

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2235960	(X3) Date Survey Completed 08/01/2023
Name of Provider or Supplier Hudson Md Group Llc	Street Address, City, State 443 Northfield Ave Suite 202, West Orange, NJ	
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
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> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control records and interview with the Technical Consultant (TC), the laboratory failed to have a complete procedure for Quality Control (QC) failures for Urinalyses, endocrinology chemistry and hematology testing from 9/14/21 to the date of survey. The findings include: 1) The PM did not state how many consecutive failed QC tests performed require corrective action. 2) The TC confirmed on 8/1/23 at 1:30 pm that the laboratory did not have the aforementioned procedure in the PM.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Consultant (TC), the laboratory failed to verify the manufacturer's reference intervals for Routine Chemistry, Endocrinology, Hematology and Urinalysis tests performed on the Abbott Architect, Beckman Coulter DXL 800 AU, DHX 500 and Arkray analyzers from 9/14/21 to the date of survey. The findings include: 1. There was no evidence that the laboratory verified manufacturer's reference intervals. 2. The TC confirmed on 8/1/23 at 1:15 pm the laboratory failed to verify that manufacturer's reference intervals.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Hematology and Urinalyses tests performed on Beckman Coulter DXH 300 and Arkray analyzers on the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The TC confirmed on 8/1/23 at 12:20 pm that the QC material was not verified before putting in use.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on surveyor review of the patient Work Records (WR), Final Reports and interview with the Technical consultant (TC), the laboratory failed to perform corrective action when the Beckman Access DXH 300 had error codes on patient

results at the time of survey. The findings include: 1. A review of five patient WR revealed error codes "R", "abnormal Diff Cellular interference suspect diff "on Cell Differential test results. 2. A review of five patient WR revealed error codes "R" for Platelets. 3. There was no documented evidence corrective action was taken. 4. The TC confirmed on 8/1/23 at 2:00 pm that corrective action was not performed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with Technical Consultant (TC) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 9/14/21 to the date of survey. The finding includes: 1. The laboratory failed to have a Quality Control Verification (QVC) procedure that stated how to verify new lots of controls before they were put in use. a. The procedure did not specify how many times to run controls or how often. 2. The TC confirmed on 8/4/23 at 11:40 am that the laboratory failed to have the aforementioned procedure.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Beckman Coulter DXH 300 analyzer were adequate on the date of survey. The finding includes: 1. Reportable Range was not verified. 2. The TC confirmed on 8/1/22 at 11:20 am that PS records were not adequate.