

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0878826	(X3) Date Survey Completed 08/01/2019
Name of Provider or Supplier Horbar And Hochweiss Md Pc	Street Address, City, State 47 East 77th Street - Suite 205, New York, 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
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 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 an interview with the laboratory director, the laboratory failed to have a complete procedure manual. Finding Include: The laboratory director confirmed in an interview on August 1, 2019, at approximately 10:15 AM, that the laboratory failed to have a procedure for the lot to lot verification of new control material.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on a review of raw data for method validation and an interview with the laboratory director, the laboratory failed to demonstrate that the raw data collected by the laboratory met the performance specifications comparable to that of the manufacturer method validation prior to patient testing. Findings Include: On August 1, 2019, at approximately 10:45 AM and confirmed in an interview with the laboratory director, the laboratory failed to have records showing accuracy, precision, and reportable range for the laboratory's new instrument, the Coulter AcT Diff, prior to patient testing. The laboratory began patient testing on the new hematology analyzer on June 17, 2017. Approximately 3930 patient specimens were tested and resulted during that time.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on a review of patient test records, and an interview with the laboratory director, the laboratory failed to have records that identify the person who performs hematology testing using the Coulter Beckman AcT Diff. Findings Include: On August 1, 2019, at approximately 11:30 AM and confirmed in an interview with the laboratory director, five of five patient test reports reviewed failed to include the identity of the person who performs hematology patient testing.

D6017

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

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of American Proficiency Institute (API) Proficiency Test (PT) records and an interview with the laboratory director, the laboratory director failed to return the API Hematology PT test results within the required timeframe established by the PT program for the second event in 2019. The laboratory director stated, "the testing person failed to submit the PT results to PT provider by the due date".

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 QA procedures, reviews and confirmed in an interview with the laboratory testing person at the time of the survey, the director failed to ensure that the laboratory's QA program for hematology testing was maintained for all phases of laboratory testing. Refer to: D5403, D5421 and D5787