Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2125179	03/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Vcu Reproductive Medicine	9109 Stony Point Drive - 3rd Floor, Richmond, VA	

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
D0000	An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00045830) was conducted at VCU Reproductive Medicine on March 28, 2019 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The laboratory held a Certificate of Registration and operated under CLIA # 49D2125179. Based on a review of documents and interviews, the inspectors found the complainant's allegation to be substantiated. Deficiencies cited are as follows:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of complete semen analysis and sperm antibody proficiency testing (PT) records, and an interview, the laboratory failed to verify the accuracy of their complete semen analysis panel testing twice annually in calendar years 2017 and 2018. Findings include: 1. Review of the laboratory's 2017 and 2018 American Association of Bioanalysts (AAB) PT documentation, a total of four (4) events, revealed that the laboratory utilized PT to verify their complete semen analysis panel's accuracy twice annually. 2. A review of the AAB Embryology, Andrology, and Fetal module PT reports revealed that the laboratory failed twice annual accuracy verification by receiving the following unacceptable semen panel scores: AAB S1 2017 - Sperm Count Traditional-no score; AAB S2 2017 - Antisperm Antibody component score 50%, Sperm Motility score 50%, Sperm Cell ID-no score, Sperm Motility Forward Progression- no score; AAB S2 2018 - Sperm Motility component score 50%, Sperm Motility Forward Progression-no score. 3. In an exit interview with

	the lab director, primary testing personnel, nurse manager, regulatory affairs coordinator, and the facility's medical director at approximately 5:00 PM, the above findings were confirmed.
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 a laboratory tour, review of policies and procedures, and interviews, the laboratory failed to ensure that nine (9) opened boxes of expired reagents stored in the laboratory refrigerator were within the manufacturer's expiration date and were of standard quality at the time of the survey on 3/28/19. Findings include: 1. During a laboratory tour at approximately 12:00 PM, the inspector noted the following 9, opened for use, expired reagent kits stored in the laboratory's reagent refrigerator: One (1) of Abbott iSTAT G3+ reagent cartridges, lot number D18037, expiration date 10/6 /18, no receive date noted; 1 box of Abbott iSTAT Chem8+ reagent cartridges, lot number H17229A, expiration date 1/28/18, no receive date; 1 box of Abbott iSTAT B-hCG reagent cartridges, lot number N17245, expiration date 2/14/18, no receive date; Two (2) boxes FertiPro Vital Screen Sperm Vitality Stain (lot number FP 17V102) expiration date 2/28/19, no receive; 1 box FertiPro SpermMar Test IgG Positive Control (lot number FP16GP03), expiration date 3/31/18, receive date 8/10/17; 1 box FertiPro SpermMar Test IgG Negative Control (lot number FP16G13), expiration date 6/30/18, receive date 8/10/17; 1 box box FertiPro SpermMar Test IgG Negative Control (lot number FP16N02), expiration date 1/31/18, receive date 3/14/17; 1 box FertiPro SpermMar Test kit (lot number SPMG5) expiration date 3/14/17, no receive date; The laboratory inspector asked if the reagents and quality control products were being used for patient testing and the primary testing personnel stated: "We are not currently using those reagents. We did use them but discontinued." 2. Review of the laboratory's policy and procedure manual revealed a quality assurance policy that included a protocol that stated: "Handling and storing of reagents and quality control will be according to manufacturer's recommendations". During the tour, the lab director reviewed the printed expiration dates on the manufacturer's packages with the inspector and stated: "It is against our policy to keep reagents or controls beyond the expiration dates. I have requested that the laboratory staff dispose of expired products". 3. In an exit interview with the lab director, primary testing personnel, nurse manager, regulatory affairs coordinator, and the facility's medical director at approximately 5:00 PM, the above findings were confirmed.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on a tour, review of policies, instrument maintenance records, and interviews, the laboratory failed to follow maintenance protocols for five (5) of eleven (11) variable volume single channel pipettes located in the specimen processing areas from 3/7/18 to 3/28/19. Findings include: 1. During a lab tour at approximately 2:00 PM, the inspector noted 11 variable volume single channel pipettes in the specimen processing area: three (3) Eppendorf, 3 Rainin, and 5 WWRBrand. 2. Review of the laboratory's policies revealed Policy #1 "General Policies for the Andrology Lab" that outlined pipette calibration to be performed at least once annually. 3. Review of the laboratory's instrument maintenance logs revealed one calibration record (dated 3/7 /17) for the WWRBrand pipettes (serial numbers 011421326, 041441781, 035861380, 041412336, and 14162322). The inspector requested to review 2018 calibration records for the 5 pipettes listed above. No additional documentation was available for review. 4. In an exit interview with the lab director, primary testing personnel, nurse manager, regulatory affairs coordinator, and the facility's medical director at approximately 5:00 PM, the above findings were confirmed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interviews, the laboratory director (LD) failed to document evaluation of and corrective action for unacceptable semen analysis parameter results on three (3) of four (4) scored PT events in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's 2017 and 2018 American Association of Bioanalysts (AAB) PT documentation, a total of 4 scored events, revealed no evidence of corrective action or self grading for the following Embryology, Andrology, and Fetal module scores: AAB S1 2017 - Sperm Count Traditional- no score, Sperm Cell ID Score 80%; AAB S2 2017 - Sperm Cell ID -no score, Antisperm Antibody Score 50%, Sperm Motility Score 50%, Sperm Motility Forward Progression- no score; AAB S2 2018 - Sperm Motility Score 50%, Sperm Motility Forward Progression-no score. The inspector requested to review documentation that the LD evaluated corrective action for the complete semen analysis parameter scores outlined above. Documentation was not available for review. 2. In an exit interview with the lab director, primary testing personnel, nurse manager, regulatory affairs coordinator, and the facility's medical director at approximately 5:00 PM, the above findings were confirmed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the

	performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, and interviews, the technical consultant (TC) failed to perform the semiannual competency assessments for two (2) of 2 laboratory testing personnel in 2017. Findings include: 1. Review of the CMS 209 laboratory personnel form revealed that the laboratory director also performs the duties of TC. 2. Review of the laboratory's personnel records revealed: Testing Personnel A - initial training documented on 1/30/17; annual competency assessment documented May 2018. Testing Personnel B - initial training documented on 1/30/17; annual competency assessment documented May 2018. (See Personnel Code Sheet.) The inspector requested to review semiannual competency assessment documentation for the testing personnel listed above. No records were available for review. 3. In an exit interview with the lab director, primary testing personnel, nurse manager, regulatory affairs coordinator, and the facility's medical director at approximately 5:00 PM, the above findings were confirmed.