

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0115429	(X3) Date Survey Completed 10/30/2024
Name of Provider or Supplier Oncology & Hematology Specialists Pa	Street Address, City, State 333 Route 46 West, Mountain Lakes, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to review PT performance codes "See note [26]", " Educational Challenge" results obtained for PT performed with the College of American Pathologists (CAP) in the calendar year 2024 The findings include: 1. The laboratory did not evaluate "See note [26]" results obtained for PT event FHS16-B-2024 for nRBC/100 WBC for specimens FH16 - 06, 07, 08, 09 and 10. 2. The LM confirmed on 10/30/24 at 11:30 am that the laboratory failed to evaluate PT performance codes.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the laboratory did not establish a corrective action procedure for the evaluation of coded or unsatisfactory PT results obtained from the PT provider from 1/11/23 to 10/30/24. The findings</p>

include: 1. The laboratory did not have a procedure to follow when coded results were obtained for event FH16- B-2024. 2. The laboratory did not have a procedure to follow if incorrect scores are obtained from the PT provider. 3. The LM confirmed on 10/30/24 at 11:35 am the laboraotry failed to establish corrective actions procedures to perform for the evaluation of PT results.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM), a lack of Instrument Correlation Records (ICR) and interview with the Laboratory Manager (LM), the laboratory did not have acceptable criteria to evaluate and define the relationship between Hematology test results performed on the two DxH 500 analyzers from 1/11/23 to 10/30/24. The finding includes: 1. The "Correlation of Hematology Analyzers and Instrument Modes" procedure states "the lab manager will review the comparative results to assure there is good correlation between the two." 2. The procedure did not have written criteria for acceptable differences in test values or state what the established correlation criteria was for the DxH 500 analyzers. 3. The LM confirmed on 10/30/24 at 11:50 am that the laboratory failed to have written criteria for acceptable differences in test values for correlation studies performed on the two DxH 500 analyzers. B) Based on surveyor review of the Procedure Manual (PM), a lack of ICR and interview with the LM, the laboratory did not perform instrument correlation studies on the two DxH 500 analyzers from 1/11/23 to 10/30/24. The finding includes: 1. There was no documented evidence the laboratory evaluated and defined the relationship between test results using the two DxH 500 analyzers twice a year. 2. The LM confirmed on 10/30/24 at 11:45 am, the laboratory did not perform correlation studies between the two DxH 500 analyzers twice a year.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on the surveyor review of the Final Reports (FR), Procedure Manual (PM), Test Records (TR) from the analyzer and interview with the Laboratory Manager (LM), the laboratory failed to have accurate Reference Intervals (RI) for Hematology tests from 4/10/24 to 10/30/24. The findings include: 1. The PM had one unisex RI to be used for both male and female patients. 2. Review of patient FR and TR from the DxH 500 analyzer revealed that eight out of ten patient reports did not have the RI that was verified in the PM. 3. The LM confirmed on 10/30/24 at 11:00 am, the laboratory did not implement the unisex RI for all patients.