

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0141101	<b>(X3) Date Survey Completed</b> 01/16/2018
<b>Name of Provider or Supplier</b> Wphpa Southern Westchester Family Medicine	<b>Street Address, City, State</b> 2 Overhill Rd - Suite 225, Scarsdale, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and confirmed by the laboratory director in an interview on January 16, 2018 at approximately 9:15 am, the laboratory failed to establish a written policy and procedure to include a procedure for lot to lot verification of new control material used on the Coulter AcT Diff hematology analyzer and a policy for quality control acceptable criteria (acceptability for 2 of 3 controls within range).</p>
<b>D5791</b>	<b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b>

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 a review of the laboratory's Quality Assessment (QA) policy and confirmed by laboratory director in an interview on January 16, 2018, at approximately 9:25 am, the laboratory failed to follow their QA policy and perform annual QA reviews for all phases of testing performed in 2016 and 2017. This is a recitation of the February 4, 2016, survey.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of records and confirmed in an interview with the laboratory director at the time of the survey, the laboratory director failed to ensure that the QA program for hematology testing was maintained to ensure quality laboratory services. Refer to D5403 & D5791 This is a recitation for D5791 February 4, 2016, survey