Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1095873	04/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Randy S Morris, M D, S C	15905 S Frederick, Plainfield, 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
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and an interview with the testing personnel (TP1); the laboratory failed to ensure other patient-specific data are accurately and reliably entered into the patients electronic medical records (EMR), affecting 5 out of 5 patients. Findings include: 1. The test results and patients' electronic medical records (EMR) were reviewed. 2. The review of 5 patients' semen analysis test results showed the following: Patient-A1's was analyzed on 10/10/2017 at 9:56 am; Patient-B2's was analyzed on 01/19/2018 at 8:56 am; Patient-C3's was analyzed on 05/01/2018 at 9:19 am; Patient-D4's was analyzed on 08/28/2018 at 9:19 am; and Patient-E5's was analyzed on 02/18/2019 at 9:16 am. 3. The EMR reports of the 5 patients' listed in findings #2 revealed the following; Patient-A1's was analyzed on 10/10/2017 at 12:00 am; Patient-B2's was analyzed on 01/19/2018 at 12:00 am; Patient-C3's was analyzed on 05/01/2018 at 12:00 am; Patient-D4's was analyzed on 08/28/2018 at 12:00 am; and Patient-E5's was analyzed on 02/18/2019 at 12:00 am. 4. Further review of the patients' EMR showed no record of the correct analysis time of the patients' semen documented in the their respective medical records. 5. On 03/16/2019 at 12:30 PM, the TP1 confirmed the above findings.

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 record review and an interview with the testing personnel (TP1); the laboratory failed to ensure test reports indicate the name of the laboratory where the test was performed, for 1 (Patient-V2A) out of 5 patients. Findings include: 1. The test results and patients' electronic medical records (EMR) were reviewed. 2. The review of 5 patients' semen analysis test results and EMR reports showed the following: Patient-V2A's semen analysis was performed at the Plainfield laboratory; Patient-V2A's EMR reported the semen analysis had been performed at the Naperville laboratory. 3. On 03/16/2019 at 12:30 PM, TP1 confirmed the findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and an interview with the testing personnel (TP); the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in transcribing patients' results into the electronic medical record (EMR) system, for 5 out 5 patients. Findings include: 1. The laboratory's standard operating procedures (SOP) manual, patients' electronic reports, and patients' semen analysis results were reviewed. 2. Review of 5 patients' semen analysis results revealed patients test information were entered into their respective electronic records incorrectly (See D5801 and D5805). 3. The SOP failed to include a policy and procedure for monitoring and preventing errors when reporting patient results in their EMR. 4. On 03/16/2019 at 12:30 PM, the TP1 confirmed the above findings.