

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D1049419	<b>(X3) Date Survey Completed</b>  06/07/2018
<b>Name of Provider or Supplier</b>  Nina Kashtelyan Md	<b>Street Address, City, State</b>  4000 Old Court Road Ste 205, Baltimore, MD	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the lab did not ensure that substandard culture media was not used for testing. Findings: 1. The lab did not record the date the culture media was received on media quality control records for April 2018; 2. The lab did not document the media characteristics upon receipt on media quality control records for January 2018; and 3. This was confirmed during interview with the technical consultant on the day of survey.</p>
<b>D5781</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review, the lab did not document corrective actions for hematology testing when quality control results failed to meet the labs criteria for acceptability. Findings: 1. The red cell count results did not meet the acceptable range of values published by the manufacturer for both the normal and high control reagents on March 9, 10, 12 and 13, 2018. The results for both levels of control reagent also consecutively failed to meet criteria for acceptability on these same dates; and 2. On these days the "Horiba Micros Review" document was incomplete and the corrective action column was not completed. It could not be determined if patient tests were performed, it could not be determined if troubleshooting procedures were performed to ensure that the RBC tests provide accurate and reliable results.

**D5789**

**TEST RECORDS**  
CFR(s): 493.1283(b)

Records of patient testing including, if applicable, instrument printouts, must be retained.

This STANDARD is not met as evidenced by:  
Based on record review and interview with lab staff, the lab did not ensure that the testing records were complete and included test results for bacteriology testing. Findings: 1. On October 16 and 17, 2017, negative throat culture results were not documented on the patient test log for two patient tests. The results were also not included in the patient chart; and 2. Lab staff confirmed during interview on the day of survey that the results were not recorded on the log and in the patient chart. Staff stated that negative throat culture results are not transcribed into the patient chart.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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;

This STANDARD is not met as evidenced by:  
Based on record review and interview with the technical consultant, the lab director did not review proficiency testing results to identify problems and ensure appropriate corrective actions if needed. Findings 1. The laboratory participates in a proficiency testing program. On a quarterly basis the proficiency test provider submits unknown samples for the lab to test. The lab reports its results to the proficiency test provider, who then evaluates the labs performance by scoring the results; 2. The lab obtained a 0% score for the first quarter urine culture test, as of the time of the survey, the lab did not review the failure. There were no records showing that an investigation into the failure was performed and the technical consultant stated that the review had not been performed; 3. The investigation into the proficiency test failure of culture testing for the third quarter of 2017 does not ensure adequate corrective actions to ensure the problem does not reoccur. The corrective action for the failure stated that urine cultures were not done on patients and the throat culture failure was caused by

incorrect "reading". The corrective action did not include retraining of staff to ensure proper "reading" of cultures, and there was no investigation to identify the problem causing failure of urine cultures. Lab staff also stated that they review patient cultures, but the cultures are observed by the physicians to interpret the test results, but proficiency tests are only interpreted by the lab staff and not the physicians; and 4. On the second quarter of 2017 culture testing the lab obtained a passing score of 80%, but still had one of five culture tests fail and did not ensure that the investigation and corrective action was complete.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
A. Based on record review and interview with the technical consultant, the lab director did not ensure that orientation and training of testing person A was complete and reviewed by appropriate staff. Findings: 1. The initial training records for testing person A show that the trainer (who is a testing person) signed the training records as the trainer, the technical consultant and the lab director, it was not evident that the technical consultant and the lab director reviewed and approved the training that was documented; and 2. This was confirmed with the technical consultant during interview on the day of survey. B. Based on record review and interview with the technical consultant, the lab director did not ensure that testing persons A and B had on file a copy of their medical assistance certificate or their highest diploma obtained.

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:  
Based on record review and interview with the technical consultant, the technical consultant did not ensure that quality control programs were maintained during the testing process. Findings: 1. The technical consultant reviews testing records for completeness and possible problems; 2. The temperature record for the lab incubator used for culturing patient throat and urine specimens must be maintained at 35 to 37 degrees Centigrade in order for bacteriology cultures to grow and test observations to

be observed; and 3. On January 15, 16 and 17, 2018, the incubator temperature was recorded as 26 degrees Centigrade and the technical consultant failed to take appropriate corrective action.