Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1082030	11/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Vincent Hospital Hot Springs Laboratory	300 Werner Street, 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: Through review of the CMS 209 form, lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to assess employee competency as directed in personnel requirements. Survey findings follow: A) Review of the CMS 209 form submitted by the laboratory revealed that the laboratory staff member (#1 on the CMS 209 form) was listed as the technical consultant for specialties 1 and 2, the laboratory staff member (#16 on the CMS 209 form) was listed as technical consultant for specialty 9, the laboratory staff member (# 26 on the CMS 209 form) was listed as technical consultant for specialty 8, the laboratory staff member (# 28 on the CMS 209 form) was listed as technical consultant for specialty 7, and the laboratory staff member (# 33 on the CMS 209 form) was listed as general supervisor. B) Upon request, the laboratory was unable to provide documentation of competency determinations for the positions and personnel identified above, four of four technical consultants and one of one general supervisor. C) In an interview at 11: 30 a.m. on November 28, 2023 the laboratory staff member (# 33 on the CMS 209 form) confirmed that competency determinations have not been performed on personnel designated as technical consultants or general supervisor based upon their position responsibilities.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Obervation, review of policy and procedure manuals, and interview showed the laboratory was not following their written policy and procedure. Findings follow: 1 - A) Review of the policy and procedure manual revealed "Clinical Laboratory: Standardized Corrective Action for QC" (policy # GEN01.4200, original date May 2015) states: "The following corrective action codes are used in the Laboratory to resolve out of control ranges." Examples - A. Test repeated: Same Control Same Reagent; B. Test Repeated: Same Control New Reagent; C:Test Repeated: New Control Same Reagent. B) Review of a selection of chemistry quality control (QC) records from November 2022, March 2023, and July 2023 showed notation explaining QC failures and steps to address the failures, but did not utilize the codes referred to above. C) In an interview on 11/30/23 at 9:47 a.m.the laboratory staff member (# 28 on the CMS 209 form) corfirmed that codes were not used in the QC records for Chemistry. 2 - A) Review of the policy and procedure manual revealed "Quality Control Program" (policy # GEN01.4300, original date May 2015) states: "the cause of the control failures and the corrective action taken must be documented by the technologist." B) Review of a selection of chemistry QC records from November 2022, March 2023, and July 2023 showed a QC failure for Haptoglobin on 7/29/23. No cause of the control failure and corrective action was documented. C) In an interview on 11/30/23 at 10:09 a.m.the laboratory staff member (# 28 on the CMS 209 form) corfirmed that cause of control failure and corrective action (s) taken were not documented in the QC records for Chemistry.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure, heamtology quality control (QC) results, a chart posted on the Sysmex XN Hematology analyzers, the "Quality Control - 1st Shift" review form and interview with laboratory staff it was determined that the laboratory was following a procedure not approved by the laboratory director. Findings follow: 1) Review of the procedure approved by the laboratory director "GEN01.4200 Standardized Corrective Action for QC" revealed the following codes utilized in documenting corrective action: "A. Test Repeated: Same Control Same Reagent B. Test Repeated: Same Control New reagent C. Test Repeated: New Control Same Reagent D. Test Repeated: New Control New Reagent" 2) Review of a chart posted on the Sysmex XN hematology analyzer revealed the following code definitions: "A. - Rerun same QC material B- Rerun with new QC material C- Replaced reagent D- Wrong control 3) Review of the "Quality Control - 1st Shift" review form listed corrective action codes consistent with those listed in findings paragraph 2 above. 4) In an interview on November 29, 2023 at 10:35 a.m., the laboratory staff member (# 26 on the CMS 209 form) confirmed that the codes posted

	on the Sysmx analyzer do not correspond with the approved codes in policy and procedure "GEN 01-4200" and the discrepancy might affect the determinations made during review of QC results.
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 observation, review of manufacturer's package insert, temperature continuous monitoring charts, and interview it was determined that the laboratory failed to follow manufacturer's instructions for storage requirements of Biorad Liquid Assayed Multiqual quality control (QC) materials. Findings follow: A) During a tour of the laboratory on November 30, 2023 at 01:05 p.m. multiple (greater than 50) vials of Biorad Assayed Multiqual QC materials lot # 45970V Expiration date 2026-01-31 were observed in a freezer in the Chemistry laboratory. The freezer interior contained no collected build-up of frost. B) Review of the continuous temperature monitoring chart revealed periodic temperature increases typical of those seen in a freezer with a defrost cycle. C) Review of the manufacturer's package insert for Biorad Liquid Assayed Multiqual QC material revealed the statement "avoid storing this product in a frost-free freezer". D) In an interview on November 30, 2023 at 01:05 p.m. , the laboratory staff member (# 7 on the CMS 209 form) confirmed that the freezer in which the Biorad Liquid Assayed Multiqual QC material was stored was frost-free with a defrosting cycle.