Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1080421	07/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Vincent Medical Group Hot Springs	1707 Airport Road, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Through review of American Proficiency Institute (API) Hematology proficiency testing reports for 2025 and 2026, laboratory policy and procedure, and interview with laboratory staff, the laboratory failed to test proficiency samples in the same manner as patient testing in three of three API hematology proficiency testing events in 2025 and one of one proficiency testing events in 2026 by testing eleven of twenty specimens twice when patient specimens would not have been tested twice . Findings follow. A) Review of the laboratory policy and procedure revealed that hematology results which exceed critical values or which have instrument flags should be retested. B) Review of the policy and procedure for proficiency testing revealed "Proficiency testing should not be tested with greater frequency than routine patient testing". C) Review of laboratory original result print outs of specimens HSY 01, HSY 03, HSY 04, in the first API proficiency testing event of 2025 revealed the specimens were tested twice, and HSY 01, and HSY 04 did not have critical results which would have required testing to be repeated D) Review of laboratory original result print outs of specimens HSY 06, HSY 08, HSY 09 and HSY 10 in the second API proficiency testing event of 2025 revealed the specimens were tested twice, and HSY 06, HSY 08 and HSY 10 did not have critical results which would require testing to be repeated.

	E) Review of laboratory original result print outs of specimens HSY 11, HSY 13, HSY 14 and HSY 15 in the third API proficiency testing event of 2025 revealed the specimens were tested twice, and HSY 11, HSY 13 and HSY 15 did not have critical results which would require testing to be repeated. F) Review of laboratory original result print outs of specimens HSY 01, HSY 02, HSY 03 and HSY05 in the first API proficiency testing event of 2026 revealed the specimens were tested twice, and HSY 01, HSY 03 and HSY 05 did not have critical results which would require testing to be repeated. G) In an interview on 7/ 8/26 at 10:45 a.m. the laboratory staff member (number two on the form CMS 209) confirmed that proficiency testing samples, identified above, should not have been tested twice.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based upon a review of the laboratory's policy for quality control (QC), Levy Jennings (LJ) graphs for hemoglobin (HGB) results for April, May, June, and July of 2025, a manufacturer provided service report, and interview with laboratory staff, the laboratory's policy and procedure for quality control did not detect errors in testing over time. Findings follow: A) Review of the laboratory's policy for quality control revealed that three levels (Lv1, Lv2, Lv3) of quality control material are tested daily and quality control is deemed acceptable if two of three levels are within the manufacturer's published acceptable range and no single level is outside three standard deviations from the target value. B) Review of LJ graphs of daily quality control for HGB determinations in April 2025 revealed that on 21 of 21 days of operation all three levels lot 502207of QC were below the target value. C) Review of LJ graphs of daily quality control for HGB determinations in May 2025 revealed that on 23 of 23 days of operation all three levels lot 510607 of QC were below the target value. D) Review of LJ graphs of daily quality control for HGB determinations in June 2025 revealed that on 23 of 23 days of operation all three levels lot 510607of QC were below the target value. E) Review of LJ graphs of daily quality control for HGB determinations in July 1 through July 22, 2025 revealed that on 15 of 15 days of operation all three levels of lot 510607 QC were below the target value. F) Review of manufacturer provided service record for the Sysmex hematology analyzer revealed that on August 8, 2025 the manufacturer reprsentative "replaced chamber unit, flushed vacuum, performed preventive maintenance, and performed calibration". G) Review of LJ graphs of daily quality control for HGB determinations in August 2025 revealed that HGB determinations returned to normal distribution around the target value. H) In an interview on 7/8/26 at 12:30 p.m. the laboratory staff member (number 2 on the form CMS 209) confirmed the quality control procedures did not identify factors affecting the accuracy of HGB determinations.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based upon a review of American Proficiency Institute (API) Hematology /Coagulation proficiency test results second event 2025, documentation on "Performance Review and Corrective Action" section of report, lack of documentation, and interview, the laboratory failed to document issues and corrective action for failures of hematocrit (HCT) performance. Findings follow: A) Review of the API Hematology/Coagulation proficiency test results for the second event in 2025 revealed a strong negative bias (greater than 2.0 standard deviation index) for hemoglobin (HGB), hematocrit (HCT), and mean cell volume (MCV) results in comparison to peers, and a 60% "unsuccessful" result for hematocrit with two of five challenges deemed unacceptable. B) Review of the documentation noted on the "Performance Review and Corrective Action" section of the report revealed an undated written note stating "60% on HCT 100% on all other values. Analyzer was having issues w/ HGB and HCT. Issue has since been fixed. No further action needed". C) Upon request, the laboratory was unable to provide documentation of the identity of the "issue" mentioned in the notation, what was done to correct the issue, and when the issue began. D) In an interview on 7/8/26 at 11:04 a.m. , the laboratory staff member (number 2 on the form CMS 209) agreed that the written notation on the "Performance Review and Corrective Action" section was not documentation identifying the issue, and the corrective action correcting the issue.