

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2130926	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Cityhealth Medical Pc	Street Address, City, State 85-15 126th Street, Kew Gardens, 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 and testing person, the laboratory failed to have a complete procedure manual. Findings Include: On April 10, 2019, 12:30 PM it was confirmed by the laboratory director and testing person, that the laboratory failed to have procedures in place for 1) lot to lot verification and a 2) Quality Control criterion for hematology testing (number of controls used, frequency of control testing, remedial action and 3) acceptance of all three levels of control material, and frequency of calibration).</p>

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control (QC) records and an interview with the technical consultant, the laboratory failed to meet the laboratory's policy for the acceptance of all three controls coming within acceptable range. Findings Include: It was confirmed with the laboratory director and testing person on April 10, 2019, at approximately 1:00 PM that the laboratory's policy is to test three (3) levels of QC material on the Beckman Coulter AcT Diff and all three levels of QC material must come within acceptable range. On the following days, the following parameters were out of acceptable range and remediation was not performed. Low Control: September 23, 2018 - RBC, WBC, Hgb, HCT & Platelets - 2 patients October 10, 2018 - WBC - 1 patient February 21, 2019 - 1 patient Normal control: October 10, 2018 - RBC - 1 patient September 7, 2018 - WBC - 1 patient February 6, 2019 - WBC - 1 patient April 9, 2019 - WBC, RBC, HCT & Platelets - 1 patient High control: September 10, 2018, - HCT - 2 patients October 1, 2018 - WBC, RBC, HGB, HCT & Platelets - 1 patient March 4, 2019, - WBC, HGB, & HCT - 3 patients Approximately 14 patient samples were tested and results reported during this 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 and testing person, the laboratory failed to have records with the identity of the person who performed the hematology test using the Coulter Beckman AcT Diff. Findings Include: On April 10, 2019, at approximately 2:15 pm and confirmed with the laboratory director and testing person six of six electronic laboratory test reports reviewed for hematology patient testing failed to have the identity of the person who performed the hematology test noted in the electronic test records.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	<p>This STANDARD is not met as evidenced by: Based on a review of the quality assurance (QA) procedure and an interview with the laboratory director and testing person, the laboratory failed to follow their procedure for performing QA reviews. Findings Include: It was confirmed by the laboratory director and the testing person on April 10, 2019, at approximately 2:00 PM that the laboratory failed to follow their QA procedure and perform QA reviews.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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 the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records and an interview with the laboratory director and testing person, the director failed ensure that the QC program for hematology was maintained to assure quality laboratory services. Refer to D5481</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of QA review records and an interview with the laboratory director and testing person, the director failed to ensure that the laboratory's yearly QA reviews were performed to assure the quality of laboratory services. Refer to D5403, D5787, and D5793</p>