Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385488	01/17/2018
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and confirmed by laboratory personnel identifier # 2 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 01/17/2018, the laboratory failed to maintain a copy of the PT attestation statement signed by the laboratory director and testing personnel for two out of six PT testing events (2016 Hematology/Coagulation events 2 and 3) in 2016-2017. At the time of the survey, the laboratory did not have attestation statements for 2016 Hematology/Coagulation PT testing events 2 and 3.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)

	Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 01/17/2018, the laboratory failed to indicate positive patient identification for three out of three patient test reports (Patient identifiers A, B, and C). The findings include: 1. Patient identifier A had prostrate specific antigen (PSA) testing performed on 07/25 /2017. 2. Patient identifier B had PSA testing performed on 07/06/2017. 3. Patient identifier C had testosterone testing performed on 07/11/2017. 4. The test reports for patient identifiers A, B, and C all included the patients' names but did not include a second identification number or unique identifier.