

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2046030	(X3) Date Survey Completed 11/27/2018
Name of Provider or Supplier Reproductive Medicine Associates	Street Address, City, State 140 Allen Road, Basking Ridge, NJ	
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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain attestation statements provided by the American Associations of Bioanalysts (AAB) for Andrology and Endocrinology PT in the calendar year 2017 and 2018. The findings include: 1. Attestation statements were not maintained for: a. 2nd Q 2017 Endocrinology PT b. 2nd Q 2018 Andrology PT c. 1st, 2nd & 3rd Q 2018 Endocrinology PT 2. The TP #9 listed on CMS 209 confirmed on 11/27/16 at 10:30 am that the attestation statements were not maintained.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as</p>

determined under 493.1253.

This STANDARD is not met as evidenced by:

a) Based on surveyor review of the Bio Rad Manufacture Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to follow the MPI for BioRad Lyphochek Immunoassay control material used on the Centaur in the calendar year 2018. The findings include: 1. The TP stated that the laboratory used the MPI control ranges. 2. A review of Quality Control (QC) documentation revealed QC ranges were outside the MPI range as follows: a. Centaur XPT: FSH High - Levels 1, 3 b. Centaur XPT: LH Low - Levels 1, 3 c. Centaur CP: FSH Low - Levels 1, 2 - High Level 1 d. Centaur CP: LH High - Levels 1, 2, 3 e. Centaur CP: PRL Low - Level 2 f. Centaur CP:HcG Low - Levels 2, 3 g. Centaur CP: E2 High- Levels 1, 2, 3 3. The TP #9 listed on CMS form 209 confirmed on 11/27/18 at 11:30 am that MPI was not followed. b) Based on surveyor review of the MPI and interview with the TP, the laboratory failed to follow the MPI for FructoScreen tests from 11/02/16 to the date of the survey. The findings include: 1. The MPI stated: a. Pipette samples and reagents into a well of the Plate but the laboratory did not use a plate. b. Read optical density of wells at 470 nm using a microplate reader but the laboratory read results visually. 2. The TP #9 listed on CMS form 209 confirmed on 11/27/18 at 11:40 am that MPI was not followed. c) Based on surveyor review of the MPI and interview with the TP, the laboratory failed to follow the MPI for Accubeads from 11/02/16 to the date of the survey. The finding includes: 1. The MPI stated to count Vial 1 and 2 two times and average if counts were within 10% of each other but the laboratory counted each vial once. 2. The TP #9 listed on CMS form 209 confirmed on 11/27/18 at 11:50 am that the MPI was not followed.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the reagents and interview with the Testing Personnel (TP), the laboratory had expired material for Semen Morphology tests from 6/29/18 to the date of survey. The findings include: 1. Reagents were expired as follows: a. Andrology Stain Solution II - Lot 6236 expired 6/29/18 b. Andrology Stain Solution III - Lot 7107 expired 11/9/18 2. Approximately 10 patients samples were stained per day. 3. The TP #9 listed on CMS 209 confirmed on 11/27/18 at 10:50 am that the laboratory had expired reagents.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as

applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on lack of Performance Specifications (PS) records and interview with the Testing Personnel (TP), the laboratory failed to have PS for FructoScreen tests from 11/02/16 to the date of the survey. The TP #9 listed on CMS form 209 confirmed on 11/27/18 at 12:30 pm PS were not established before reporting patients.

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 surveyor review of the Laboratory Records and interview with the Testing Personnel (TP), the laboratory failed to perform correlation studies for Endocrinology tests performed on the Advia Centaur analyzers twice per year from September 2017 to the date of the survey. The TP #9 listed on CMS form 209 confirmed on 11/28/18 at 11:00 am that the laboratory did not perform a correlation study twice a year.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure to verify new QC material used in Endocrinology tests before use from 11/02/16 to the date of the survey. The TP #9 listed on CMS form 209 confirmed on 11/28/18 at 12:10 pm the laboratory did not have a procedure to verify new Endocrinology QC.

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 surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the FR for Endocrinology testing included all required information from 11/02/16 to the date of the survey. The findings include: 1. The FR did not have the "Test Report Date". 2. The FR did not have units of measurement for all analytes on the FR. 3. The FR did not have the name of test performed and reported one test as "P". 4. The TP #9 listed on CMS form 209 confirmed on 11/27/18 at 12:20 pm that the laboratory did not have required information on the FR.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on surveyor review of the laboratory's Quality Assurance (QA) Plan and interview with the Testing Personnel (TP), the laboratory failed to maintain Andrology Data Entry Verification in the QA plan from December 2016 to the date of the survey. The TP #9 listed on CMS form 209 confirmed on 11/27/18 at 12:00 pm the QA plan was not maintained.