

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2117115	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier Kbmo Diagnostics	Street Address, City, State 1a Business Way, Hopedale, 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 recertification survey was conducted for the KBMO Diagnostics laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 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: Result reporting to government agencies: a) A review of the laboratory procedure manual for the SARS-COV2 PCR procedure</p>

	<p>revealed that there were no procedure for reporting results to the appropriate State and Federal agencies. b) The general supervisor interviewed on 11/17/20 at 8:50 AM confirmed that a written procedure for reporting results to the appropriate State and Federal agencies was not available. Accuracy of manually transcribed result entry: a) Interview with the general supervisor and laboratory technologist on 11/17/20 at 9:25 AM revealed that results for SARS- COV 2 are to be manually transcribed into the laboratory database. However procedure manual review revealed that there was no procedure available for confirming correct result entry of manually transcribed COVID results. b) The general supervisor interviewed on 11/17/20 at 9:30AM confirmed that a written procedure for confirming correct result entry of manually transcribed COVID results was not available. .</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date new test procedures as evidenced by the following: a) A review of the laboratory procedure for one (1) new tests (SARS-COV2 PCR) revealed that the laboratory director failed to review and approve the new procedure. b) Interview with the general supervisor on 11/17/20 at 8:48 AM confirmed that the laboratory director had not reviewed and approved the above procedure. .</p>
<p>D6102</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on an interview, the laboratory director failed to ensure that documentation was maintained to verify that newly hired personnel were appropriately trained for the type and complexity of the services offered as evidenced by the following: a) One (1) new laboratory technologist, the sole person performing testing in the laboratory, had been hired since the last CLIA survey performed. There was no documentation maintained to verify that the technologist had received training in all aspects of the laboratory operation prior to performing specimen processing, testing, and reporting procedures. b) Interview on 11/17/20 at 8:30 AM with the general supervisor confirmed that documentation was not available of initial training of the one (1) new laboratory technologist. .</p>
<p>D6115</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures</p>

performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date verification of a new test procedure's performance characteristics, including the precision and accuracy of the test and test system as evidenced by the following: a) A review of the laboratory validation for one (1) new test (SARS-COV2 PCR) revealed that the laboratory director failed to review and approve the new procedure. b) Interview with the general supervisor on 11/17/20 at 9:15 AM confirmed that the laboratory director had reviewed the validation for SARS-COV2 PCR but had not documented the review (signature and date).