Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D0364900	**(X3) Date Survey Completed** 04/05/2023
Name of Provider or Supplier Franklin Medical Consultants	**Street Address, City, State** 29829 Telegraph Road Suite 100, Southfield, MI	
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**
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Technical Consultant (TC), the laboratory failed to perform and document thermometer calibrations and/or replace an expired thermometer for 1 (S/N 90817839) of 1 thermometer in use. Findings include: 1. During a tour of the laboratory on 4/05/2023 at 9:04 am, the surveyor observed a Fisher Scientific thermometer on top of the paper towel rack for the room temperature and humidity with an expiration date of 03/18/2011. 2. A record review of the "Thermometer Accuracy Verification Log" revealed a lack of documentation for the humidity. 3. When queried on 4/05/2023 at 11:15 am about the verification of the humidity readings, the TC was not able to provide the surveyor documentation to show the thermometer humidity had been calibrated. 4. An interview on 4/05/2023 at 11:15 am, the TC confirmed the laboratory failed to perform and document thermometer calibrations and/or replace the expired thermometer for the humidity readings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform and document corrective actions for out-of-range humidity readings for 335 (November 2021 to March 2023) of 400 days testing was performed. Findings include: 1. A record review of the "Temperature and Humidity Log" revealed the range for acceptable humidity was incorrect (20-70%) since the new Sysmex XP-300 instrument was put into use (30-85%). 2. A record review revealed for 335 of 400 days of testing the humidity ranges were below the instrument stated range of 30-85% as follows: 2021 a. November - 2-6, 8-12, 5-19, 22-24, and 29-30. b. December - 1-4, 6-10, 13-17, 20-23, and 27-30. 2022 a. January - 3-7, 10-15, 17-21, 24-28, and 31. b. February - 1, 4-5, 7-11, 14-19, 21-25, and 28. c. March - 1-5, 7-11, 14-19, 21-25, and 28-31. d. April - 1-2, 4-8, 11-15, 18-22, and 25-29. e. May - 2-7, 9-13, 16-18, 23, and 25. f. June - 1-4, 6, and 28. g. September - 23 and 30. h. October - 4-7, 10-15, 17-21, 24-25, 27-28, and 31. i. November - 2-5,7-11, 14-19, 21-23, and 28-30. j. December - 1-3, 5-9, 12-17, 19-22, and 27-30. 2023 a. January - 3-7, 9-13, 15-21, 23-27, and 30-31. b. February - 1-4, 6-10, 13-18, 20-24, and 27-28. c. March - 1-3, 6-10, 13-18, 20-24, and 27-31. 3. A record review of the "Maintenance Procedures Outline" under section I. "Temperature and Humidity Checks" step #4 "If any temperature or the humidity level is outside of their acceptable ranges notify Tina H., the office manager and she will contact maintenance or service." 4. An interview on 4/05/2023 at 11:15 am, the TC confirmed no corrective action was taken for the 335 days the humidity readings were below the range as the range was incorrect.