

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0916965	(X3) Date Survey Completed 02/27/2018
Name of Provider or Supplier Amb Medical Services Pc	Street Address, City, State 66-86 Fresh Pond Road, Ridgewood, NY	
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
D2004	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency test (PT) reports from American Academy of Bioanalysts (AAB) and an interview with the laboratory testing person, the laboratory failed to participate in an approved proficiency testing program. Findings Include: On February 27, 2018 and confirmed by the testing person, the laboratory failed to remain in AAB PT program for the year of 2017. The testing person stated "the manufacturer's technical representative told them to cancel AAB (which they did) and the technical representative would enroll the laboratory in American Proficiency Institute (API)." The technical representative never enrolled the laboratory with API.</p>
D5403	<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</p>

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.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory procedure manual and an interview with the laboratory testing person, the laboratory failed to have a complete procedure manual to include a procedure for lot to lot verification of new control material used on the Diatron Abacus 3 hematology analyzer.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on a review of PT records and an interview with laboratory testing person, the laboratory director failed to ensure that the laboratory was enrolled at all times in a PT program for hematology testing. Refer to D2004

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 by the laboratory testing person in an interview on February 15, 2018 at approximately 11:15 AM, the laboratory director failed to ensure that the QA program for hematology testing was maintained to ensure quality laboratory services. Refer to D5403