Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385488	03/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Iowa Urologists, Pc	1200 1st Avenue East Suite B, Spencer, IA	

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 review of the Qualigen calibration verification records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 3:30 pm on 03/28/2022, the laboratory failed to perform prostatic specific antigen (PSA) and testosterone calibration verifications every six months for two out of three time periods from 1/1/2021 - 3/28/2022 on the Qualigen test system. The findings include: 1. The laboratory performed PSA and testosterone calibration

	verifications for the Qualigen test system on 1/1/2021. 2. The laboratory did not perform any additional PSA or testosterone calibration verifications after 1/1/2021.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observations made during the survey, Qualigen test records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 3:30 pm on 03/28/2022, the laboratory failed to perform prostatic specific antigen (PSA) comparison testing twice annually for one out of three semiannual time periods from 1/1/2021 - 3/28/2022. The findings include: 1. The laboratory performed PSA testing using Qualigen analyzers 0334 and 0935. 2. The laboratory performed PSA comparison testing between the two analyzers on 2/25 /2021 and 2/1/2022. 3. The laboratory did not perform PSA comparison for the time period between 2/25/2021 and 2/1/2022.