

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0110907	<b>(X3) Date Survey Completed</b> 04/27/2021
<b>Name of Provider or Supplier</b> Wayne Hematology-Oncology Assoc Pc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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: Based on surveyor review of the Performance Specification (PS) record and interview with the General Supervisor (GS), the laboratory failed to ensure that all PS procedures were adequate for the Beckman Coulter AcT diff 2 Analyzer before use from March 2020 to the date of survey. The finding includes: . 1. There was no data found for Precision. 2.. The GS confirmed at 2:10 pm on 04/27/2021 that only Linearity and Accuracy was performed for the new Beckman Coulter AcT diff 2 Analyzer</p>
<b>D5787</b>	<p><b>TEST RECORDS</b> CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p>

This STANDARD is not met as evidenced by:  
Based on lack of Work Records(WR) and interview with the General Supervisor (GS), the laboratory failed to maintain WR for Hematology CBC tests from 07/17 /2018 to the date of survey. The GS confirmed on 04/27/2021 at 2:15 pm that the laboratory did not maintain WR for the Beckman Coulter AcT diff 2 Analyzer.

**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 Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to ensure that FR had accurate information from 07/17 /2018 to the day of survey. The finding includes: 1. Critical Results (CR) on the FR included a statement " Critical Values verified by repeat analysis and results given to physician". 2. There was no documented evidence that CR were repeated on the Beckman Coulter AcT diff 2 Analyzer. 3. Four out of five patient samples with CR had this statement printed on the final report. 4. The GS confirmed on 04/27/2021 at 2: 30 pm that the FR was not accurate.