

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0115429	(X3) Date Survey Completed 02/05/2020
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Nursing Supervisor (NS), the laboratory failed to perform the CA correctly for six out of six Testing Personnel (TP) from 2/13/18 to the date of the survey. The finding includes: 1. The laboratory did not document monitoring and recording of test results or assessment of problem solving skills on six of six TP. 2. The NS confirmed on 2/5/20 at 1:30 pm that the CA was not performed correctly.</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), patient Work Records (WR) and interview with the Nursing Supervisor (NR), the laboratory failed to follow the flag procedure found in the PM from May 2019 to the date of the survey. The findings includes: 1. The PM stated "the laboratory will follow manufacturer guidelines addressing flag parameters" but a review of ten flagged patient work</p>

records revealed flags as below: a. WBC Interpretation Not Possible b. Platelet Aggregates c. Differential Flags 2. Manufacturer guidelines stated samples should be repeated. 3. Results with flags and comments listed above were reported and there was no documented evidence patient samples were rerun. 4. five out of ten WR were not reviewed as stated in the PM "all flagged results will be signed by the hematologist." 5. The NS 2/5/20 at 2:30 pm the above mentioned procedures were not followed.

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 Laboratory Records and interview with the Nursing Supervisor (NS), the laboratory failed to perform and document correlation studies for Complete Blood Counts (CBC) performed on the Beckman AcT 5 Differential (Diff) analyzers twice per year from 2/13/18 to the date of the survey. The NS confirmed on 2/5/20 at 1:20 pm that the laboratory did not do correlation studies.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(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 Final Report (FR) and interview with the Nursing Supervisor (NS), the laboratory failed to identify problems on the FR from 2/13/18 to the date of the survey. The findings include: 1. Ten of ten FR reviewed had "CBC-Denville" but the Complete Blood Count (CBC) was performed in Mountain Lakes. 2. The NS confirmed on 2/5/20 at 2:00 pm that the laboratory failed to identify problems on the FR.