

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0973051	(X3) Date Survey Completed 02/08/2019
Name of Provider or Supplier Chitra Venkatraman Md Pa	Street Address, City, State 7300 Hanover Drive, Suite 301, Greenbelt, MD	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the lab did not maintain refrigerator temperature records and room temperature records for six of twenty-four months reviewed for 2017 and 2018. Findings: 1. The laboratory stores reagent for the automated hematology analyzer in the refrigerator and has written procedures to observe and record the refrigerator temperature, the laboratory also observes and records the temperature of the room that automated hematology testing is performed to ensure it meets the hematology analyzer manufacturer requirements; 2. The lab has a written record to document the refrigerator and room temperatures each day of testing; 3. The laboratory did not have refrigerator and room temperature records for the months of December 2017, November 2017, October 2017, September 2017, July 2017 and April 2017; and 4. It was confirmed during interview with the technical consultant (TC) at noon on the day of survey, the laboratory was unable to provide the records.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures</p>

that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and interview, the lab did not maintain the individual quality control test results obtained from testing hematology quality control reagents. Findings: 1. The laboratory quality control records did not include the individual quality control test results for the high, normal and low control levels for April 1, 2017 to April 23, 2017, March 23, 2017 to March 30, 2017 and January 1, 2017 to January 16, 2017; 2. The laboratory quality control records did not include the individual quality control test results for the high control level for August 24, 2017 to August 31, 2017; and 3. It was confirmed during interview with the technical consultant (TC) at noon on the day of survey, the laboratory was unable to provide the records.

D5779

CORRECTIVE ACTIONS
CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:
Based on record review and interview, the lab did not maintain corrective action records for three of twenty-four months reviewed for 2017 and 2018. Findings: 1. The laboratory written procedures include a worksheet to document corrective actions when hematology quality control test results fail to meet the laboratory's criteria for acceptability; 2. The laboratory did not have corrective action records for hematology for the months of December 2017 and September 2017; and 3. It was confirmed during interview with the technical consultant (TC) at noon on the day of survey, the laboratory was unable to provide the records.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on record review and interview with the technical consultant, the lab did not have competency assessment records for testing person number 4 for the year 2017. Findings: 1. Testing person number 4 tested patient specimens for hematology in

2017. The lab did not have 2017 competency assessment records for this person; 2. It was confirmed during interview with the technical consultant (TC) at noon on the day of survey, the laboratory was unable to provide the competency check records.