Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0430798	08/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Heartland Clinic Llc	608 35th Ave, Moline, IL	

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 the surveyor's review of the laboratory's manual, records, and an interview with the testing personnel (TP); the laboratory failed to follow the manufacturer's instructions to perform calibration verifications every 6 months on the analyzer used for Endocrinology testing, affecting 2130 patients. Findings: 1. The manual of the Qualigen analyzer used to test Prostate Specific Antigen (PSA) and Testosterone (Testo) specimens state that Calibration Verifications are to be performed "every 6

	months". 2. The quality control and maintenance logs revealed the following: a). The laboratory begin testing on a new Qualigen endocrinology analyzer in December of 2016. b). The validation for PSA analysis was completed on 12/16/2016 and the validation for Testo was completed on 12/19/2016, which showed no evidence of being reviewed and accepted. c). The only documented calibration verification is dated 03/28/2018 for both PSA and Testo analysis. No documented evidence was presented as proof that calibration verifications had been performed on the Qualigen analyzer during the year of 2017. 4. The test volume worksheet reports that 1764 tests for PSA and 366 for Testo were conducted from August 2017 through August 2018, using this analyzer. 5. On a Recertification survey conducted on 08/29/2018 at 12:15 PM, the TP confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory records, manuals, and an interview with the testing personnel (TP); the laboratory failed to document a complete IQCP for testing performed in the subspecialty of Endocrinology. Findings: 1. A review of the IQCP documentation revealed the following: a). The plan does not include a quality control (QC) plan which defines the reduced QC procedure to be performed on the new Prostate Specific Antigen (PSA) and Testosterone (Testo) test systems in-use, prior to testing patients. b). The plan's Risk Assessment is incomplete; c). The Quality Assessment (QA) plan reviewed does not include an ongoing mechanism which monitors, assesses, and when indicated, adjusts to changes in the Risk Assessment or the QC plan. 2. On a Recertification survey conducted on 08/29/2018 at 12:00 PM, the TP confirmed the above findings.