Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301989	06/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jasper Family Practice	2201 North Airport Road, Jasper, AL	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Dimension calibration verification records and an interview with Testing Personnel #1, the laboratory failed to perform calibrations verifications at least every six months as per CLIA regulations. This was noted for two out of four calibration verifications reviewed by the surveyor. The findings include: 1. A review of the Dimension calibration verification records (2019 - 2021) revealed the following: a) Sodium, Potassium, and Chloride performed on 05/28/2020. b) Sodium,

	Potassium, and Chloride performed on 12/02/2020. 2. During an interview on 06/09 /2021 at 2:15 PM, Testing Personnel #1 confirmed the laboratory could not locate the May 2019 and December 2019 calibration verifications for Sodium, Potassium, and Chloride for the Dimension. Testing Personnel #1 also confirmed only 1 level is used for each analyte routine calibration.
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 a review of temperature logs, Quidel Triage Total 5 Control Product Insert, Bio-Rad Liquid Assayed Multiqual Product Card, Bio-Rad Liquichek Immunoassay Plus Control Product Card, and an interview with Testing Personnel #1, the laboratory failed to document corrective actions when temperatures were not within acceptable limits. This was noted in 25 out of 25 months reviewed by the surveyor. The findings include: 1. A review of temperature logs revealed Freezer temperature range below -20 degrees Celsius (C) was outside of range the following month: a) April 2019 - 13 days were greater than -20 degrees C. b) May 2019 - 16 days were greater than -20 degrees C. c) June 2019 - 13 days were greater than -20 degrees C. d) July 2019 - 17 days were greater than -20 degrees C. e) August 2019 - 18 days were greater than -20 degrees C. f) September 2019 - 21 days were greater than -20 degrees C. g) October 2019 - 23 days were greater than -20 degrees C. h) November 2019 - 19 days were greater than -20 degrees C. i) December 2019 - 22 days were greater than -20 degrees C. j) January - December 2020 - the temperature was never below -16 degrees Celsius for the whole year. k) January - April 2021 - the temperature was never below -20 degrees Celsius. 2. A review of Quidel Triage Total 5 Control Product Insert stated "Store frozen at -20 degree C or colder in a non-defrosting freezer." A review of Bio-Rad Liquid Assayed Multiqual Product Card stated storage range is -20 to -70 degrees C. A review of Bio-Rad Liquichek Immunoassay Plus Control Product Card stated storage range is -20 to -70 degrees C. 3. During an interview on 06/09/2021 at 12:15 PM, Testing Personnel #1 confirmed freezer temperatures should have been below -20 degrees Celsius and no corrective actions were documented for the days listed above.