all Protime tests performed. As evidenced by: A. The laboratory uses the Sysmex CA-500 Coagulation instrument for performing Prothrombin Time coagulation tests and reporting INR (International Normalized Ratio). B. A review of the Dade Innovin package inserts revealed that the manufacturer states when converting to new lots of reagents for hemostasis analyzers the Mean Normal Prothrombin Time (MNPT) for INR calculation should be geometric mean. It further states, "CLSI H54-A recommends using geometric mean for determining MNPT". The Dade Innovin package insert also includes the lot-specific and technique specific ISI values which are used in the calculation of the INR. For the current lot (#539384) in use on the Sysmex CA-500 Coagulation analyzer the package insert listed an ISI of 0.99. C. A review of the normal patient "Geometric Mean Calculation" form for the current lot of Innovin revealed the laboratory calculated both the arithmetic mean and the geometric mean. The arithmetic mean was documented as 10.325 and the geometric mean was 10.31629. It listed the Normal Patient Mean to be used in the calculation as 10.33 (which is the arithmetic mean instead of the geometric mean as required by the manufacturer's instructions. D. During a tour of the laboratory on 8/29 /2018 at 1430, the surveyor requested the instrument printout of the current lot of

	Innovin reagent in use on the Coagulation analyzer. Current lot documented on the instrument printout was lot #539384 expiration 4/12/2019 with an International Sensitivity Index (ISI) value of 0.96 (which is not the ISI listed in the package insert for this lot of Innovin). E. In an interview on 8/29/2018 at 1430, technical consultant (as listed on CMS form 209) confirmed that the did not use the correct Normal Patient Mean or the correct ISI value for the current lot of Innovin in use at the time of the survey. 8. The failure to perform new Prothrombin reagent rollover studies as directed by the manufacturer represents an immediate jeopardy to patient care. It has the potential to affect all patient Prothrombin results reported.
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: Through a review of method validation reports, a review of test configuration data, and through interviews with laboratory staff it was determined the laboratory failed to demonstrate that it can obtain the reportable range established by the manufacturer. Survey findings follow: A. The method validation report for Glucose dated 2/27/2017 includes results for five standards. The results of the linearity testing were flagged as unacceptable for four of five standards tested. B. The test configuration data for Glucose printed from the Vitros 5,1 chemistry analyzer includes a reportable range of 20 to 625 mg/dL although the validation report revealed the laboratory only tested standards in the range of 30 to 585 mg/dL and four of five standards failed to be within the acceptable limits. C. The method validation report for Albumin dated 2/27/2017 includes results for five standards. The results of the linearity testing were flagged as unacceptable for one (6.2 g/dL) of five standards tested. D. The test configuration data for Albumin printed from the Vitros 5,1 chemistry analyzer includes a reportable range of 1 to 6 g/dL although the validation report revealed the laboratory tested standards in the range of 1.4 to 5.4 g/dL and the results for the 5.4 standard failed to be within the acceptable limits. Acceptable results were only reported on standards that spanned the range of 1.4 to 4.8 g/dL. E. The method validation report for BUN (Blood Urea Nitrogen) dated 2/27/2017 includes results for five standards. The results of the linearity testing were flagged as unacceptable for one (119.33 mg/dL) of five standards tested. F. The test configuration data for BUN printed from the Vitros 5,1 chemistry analyzer includes a reportable range of 2 to 120 mg/dL although the validation report revealed the laboratory tested standards in the range of 3 to 112 g/dL and the results for the 112 standard failed to be within the acceptable limits. Acceptable results were only reported on standards that spanned the range of 3 to 87.67 g/dL. G. The method validation report for Phosphorous dated 2/27/2017 includes results for five standards. The results of the linearity testing were flagged as unacceptable for four of five standards tested. H. The test configuration data for Phosphorous printed from the Vitros 5,1 chemistry analyzer includes a reportable range of 0.6 to 12 mg/dL although the validation report revealed four of five standards failed when the laboratory performed the linearity validation. I. The

	method validation report for Cholesterol dated 2/27/2017 includes results for five standards. The results of the linearity testing were flagged as unacceptable for four of five standards tested. J. The test configuration data for Cholesterol printed from the Vitros 5,1 chemistry analyzer includes a reportable range of 50 to 325 mg/dL although the validation report revealed four of five standards failed when the laboratory tested standards in the range of 59 to 290.3 mg/dL. K. The method validation report for Creatinine dated 2/27/2017 includes results for five standards. The results of the linearity testing were flagged as unacceptable for two (10.37 and 13.47 mg/dL) of five standards tested. L. The test configuration data for Creatinine printed from the Vitros 5,1 chemistry analyzer includes a reportable range of .15 to 14 mg/dL although the validation report revealed two of five standards failed when the laboratory performed the linearity validation. Acceptable results were only reported on standards that spanned the range of .20 to 8.23 mg/dL. M. In an interview at 11:36 on 8/30/2018 the technical consultant (as listed on the form CMS-209) confirmed the reportable ranges configured in the Vitros 5,1 instrument were not proven by the linearity validations performed on 2/27/2017, when the instrument was moved to the current laboratory location.