

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0066772	(X3) Date Survey Completed 05/02/2019
Name of Provider or Supplier Holyoke Medical Center, Inc	Street Address, City, State 575 Beech St, Holyoke, MA	
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	A CLIA CAP validation survey was conducted for the Holyoke Medical Center, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 procedure review and interview the laboratory failed to have a procedure manual which included the following: a) A review of the laboratory's procedure for comparing the two Abbott Architect c8000s performing general immunology, routine chemistry, endocrinology, and toxicology testing revealed that the procedure did not</p>

include criteria which the two instrument comparisons must meet to be acceptable. b) The general supervisor interviewed on 5/2/19 at 11:30 AM. confirmed that the procedure did not include the above stated information and that it had to be updated. .

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to adequately evaluate their system that twice a year evaluated and defined the relationship between multiple analyzers performing the same type of testing as evidenced by the following: a) The laboratory performs testing on two Abbott Architect c8000s performing general immunology, routine chemistry, endocrinology, and toxicology testing. b) A review of the laboratory documentation for cross comparisons of the two analyzers for calendar year 2018 revealed that: 1) the comparisons were not dated making it impossible to determine when they were completed; 2) there was no documented evaluation of the data to ensure that the comparisons met the laboratory's criteria for acceptability; and 3) there was no documented review by the designated technical supervisor. c) The general supervisor confirmed in an interview on 5/2/19 at 11:35 AM that the cross comparisons between the two chemistry analyzers were not adequately documented and evaluated. .