

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0978872	(X3) Date Survey Completed 06/06/2019
Name of Provider or Supplier Charles E Miller Mdsc	Street Address, City, State 1700 Luther Lane, Suite 3150, Park Ridge, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, record review, and an interview with the office staff; the laboratory failed to follow written maintenance procedures for the equipment used to perform semen analysis. Findings include: 1. On 06/06/20149 at 11:00AM during a tour of the laboratory, the surveyor observed 2 microscopes, both with service labels dated 04/2017. 2. The laboratory procedures manual and maintenance records were reviewed. 3. The procedure manual require the microscopes to be serviced every 2 years. 4. The laboratory failed service the 2 microscopes used for semen analysis before the end of April of 2019. 5. The office staff confirmed the above findings on 06 /06/2019 at 12:00 PM.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on record review and an interview with the office staff; the laboratory failed to ensure test reports indicate the name and address of the laboratory where tests were performed, for 6 out of 6 patients. Findings include: 1. The patients' log, test results and patients' electronic medical records (EMR) were reviewed. 2. The review of 6 patients' semen analysis test results and EMR reports showed the following: *The patients' reports failed to provide the correct name and address of the testing facility for 6 out of 6 patients. The reports list Dallas, TX as the testing site for 5 patients and Naperville for 1 Patient. *The patients' test log showed that all 6 patients' semen analysis were performed at the Park Ridge location. 3. Office staff confirmed the above findings on 06/06/2019 at 12:00 PM.