Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0067532	01/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
James Haines Md & William Belcastro Md	299 Carew Street, Ste 322, Springfield, MA	

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	A CLIA recertification survey was conducted for the James Haines, MD & William Belcastro, MD laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 record review and interview, the laboratory failed to perform calibration verification as appropriate as evidenced by the following: Envoy 500 chemistry

	analyzer: a) A review of quality control records for calendar years 2020, and 2021 was performed. The review revealed that calibration verifications of at least 3 points were not performed once every six months for all twenty one (21) of twenty one (21) routine chemistry analytes performed on the analyzer. Calibration verification documentation showed that calibration verifications had only been performed once on 12/30/20 for the two year time period reviewed. b) The designated technical consultant (refer to D6033) interviewed on 1/26/22 at 9:50 AM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months for the twenty one (21) analytes performed on the analyzer. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interview the laboratory failed to have a individual qualified under 493.1411 - Technical Consultant Qualifications to fulfill the duties and responsibilities as evidenced by the following: On the day of the survey a review of the CLIA personnel listing revealed that the designated technical consultant did not have the requisite educational experience to qualify for the position. Interview with the designated technical consultant on 1/26/22 at 10:20 AM revealed that she did not have a bachelors degree in a chemical, physical, or biological science.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on observation, record review and interview, a qualified technical consultant failed to maintain documentation to verify the competency evaluation of the staff through review of quality control records as evidenced by the following: Quality Control: a) During the time of the survey a request was made to review cumulative quality control records for calendar years 2020 and 2021. It was observed on 1/26/22 at 10:16 AM that the designated technical consultant (refer to D6033) was printing out cumulative quality control data from the laboratory's information system. When asked if there was documentation of quality control reviews the designated technical consultant replied that she only reviews the quality control data on the screen and that the reviews were not documented.