

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0672796	(X3) Date Survey Completed 07/30/2025
Name of Provider or Supplier Monmouth Hematology Oncology	Street Address, City, State 456 Chestnut Street, Lakewood, 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) 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 (QC) and interview with the Technical consultant (TC) the laboratory failed to follow the PM for "Policies for QC" and "Procedure for out of control control" for the Beckman Coulter DHX520 analyzer used to perform Hematology testing from 2/18/25 to 7/30/25. The findings include: 1. The PM "Policies of QC" states "Do not run controls more than 3 times if they do not come out - start corrective action. (CA)" 2. QC was run more than three times with no CA as follows: a) Normal level QC for Red Blood Cell Count (RBC) was run seven times consecutively 2/18/25. b) High level QC for Mean Corpuscular Volume (MCV) was run seven times consecutively 3/20/25. c) High level QC for MCV was run six times consecutively 3/25/25. d) Normal level QC for Hematocrit (HCT) was run twelve times consecutively 4/10/25. e) High Level QC for HCT was run ten times consecutively 4/10/25. f) High level QC for HCT was run seven times consecutively 6/10/25. g) High level QC for HCT was run ten times consecutively 7/3/25. h) High level QC for MVC was run four times consecutively 7/17/25. i) Low level QC for White Blood Cell count (WBC) was run four times consecutively 7/23/25. j) Low level QC for WBC was run five times consecutively 7/24/25. 3. No corrective action was documented for the above QC failures 4. The PM "Procedure for out of controls controls" stated as follows a) "1. Check controls and reagents for contamination, out dating or poor storage" b) "2. Re-analyzer the same control, - if they are O.K. run patient - if they are still out of limits -" c) "3. Use a fresh vial of controls - if they are O.K. run patient - if they are still out of limits -" d) "4.</p>

Calibrate the instrument (if applicable) and run controls again - if they are O.K. run patient - if they are still out of limits - " e) "5. Call Manufacturers for help or service - if problem can be corrected by phone and controls come out - run patient - if not - notify the ordering physician, send specimen out to reference lab for testing - or - specimens maybe stored until problem is corrected - if storage is acceptable for test and result is not needed immediately. The decision to send out or store will be made by the ordering physician or laboratory manager." f) "6. records all QC corrective action and/or maintenance on the instrument that was needed to correct control problem on corrective action logs." 5. There was no documentation the above mentioned procedures were performed for failed QC. 6. The TC confirmed on 7/30/25 at 10:55 am, the laboratory did not follow the above mentioned procedures.

D5803

TEST REPORT
CFR(s): 493.1291(b)

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:
Based on the surveyor review of Work Records (WR), Final Reports (FR) and interview with the Technical consultant (TC), the laboratory failed to have FR on one out of ten FR reviewed on 7/30/25. The TC confirmed on 7/30/25 at 1:00 pm that the laboratory did not maintain all FR.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM), Electronic Medical Records (EMR) and interview with the Technical Consultant (TC), the laboratory failed to establish a procedure for verifying manually entered results from 9/7/23 to 7/30/25. The findings include 1. The laboratory electronically scanned in patient test results and then uploaded them into the patient EMR. 2. There was no procedure to verify that the patient results were correctly uploaded into the EMR. 3. The TP confirmed on 7/30/25 at 1:30 pm that the laboratory did not have the procedure mentioned above.