

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0110907	(X3) Date Survey Completed 05/10/2023
Name of Provider or Supplier Wayne Hematology-Oncology Assoc Pc	Street Address, City, State 500 Valley Road, Wayne, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Calibration Records (CR), User Manual (UM) for the Beckman Coulter Act diff 2 analyzer and interview with the Office Manager (OM), the laboratory failed to retain all CR in calendar years 20223 and 2022. The finding includes: 1. CR for 4/13/23 was missing the Calibration Summary report. 2. 10/19/22 was missing the Quality Control run after calibration was complete. 3. The OM confirmed on 5/10/23 at 11:30 am all CR were not retained.</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> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), monthly Quality Control (QC) and interview with the Offiice Manager (OM), the laboratory failed to have a procedure for failed QC for Hematology testing from 4/27/21 to the date of survey. The OM confirmed on 5/10/22 at 10:30 am that the laboratory failed to have a procedure failed QC.</p>

D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Office Manager (OM), the laboratory failed to take corrective action when controls were out of range for Hematology Testing on the Beckman Coulter Act diff 2 from March 2023 to the date of survey. The findings include: 1. A review of the QC records revealed: a. On 4/18/23 Platelet (PTL) was out of range on two out of three levels of controls. b. On 3/28/23 & 3/29/23 White Blood Cells (WBC) were out of range on two out of three levels of controls. 2. Approximately 15 patients were run and reported each day of testing. 3. The OM confirmed on 5/10/23 at 11:00 am that corrective action on failed QC was not performed.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 10/25/22 to the date of survey. The findings include: 1. The LD failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action . Cross refer D6018 2. The LD failed to ensure a Quality Control program was established and maintained. Cross refer D6020. 3. The laboratory failed to follow procedures for test analyses. Cross refer D6070.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p>

This STANDARD is not met as evidenced by:
 Based on surveyor review of Proficiency Testing (PT) records and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Hematology testing performed with the College of American Pathologists (CAP) in the calendar year 2023 the findings include; 1) FH2-A 2023 Hematology Auto Differential, FH2 Monocytes/mid sample FH2-02 was graded "see Note 30", sample FH2-05 was graded unacceptable. 2) FH2-A 2023 Hematology Auto Differential, FH2 Monocytes/mid absolute FH2-02 was graded "see Note 30". 3) FH2-A 2023 Hematology Auto Differential, FH2 Granulocyte FH2-02 was graded "see Note 30". 4) FH2-A 2023 Hematology Auto Differential, FH2 Granulocyte Absolute FH2-02 was graded "see Note 30". 5) There was no documented corrective action on the above mentioned unacceptable and coded PT results. 6) The OM confirmed on 5/10 /23 at 10:30 am that the CAP PT results were not reviewed.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
 Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure that the QC program was maintained for laboratory services provided from April 2022 through July 2022. The findings include: 1. The QC peer group review stated the laboratory had the following issues with the Interlaboratory Quality Assurance Program (IQAP) results as follows: a) "Lot 067600 has been excluded for statistical peer comparison due to the high Standard Deviation(SD) values contained within your control file". b) "Please review your Coefficient Variation (CVI) for the following parameters(s). Refer to your IQAP manual for troubleshooting suggestions. 077600 PLT". c) "Lot 087600 has been excluded for statistical peer comparison due to the high SD values contained within your control file." 2. There was no documented corrective action for the aforementioned IQAP results. 3 The OM confirmed on 5/10 /23 at 11:30 am the LD did not ensure the QC plan was maintained. .

D6070

TESTING PERSONNEL RESPONSIBILITIES
 CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
 Based on surveyor observation of Work records (WR), User Manual (UM) and interview with the Office Manager (OM)), Testing Personnel (TP) failed to follow

procedures for test analyses performed on the Beckman Coulter Act diff2 analyzer on 3/6/23. The findings include: 1. The 13 patent test results flagged with an "X" on all analytes on 3/6/23. 2. The UM stated "Review Results. X flag indicates that on of the multiple Aperture alert criteria was not met". a) "Thoroughly mix and rerun the sample." c) "If flag does not repeat, report result" d) "If flag repeats, Clean the aperture as instructed in heading 6.3" e) "If after cleaning, problem persist, contact your Beckman Coulter Representative". 2. There was no documented evidence that the TP followed the UM as mentioned above. 3. The OM confirmed on 1/31/19 at 12:30 pm that the laboratory failed to follow laboratory procedures for test analyses.