Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2012272	03/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Care Of Thomasville	33650 Hwy 43, Thomasville, 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
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 a review of the calibration records for the Medonic and an interview with the testing personnel and technical consultant, the surveyor determined the laboratory failed to retain the manufacturer's assay information sheets for the calibration materials, used during the survey review period of February 1, 2018 - March 23, 2021. This affected 3 of 6 calibration records reviewed by the surveyor. The findings include: 1. A review of the Medonic calibration records revealed on the following dates the analyzer was calibrated, but the package inserts (manufacturer's information assay sheets) were not retained: 2/15/2018, 8/9/2018 and 9/19/2019. 2. The above noted findings were confirmed by the technical consultant and testing personnel, during an interview on March 23, 2021 at 2:55 PM.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as

	acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the calibration records for the Medonic, Hematology analyzer, and an interview with the testing personnel and technical consultant, the surveyor determined the laboratory failed to ensure calibrations were performed at least every six months, according to the laboratory's usual practice and protocol and according to the manufacturer's recommendations. This affected the survey review period of February 1, 2018 - March 23, 2021. The findings include: 1. The online User's Manual for the Medonic included the following, under Section 7: Calibration, page 59: "...It is recommended to calibrate the instrument every 6 months." 2. A review of the calibration records for the Medonic revealed a calibration performed on 9/19 /2019, almost nine months after the calibration, performed on 1/28/2019. After the 1 /24/2020 calibration (performed during preventative maintenance by the manufacturer), the laboratory did not perform the calibration until 3/12/2021, a fourteen months span. 3. During an interview on March 23, 2021 at 2:53 PM, the technical consultant confirmed the calibration was missed at the end of 2020, and late between January 2019 and September 2019. When the surveyor asked the testing personnel, how often calibrations are performed, the testing personnel replied the calibrations should be performed every six months.
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 calibration verification records for the Dimension and an interview with the Technical Consultant, the laboratory failed to perform calibrations verifications at least every six months as per CLIA regulations. This was noted for one out of six calibration verifications performed on the Dimension for Sodium, Potassium, and Chloride. The findings include: 1. A review of the calibration

	verification records for the Dimension revealed a calibration verification was performed on 05/27/2020 and the next calibration verification was on 02/11/2021 (8 month span). 2. During an interview at 3:00 PM on 03/23/2021, the Technical Consultant confirmed the laboratory was late on performing the calibration verification for Sodium, Potassium, and Chloride on the Dimension.