Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1080428	08/18/2026
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
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 upon a review of the CMS 209 form, review of laboratory documentation of competency assessment, lack of documentation and interview with laboratory staff the laboratory failed to assess testing personnel competency twice during the first year of employment for two of seven testing personnel listed on the CMS 209 form. Findings follow: A) Review of the CMS 209 form revealed that seven testing personnel were employed by the laboratory. B) Review of competency assessment records revealed that the testing personnel (# 5 on the CMS 209 form) had a date of hire of February 2025 and had a record of competency performed in August 11, 2025 and August 12 /26 with no record of a second competency evaluation before February 2026, and testing personnel (# 7 on the CMS 209 form) was hired in December 2024 and only a single competency evaluation dated December 12, 2025. C) Upon request, the laboratory was unable to provide second competency assessments during the first year of employment for the testing personnel identified above. D) In an interview on 8/17 /26 at 10:45 a.m, the laboratory staff member (# 2 on the form CMS 209) confirmed that two competency assessments during the first year of employment for the employees identified above were not performed and the employees had performed testing in the laboratory.
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 review of Technopath Clinical Diagnostics Instructions for Use (IFU) of Multichem Quality Control (QC) reagents for clinical chemistry analytes performed on the Abbott Alinity chemistry analyzer, review of the laboratory's policy and procedure for QC of chemistry analysis, review of the laboratory's "QC Levey-Jennings Report" for Aspartate Aminotransferase (AST) procedures for May, 2025, review of instrument print-outs of AST procedures performed for proficiency testing (PT) supplied by the American Proficiency Testing Institute (API), review of the results for AST API proficiency testing for the 2nd testing event in 2025, review of the laboratory's review of results of the API Chemistry 2nd event 2025, and interview with laboratory staff members, the laboratory failed to establish acceptable ranges for QC of chemistry procedures adequate to detect immediate inaccuracies in test results. Findings follow: A) Review of the IFU for Technopath QC reagent for the Alinity clinical chemistry analyzer revealed "values are provided only as guidelines, each laboratory should establish its own statistical limits". B) Review of the laboratory's policy and procedure for QC of chemistry analytes revealed, "after calibration, controls are tested a minimum of twice and the calculated mean from the runs is entered along with the standard deviation (SD) calculated from the packge insert range. A 2 SD standard deviation range is set and reviewed and adjusted from the monthly data or when lot numbers of the material changes." C) Review of the "QC Levey-Jennings Report" for AST analysis for May 2025 revealed that QC a SD value of 4.87 for level 1 and 32 for level 3 with both of the acceptable range SD being the same as the acceptable range furnished in the package insert. D) Review of the "QC Levey-Jennings Report" for AST analysis for May 2025 revealed that the actual SD calculated including all the QC results for the month was 0.73 for level 1 and 1.37 for level 3. E) Review of instrument print-outs of AST procedures performed for proficiency testing (PT) supplied by the American Proficiency Testing Institute (API) revealed that API PT 2nd event 2025 testing was performed on 5/19/25 and 5/21/25. F) Review of the result evaluation for AST 2nd event 2025 PT testing revealed a score of 20% "unacceptable" with the laboratory results being determined to be unacceptable for four of the five challenges. G) Review of the laboratory's review of the API Chemistry PT report for the 2nd event 2025 revealed the laboratory did not determine the cause of the failures. H) In an interview on 8/18/26 at 12:58 p.m. , the laboratory staff member (# 2 on the form CMS 209) confirmed that acceptable ranges for all chemistry analytes are determined by the ranges on the TechnnPath package insert instead of a calculated SD and ranges were too broad to detect immediate inaccuracies in AST testing.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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: Based upon review of the laboratory's policy and procedure for "Coagulation Quality Control (QC) Prothrombin Time (PT) and Partial Thromboplastin (PTT)", Sysmex CA-600 QC report, the corrective action report for coagulation , patient results, lack of documentation, and interview, the laboratory failed to evaluate patient results back to the last successful Prothrombin Time (PT) QC results when quality control (QC) results were outside of the laboratory's acceptable range on one of two instances reviewed. Findings follow: A) Review of the laboratory policy and procedure for quality control of coagulation testing revealed that "both levels of control should be within tolerance limits established for that specific lot number of control before patient testing". B) Review of the July 2026 Sysmex CA-600 QC report for PT testing revealed that QC03 lot# 556595 with a laboratory defined acceptable range of 44.6 to 48.4 seconds was reported 44.4 on 7/11/26 at 09:32 a.m., 44.2 at 09:42 a.m.. 43.9 at 10:20 a.m., before being acceptable on 7/11/26 at 11:31 a.m. C) Review of the Sysmex CA-600 QC report for July 2026 revealed that the last successful PT QC results occured on 7/10/26 at 11:10 a.m.. D) Review of the coagulation testing corrective action sheet for the failures on 7/11/26 revealed the corrective action taken to bring QC results into acceptable range was " change innovin and repeat". The replacement of innovin (the PT assay reagent) represented a change in the testing system. E) Review of patient results revealed that one PT test was performed and reported on patient, identified as number 1 on a separate patient identification list on 7 /10/26 at 02:42 p.m. F) Upon request, the laboratory was unable to provide documentation that the patient result identified above had been evaluated. L) In an interview on 8/17/26 at 02:36 p.m., the laboratory staff members (# 2 on the CMS form 209) confirmed that a PT test was performed and reported on patient identified above and had not been evaluated.
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. This STANDARD is not met as evidenced by: Based upon review of American Proficiency Testing Institute (API) proficiency testing (PT) results for white blood cell differential (WBC Diff) for the second and third testing events in 2025, review of the evaluation of results documented by the laboratory, lack of documentation, and interview with laboratory staff, the laboratory failed to take effective corrective action when failing PT events for Lymphocytes (Lymphs) and Neutrophil (Neut) on the second and third PT events in 2025. Findings follow: A) Review of the API Hematology/Coagulation PT second event 2025 revealed the scores Lymph 0% (unacceptable) and Neut 40% (unacceptable). B) Review of the laboratory evaluation for the event revealed "QC in and OK". C) Review of the API Hematology/Coagulation PT third event 2025 revealed the scores Lymph 40% (unacceptable) and Neut 60% (unacceptable). D) Review of the

	laboratory evaluation for the event revealed no comment regarding the scores for Lymph and Neut. E) Upon request, the laboratory could not furnish documentation of the corrective action taken for the unsuccessful PT results for Lymph and Neut on the second and third PT events in 2025. F) In an interview on 8/17/25 at 11:36 a.m. the laboratory staff member (# 2 on the form CMS 209) stated "it looks like I did not complete and write that up".