

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0225083	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Riverside White Stone Family Practice	Street Address, City, State 30 Shady Lane, White Stone, 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 Riverside White Stone Family Practice on May 23, 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:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedures and policies, hematology calibration records, and interviews, the laboratory failed to document calibration procedures for hematology Complete Blood Count (CBC) patient testing according to their written procedure in calendar year 2016. Findings include: 1. Review of the laboratory's procedure manual 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 calibration documentation from May 2016 to the date of the inspection on 5/23/18, a total of twenty-four (24) months, revealed the following two (2) month lapse in CBC calibration in calendar year 2016: The inspector noted documentation that calibration</p>

procedures were performed by a Sysmex field service specialist and approved by the lab director (LD) on 5/17/16. No other calibration documentation in 2016 was available for review. The inspector requested to review additional calibration records for 2016. The primary testing personnel stated, "I do not perform the calibrations. I am not sure where the documentation would be if it is not in the QC records. The lab director comes in to do the calibration when it is due each time." 3. In an email interview with the LD at approximately 4:00 PM on 5/23/18, it was revealed that a November 2016 hematology pocH-100i calibration was not performed and that a calibration lapse of two (2) months occurred between May 2016 and January 2017. 4. In an exit interview with the office manager and primary testing personnel at approximately 4:30 PM on 5/23/18, it was confirmed that the laboratory failed to document calibration procedures for CBC testing, in calendar year 2016, according to their written QC policy.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

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, policies and procedures, and interviews, the laboratory director (LD) failed to document Hematology initial training competency assessment for one (1) of six (6) testing personnel in calendar year 2016. Findings include: 1. Review of the CMS 209 form revealed six (6) Hematology testing personnel. (See Personnel Code Sheet) 2. Review of the laboratory's personnel files from May 2016 to the date of the survey on 5/23/18, revealed no laboratory training or competency assessment documents for testing personnel E. The inspector requested to review the training and competency documentation. The documentation was not available for review. 3. Review of the laboratory's procedure manual revealed a quality assurance (QA) policy (Competency Evaluation Program Policy) that stated "The competency evaluation program for White Stone Family Practice Laboratory has been designed to ensure that all staff members are trained and maintain competency. At the beginning of training, each new employee will be given an orientation and training package. Our Laboratory Checklist will be used to document initial lab training." 4. In an email interview with the LD on 5/23/18 at approximately 4:00 PM, it was revealed that the initial training checklist was not documented, prior to patient testing, for testing personnel E in 2016 . 5. In an interview with the office manager and testing personnel A on 5/23/18 at approximately 4:30 PM, it was confirmed that the LD had not maintained the initial Hematology training documentation for testing personnel E in 2016.

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), testing personnel records, and interviews, the technical consultant (TC) failed to perform the semiannual competency assessment for one (1) of six (6) testing personnel in calendar year 2016 or 2017. Findings include: 1. Review of the CMS 209 form revealed six (6) testing personnel and that the laboratory director (LD) also performs the duties of TC. 2. Review of testing personnel records revealed no semiannual competency assessment documentation for testing personnel E in calendar year 2016 or 2017. (See Personnel Code Sheet) The inspector requested to view the semiannual competency assessment documentation. The documentation was not available for review. 3. In an email interview with the LD on 5/23/18 at approximately 4:00 PM, it was revealed that the semiannual training documentation was not completed on testing personnel E in 2016 nor in 2017. 4. In an exit interview with the office manager and testing personnel A on 5/23/18 at approximately 4:30 PM, it was confirmed that the TC failed to document the semiannual competency assessment for testing personnel E.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), available testing personnel records, patient test logs, proficiency testing (PT) records, and interviews, the laboratory failed to maintain documentation of personnel qualifications for one (1) of six (6) Hematology testing personnel. Findings include: 1. Review of the laboratory's CMS 209 form revealed six (6) Hematology testing personnel. (See Personnel Code Sheet) 2. Review of the laboratory records revealed no documentation of education or training for testing personnel E. The inspector requested to review the education documentation. It was not available for review. 3. Review of the laboratory's patient test logs and American Proficiency Institute PT records from May 2016 to the date of the survey on 5/23/18, revealed that testing personnel E resulted Hematology reports and patient testing in calendar years 2016 and 2017. 4. In interviews with the office manager and testing personnel A on 5/23/18 at approximately 4:30 PM, and a follow up email interview with the laboratory director on 5/24/18 at approximately 2:30 PM, it was confirmed that the laboratory failed to maintain documentation of personnel qualifications for one (1) of six (6) testing personnel as outlined above.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, available testing personnel records, patient test logs and proficiency testing records, and interviews, the laboratory failed to maintain documentation of personnel qualifications for one (1) of six (6) Hematology testing personnel. See D6063