Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403647	10/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cook Hospital & Care Center	10 Fifth Street Se, Cook, 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 Cook Hospital & Care Center 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 recertification survey which concluded on October 9, 2024. The following standard-level deficiencies were cited: 493.1256 Control Procedures 493.1271 Immunohematology 493.1291 Test Report .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 document Hematology quality control procedures performed to evaluate stain for intended reactivity each day of use in 24 of 24 months from September 2022 through October 2024. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:05 p. m. on 10/08/24. 2. Manual differential stains and an Olympus CH 30 microscope used to perform manual differentials were observed as present and available for use during the tour. 3. Direction to determine overall staining quality and direction to document this activity for manual differentials was not found in the Hematology Blood Smears (Wright Stain) procedure found in the Sysmex manual. 4. In an interview at 1:45 p.m on 10/09/24, the GS confirmed the above finding and stated the laboratory did not document the quality of staining when performing a manual differential. .

D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document alarm system function checks for the blood storage refrigerator with the frequency defined by the laboratory in nine of nine calendar quarters between September 2022 and September 2024. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor during a tour of the laboratory at 1:05 p.m. on 10/08/24. 2. A blood product designated Jewett refrigerator with a temperature alarm system was observed as in use during the tour. 3. Quarterly blood product storage alarm check requirements were established in the Quarterly Blood Bank Temperature Check procedure located in the Blood Bank Procedure Manual. 4. Blood product storage alarm checks were not completed in the time period reviewed, September 2022 through September 2024, as indicated on service reports completed by vendor Agility. The last documented alarm check was performed in February 2022. 5. The laboratory performed approximately 156 Immunohematology tests annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 3: 10 p.m. on 10/09/24, the GS confirmed the above finding. .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure two of seven blood gas Chemistry reference intervals were consistent between a procedure and a patient test report in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS)) during a tour of the laboratory at 1:05 p.m. on 10/08/24. 2. An Abbott i-STAT blood analysis system was observed as present and available for use during the tour. The laboratory performed blood gas testing using this analyzer. 3. Two arterial blood gas reference intervals listed in the Arterial Blood Gas and Venous Blood Gas procedure, located in the I STAT manual, were not consistent with those included on a patient test report from 09/05/23 as indicated below. Analyte Procedure Report PO2 10-105 75-85 SO2 95-98 96-100 4. In an interview at 1:40 p.m. on 10/09 /24, the GS confirmed the above finding and indicated the reference range values in the procedure were correct. .