Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D2093391	**(X3) Date Survey Completed** 08/22/2023
Name of Provider or Supplier State Of Franklin Healthcare, Wic	**Street Address, City, State** 301 Med Tech Pkwy, Suite 110, Johnson City, TN	

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**
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: Based on direct observation, review of the laboratory's procedures and environmental logs, and interview with the laboratory's technical consultant, determined the laboratory failed to follow their own written procedure for performing and documenting corrective actions for unacceptable refrigerator temperature for 155 out of 448 days from June 2022 through the survey date of August 22, 2023. Findings included: 1. Direct observation of the laboratory on 08.22.2023 at 1:10 pm revealed a Thomson refrigerator (S#A1807246000136) in use for storing complete blood count (CBC) quality control (QC). 2. Review of the laboratory's "Temperature Ranges" procedure stated, "PROCEDURE: Record humidity, refrigerator, freezer and room temperatures every day in use. Refrigerator: 2-8 C (degrees Celsius) If any temperature is out of range corrective action should be taken immediately by adjusting temperature and documenting corrective action on temperature log. If temperature does not correct or humidity is out of range then notify the Technical Consultant at the Central Lab (477-6610). Any reagents or specimens should be moved to a refrigerator or freezer that is within range."3. Review of the laboratory's environmental logs revealed refrigerator temperature was out of acceptable range and no corrective action documented for the following dates: 2022-06-19 2022-08-14 2022-11-14 2022-12-01 2022-12-02 2022-12-19 2022-12-21 2023-01-06 2023-01-18 2023-01-29 2023-01-30 2023-01-31 2023-02-01 2023-02-03 2023-02-04 2023-02-05 2023-02-06 2023-02-07 2023-02-08 2023-02-09 2023-02-11 2023-02-13 2023-02-14 2023-02-15 2023-02-16 2023-02-17 2023-02-18 2023-02-21 2023-02-22 2023-02-23 2023-02-24 2023-02-25

	2023-02-26 2023-02-27 2023-02-28 2023-03-01 2023-03-02 2023-03-03 2023-03-04 2023-03-05 2023-03-06 2023-03-07 2023-03-08 2023-03-09 2023-03-10 2023-03-11 2023-03-12 2023-03-13 2023-03-15 2023-03-17 2023-03-18 2023-03-19 2023-03-20 2023-03-21 2023-03-22 2023-03-24 2023-03-26 2023-03-27 2023-03-28 2023-03-30 2023-03-31 2023-04-01 2023-04-02 2023-04-03 2023-04-04 2023-04-08 2023-04-10 2023-04-11 2023-04-12 2023-04-13 2023-04-14 2023-04-15 2023-04-17 2023-04-18 2023-04-19 2023-04-24 2023-04-25 2023-04-26 2023-04-29 2023-05-02 2023-05-03 2023-05-04 2023-05-05 2023-05-06 2023-05-10 2023-05-11 2023-05-12 2023-05-17 2023-05-19 2023-05-20 2023-05-21 2023-05-22 2023-05-24 2023-05-25 2023-05-26 2023-05-27 2023-05-28 2023-05-29 2023-05-30 2023-05-31 2023-06-02 2023-06-05 2023-06-06 2023-06-07 2023-06-10 2023-06-12 2023-06-14 2023-06-15 2023-06-20 2023-06-21 2023-06-27 2023-06-28 2023-07-02 2023-07-03 2023-07-04 2023-07-05 2023-07-06 2023-07-07 2023-07-08 2023-07-10 2023-07-13 2023-07-15 2023-07-16 2023-07-17 2023-07-18 2023-07-19 2023-07-20 2023-07-22 2023-07-23 2023-07-25 2023-07-26 2023-07-27 2023-07-28 2023-07-29 2023-07-30 2023-08-01 2023-08-02 2023-08-03 2023-08-04 2023-08-05 2023-08-06 2023-08-07 2023-08-08 2023-08-09 2023-08-10 2023-08-11 2023-08-12 2023-08-13 2023-08-14 2023-08-15 2023-08-17 2023-08-18 2023-08-19 2023-08-21 2023-08-22 4. Interview with the laboratory technical consultant on August 22, 2023 at 3:00 p.m. confirmed the laboratory failed to follow their own written procedure for performing and documenting corrective actions for unacceptable refrigerator temperature for 155 out of 448 days from June 2022 through the survey date of August 22, 2023.