| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D0859009 | 03/29/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Vcu Health Tanglewood Family Medicine | 9782 Hwy 903, Bracey, 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 |
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| **D0000** | An announced CLIA recertification survey was conducted at VCU Health Tanglewood Family Medicine on March 29, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of the laboratory's 2016, 2017, and the first 2018 proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director for one (1) of seven (7) events reviewed, and testing personnel for two (2) of seven (7) events reviewed. See D 2015. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director for one (1) of seven (7) events reviewed, and testing personnel for two (2) of seven (7) events reviewed. Findings include: 1. The inspector reviewed the laboratory's American Proficiency Institute (API) hematology PT documentation which included three (3) events in 2016, three (3) events in 2017, and one (1) event in 2018, a total of seven (7) events. The review revealed no signed attestation statements by the laboratory director for: 2016 Event 3, and no signed attestation statements by the testing personnel for: 2016 Event 3, 2017 Event 3. The inspector requested to review the attestation documentation for the hematology events listed above. No documentation was available for review. 2. In an exit interview with the primary testing personnel at approximately 2:30 PM , it was confirmed that the laboratory failed to retain copies of the API attestation statements for the PT events outlined above in 2016 and 2017. *REPEAT DEFICIENCY |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory policies and procedures, a tour, and an interview, the laboratory failed to follow the established Urine Microscopic Examination centrifuge revolutions per minute (RPM) protocol during twenty-four (24) of twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's VCU Physicians Point of Care Testing policies revealed a procedure for Urine Microscopic Examination that stated "Centrifuge urine for 5 minutes at 1,500 to 1,800 RPM." 2. During a lab tour on 3/29/18 at approximately 1:00 PM, the inspector noted a Hettich EBA 200 centrifuge (Clinical Engineering Serial Tag Number 5603177) in the urinalysis and specimen processing area with a pre-set speed of 3,500 RPM. The inspector inquired if the centrifuge was used for both blood and urine sediment sample processing. The primary testing personnel stated, "Yes, we spin patient blood samples and urinalysis tubes in the centrifuge." The inspector asked if both sample types were spun at the pre-set speed of 3,500 RPM. The primary testing personnel stated "Yes, we have been centrifuging all samples at 3,500". 3. In an exit interview with the primary testing personnel at approximately 2:30 PM, it was confirmed that the laboratory failed to follow their policy to centrifuge urine specimens for 5 minutes at 1,500 to 1,800 RPM's as outlined above. |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS |

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| | CFR(s): 493.1254(b)(2)<br><br>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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of procedures, a laboratory tour, review of maintenance logs, and interviews, the laboratory failed to define and document function checks for centrifuge revolutions per minute (RPM) for one (1) centrifuge during twenty-four (24) of the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed a procedure for Urine Microscopic Examination that stated "Centrifuge urine for 5 minutes at 1,500 to 1,800 RPM." 2. During a lab tour on 3/29/18 at approximately 1:00 PM, the inspector noted a Hettich EBA 200 centrifuge (Clinical Engineering Serial Tag Number 5603177) in the urinalysis and specimen processing area with a pre-set speed of 3,500 RPM. The inspector inquired if the centrifuge was used for both blood and urine sediment sample processing. The primary testing personnel stated, "Yes, we spin patient blood samples and urine tubes in the centrifuge." 3. Review of the laboratory's maintenance documentation revealed no records of RPM verifications for the Hettich EBA 200 centrifuge. The inspector requested to review the 2016 and 2017 centrifuge RPM documentation. No documentation was available for review. 4. In an interview with the primary testing personnel at approximately 2:30 PM, it was confirmed that the laboratory failed to define and document the RPM checks for the Hettich EBA 200 centrifuge as outlined above. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the Centers for Medicare and Medicaid Services (CMS) 116 form, two (2) patient reports, and an interview, the laboratory's patient report failed to include the name and address of the testing facility from May 2016 to the date of the survey on 3/29/18. Findings include: 1. Review of the laboratory's CMS 116 form, on 3/29/18 at approximately 11:30 AM, revealed a laboratory name and physical facility location as follows: VCU Health -Tanglewood Family Medicine 9782 HWY 903 Bracey, Virginia 23919 2. Review of two (2) randomly selected patient Complete |

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| | Blood Count (CBC) reports from the laboratory's Cerner Electronic Medical Record revealed a testing location of: VCU Health, MCV Hospitals Richmond, Virginia 23298 The primary testing personnel stated that "Our laboratory merged with VCU Medical Health group in May 2016. We had not noticed that our lab name and address was not included on the reports". 3. In an interview with the primary testing personnel at approximately 2:30 PM on 3/29/18, it was confirmed that the laboratory's test reports failed to include the correct name and address of the testing facility for twenty-two (22) of twenty-four (24) months reviewed. |