

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1079331	(X3) Date Survey Completed 03/11/2019
Name of Provider or Supplier Modern Laboratory Inc	Street Address, City, State 1793 Bloomingdale Rd, Glendale Heights, IL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals, personnel records, and interview with the technical supervisor; the laboratory failed to establish and follow written policies and procedures to assess consultant competency. Findings include: 1. Review of the laboratory's policies and procedures manual revealed that there was no policy that describes the laboratory's process for assessing competency of personnel who fulfil the duties and responsibilities of persons in the following positions: a. Clinical Consultant b. Technical Supervisor/Technical Consultant c. General Supervisor 2. Review of personnel records revealed that there was no documentation to show that a competency assessment was performed, from January 1, 2017 to March 11, 2019, on the following personnel : a. Clinical Consultant b. Technical Supervisor/Technical Consultant c. General Supervisor 3. At 10:40 AM on 03/11/19, the Technical Supervisor confirmed the surveyor's findings.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:
 Based on observation, review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (FORM 116) and laboratory policies and procedures manuals, and interview with the technical supervisor; the laboratory failed to have a written procedure, for all tests, assays, and examinations it performs. Findings include: 1. At 10:00 AM on 03/11/19, the surveyor did a "walk-through" of the laboratory, where she observed the following laboratory equipment and analyzers: a. Microscope (Urinalysis and Manual Differentials and Cell Morphology) b. Horiba AB XL80 CBC Analyzer c. ALPHA WASSERMAN ACE AXCEL Chemistry Analyzer d. ACL Coagulation Analyzer e. TOSOH AIA 900 Automated Immunoassay Analyzer 2. Review of Form 116 revealed that the laboratory listed the following specialty/subspecialty as tests it performed: a. Routine Chemistry b. Urinalysis c. Hematology 3. Review of laboratory policies and procedures revealed that there were no procedures that instructed laboratory personnel on performing Urinalysis and Manual Differentials and/or Cell Morphology. 4. At 11:30 AM on 03/11/19, the Technical Supervisor confirmed the surveyor's findings.

D5403

PROCEDURE MANUAL
 CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures manuals and interview with the Technical Supervisor, the laboratory failed to have an all-inclusive, comprehensive procedures manual. Findings include: 1. The laboratory's policies and procedures manual did not include instruction for performing microscopic examination, including the detection of inadequately prepared slides when it performed Blood Cell Identification and/ or Differential Counts. 2. The laboratory's policies and procedures manual did not include the laboratory's process for preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. 3. The laboratory's policies and procedures manual did not include the reportable range for PTINR results for the test system as established or verified in 493.1253. 4. The laboratory's policies and procedures manual did not include control procedures, for each test, that included the following information: a. Type of control b. Identity (e.g., normal, abnormal, level I, II, patient or a control); c. Number and frequency of testing

controls; d. Control limits. 5. The laboratory's policies and procedures manual did not include description of the course of action to take if a test system becomes inoperable.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures manuals, patients' test records, and interview with the Technical Supervisor; the test report did not indicate the name and address of the laboratory location where the test was performed. Findings include: 1. Review of the laboratory's policies and procedures manuals revealed that the laboratory's testing menu included the following: a. Routine Chemistry b. Microscopic Urinalysis c. High Complexity Hematology d. Coagulation 2. Review of patients test records revealed that that another laboratory performed Vitamin B12 and Vitamin D testing on 2 of 10 patients' test records reviewed. The name and address of the laboratory location where the Vitamin B12 and Vitamin D test was performed was not documented on the test reports. 3. At 3:30 PM on 03/11 /19, the Technical Supervisor confirmed the surveyor's findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures manuals, personnel records, and interview with the technical supervisor; the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant, supervisor, and testing person engaged in the testing of patients' specimens. Findings include: 1. Review of the laboratory's policies and procedures revealed that there were no procedures that show which laboratory personnel were assigned to the following positions in the laboratory: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor/Technical Consultant d. General Supervisor e. High Complexity Testing Personnel or Moderate Complexity Testing Personnel 2. Review of personnel records revealed that there was no documentation to show which personnel were assigned to the following positions in the laboratory: a. Laboratory Director b. Clinical Consultant

c. Technical Supervisor/Technical Consultant d. General Supervisor e. High Complexity Testing Personnel or Moderate Complexity Testing Personnel 3. Personnel records did not describe which test procedures each testing person was authorized to perform for 4 of 4 testing personnel. 4. At 10:30 AM on 03/11/19, the Technical Supervisor confirmed the surveyor's findings.