

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466470	(X3) Date Survey Completed 05/26/2021
Name of Provider or Supplier St Vincent Morrilton Lab	Street Address, City, State #4 Hospital Drive, Morrilton, AR	
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: Through review of manufacturer's package insert, observation, lack of documentation and interview it was determined that the laboratory failed to note the date and time of one of one container of innovin (thromboplastin reagent) placed on the Siemens CA 660 coagulation analyzer. Findings follow: A) On a tour of the laboratory on 5/25/21 at 01:30 PM one of one vials of Dade Innovin, lot # 549758, was observed in use in a container on the Siemens CA 660 instrument without a date and time of being placed into use. B) Review of the manufacturer's package insert for Dade Innovin revealed that once reconstituted and placed into the instrument the product would expire in twenty-four hours. C) Upon request, the laboratory was unable to provide documentation of the date and time the Innovin was placed into use. D) In an interview on 5/25/21 at 01:30 PM the laboratory staff member, identified as number 5 on the CMS 209 form, confirmed that there was no documentation of when the Innovin , identified above, had been placed into use on the instrument.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Through review of laboratory "Out of Range QC " policy and procedure, laboratory quality control (QC) records, review of patient results, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results back to the last successful QC performance on one of one occasions surveyed when QC for Creatinine (CR) failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of the laboratory's policy and procedure for "Out of Range QC "revealed that when QC performance fails to meet the laboratory's criteria for acceptability and instrument/system failure is suspected "all patient results in current analytical run are suspect and may require repeat analysis (analytical run is defined as the time interval since the last acceptable QC run)". B) Review of the laboratory's quality control records for CR revealed that on 1/3/21 QC for level 1, lot # 56611, failed to meet the laboratory's criteria for acceptability (plus/minus 2 standard deviations (SD)) at 06:06 AM reporting plus 2.25 SD, at 06:26 AM reporting plus 2.75 SD, at 06:35 AM reporting plus 3.00 SD, at 06:37 AM reporting plus 2.25 SD before being acceptable at 06:39 AM. Corrective comments stated "new wells". The new wells represents a change in the test system. C) Review of the laboratory's quality control records revealed that the last successful QC for CR was reported on 1/2/21 at 05:39 AM D) Review of patient results for CR revealed that CR assays were performed and reported on four patients, identified as numbers 1 through 4 on a separate patient identification list, between 05:39 AM on 1/2/21 and 06:39 AM on 1/3/21. E) Upon request, the laboratory could not produce documentation that the CR results for the patients identified above had been evaluated and remediated, if necessary. F) In an interview on 5/26/21 at 10:27 AM the laboratory staff member, identified as number one on the CMS 209 form, confirmed that the CR QC performed on 1/3/21 failed to meet the laboratory's criteria for acceptability and CR results for patients performed since the last acceptable QC were not evaluated.