Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405966	12/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Gabriel's Health	815 2nd Street Se, Little Falls, MN	

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	The St. Gabriel's Hospital laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the validation survey performed December 14-15, 2023. The following standard-level deficiencies were cited: 493.801 Proficiency testing enrollment 493.1105 Retention requirements 493.1256 Control Procedures
D2004	ENROLLMENT CFR(s): 493.801(a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to participate in one approved proficiency testing (PT) program for one year before designating a different program for Blood Gas analysis in 2022. Findings are as follows: 1. The laboratory enrolled in American Association of Bioanalysts (AAB) PT program for Blood Gas analysis for the year 2022. 2. The laboratory did not receive PT material for the first event of 2022 for Blood Gas analysis from AAB, and therefore did not participate, receiving scores of "0". 3. The laboratory enrolled in the College of American Pathologists (CAP) PT program for Blood Gas analysis for the second and third events of 2022 due to the issues they had not receiving the AAB material for the first event. The laboratory received successful scores through CAP for the second and third events of 2022. 4. In a interview with at 11:30 a.m. on December 14, 2023, the Technical Supervisor 1 confirmed the above findings. .
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review, observation, and an interview with laboratory personnel, the laboratory failed to retain all analytic records of activities as specified in 493.1256 (e)(2), specifically records of lot numbers and expiration dates of the stains used by the laboratory each day of use in 2022 and part of 2023. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the Technical Supervisor 1 (TS1) during a tour of the laboratory at 10:45 a.m. on December 14, 2023. 2. The Aerospray automated hematology slide stainer, the reagent bottles of staining material, and the Olympus CX43 microscope used to perform the blood smears were observed as present and available for use during the tour of the laboratory. Also observed was a log sheet on which the laboratory was currently documenting the lot numbers and expiration dates of the staining materials used to stain the blood smears. 3. A patient who had a manual blood smear performed on November 1, 2022 (MRN XXX495) was reviewed on the day of survey. Records of the lot numbers and expiration dates of the staining material used could not be found. The laboratory was unable to provide the records at request. 4. In an interview at 9:11 a.m. on December 15, 2023, TS1 confirmed the lot numbers and expiration dates of the staining material were not getting documented on the day of patient testing in 2022. TS1 further clarified that the laboratory did not start documenting the lot numbers and expiration dates of the staining reagents until October of 2023. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform established quality control (QC) activities required for a Hematology test system for 2022 and 2023. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 10:45 a.m. on December 14, 2023. 2. The Sysmex XP-300 Hematology instrument, used to perform back-up hematology testing, was observed as present and available for use during the tour of the laboratory. In an interview at 10:50 a.m., during the tour, TS1 and testing personnel 7 confirmed the laboratory performs three levels of quality control (QC) each night on the instrument and that they will perform an additional 2 levels during the day if needed when they use the instrument for patient testing. 3. The SYSMEX XP-300 AUTOMATED HEMATOLOGY ANALYZER procedure, found in the electronic

	procedure manual, established the following QC requirements for the instrument: Frequency of Control Use Run 2 levels of control every 8 hours (0300, 1100, 1900). QC should be run as close to the 8 hour mark as possible, however a +/- 30 minute window on either side of the 8 hour mark is acceptable. Levels: Abnormal High & Abnormal Low will be run on night shift (0300) Levels: Abnormal Low & Normal will be run on day shift (1100) Levels: Normal & Abnormal High will be run on relief shift (1900) 4. The Sysmex XP-300 raw QC data was reviewed for November 2022. It was found the laboratory was performing Abnormal High, Normal and Abnormal Low QC levels around 0400 every night. If a patient was run during the day an Abnormal Low and a Normal control level was performed. 5. In an interview at 9:37 a. m. on December 15, 2023, TS1 confirmed the laboratory was not following the current established QC procedure on the back-up hematology analyzer. .