

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0925370	(X3) Date Survey Completed 09/29/2021
Name of Provider or Supplier Vcu Health /Mcv Family Medicine Warsaw	Street Address, City, State 16 Delfae Drive, Warsaw, 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 announced CLIA recertification survey was conducted at VCU Health / MCV Physicians -Warsaw on September 29, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included an initial remote record review and interview with the primary testing personnel on 09/28/21. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to document remedial action taken for 6 unsatisfactory analyte challenged results (3 Lead Level, 2 Infectious Mononucleosis, 1 Hematocrit) during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) proficiency documentation, a total of 6 events (2019 Event 3, 2020 Events 1-3, 2021 Events 1-2), revealed no evidence of remedial action for the following unsatisfactorily scored analytes: 2019 API Chemistry Core Event 3 - 0% Lead (LEA-11, LEA-12 scored unacceptable); 2019 API Immunology Event 3 - 0 % Infectious Mononucleosis (IM-06, IM-07 scored unacceptable); 2020 API Chemistry Core Event 2 - 50% Lead (LEA-07 scored unacceptable, long term performance unsuccessful); 2020 API Hematology Event 3 - 80% Hematocrit (HSY-12 scored unacceptable). 2. Review of available PT corrective action forms (September 2019 to September 2020) revealed no remedial or</p>

verification action documented for the unsatisfactory scores outlined above. 3. An exit interview with laboratory staff members and office manager on 09/29/21 at approximately 11 AM confirmed the above findings.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of procedures, hematology calibration records, and interviews, the laboratory failed to document calibration procedures twice annually for hematology Complete Blood Count (CBC) patient testing according to their procedure during the twenty-four (24) months reviewed (September 2019 through 09/29/21). Findings include: 1. Review of the laboratory's procedures revealed a Hematology Quality Control (QC) policy that outlined to calibrate the CBC testing on the Sysmex pocH-100i hematology analyzer at a frequency of every six (6) months. 2. Review of the pocH-100i hematology instrument QC documentation from September 2019 to the date of the inspection on 09/29/21, revealed calibration procedure records dated 08/12/20 and 03/05/21. The inspector requested to review additional calibration documentation during the 24 month review timeframe. No additional calibration documentation was available for review. 3. An exit interview with laboratory staff members and office manager on 09/29/21 at approximately 11 AM confirmed the above findings.

D6054

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 annually, after the first year.

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), laboratory personnel files, and an interview, the technical consultant (TC) failed to perform annual hematology competency evaluations for testing personnel A and B in calendar years 2020 and 2021. *See Personnel Code Sheet Findings include: 1. Review of the CMS 209 form revealed that the lab director (LD) also performed the duties of TC. The LD identified 2 testing personnel (TP) as responsible for performing patient Complete Blood Count (CBC) hematology testing during the twenty-four (24) month review timeframe (September 2019 to September 2021). 2. Review of the laboratory personnel files revealed TP A

and TP B's annual hematology CBC competency evaluations completed in calendar years 2020 and 2021 were signed by each other with no TC signature of oversight /approval. The inspector requested to review documentation that the director in his role as TC had participated in the hematology competency evaluations for TP A and B. No record was available for review. 3. An exit interview with laboratory staff members and office manager on 09/29/21 at approximately 11 AM confirmed the above findings .