

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  30D0666401	<b>(X3) Date Survey Completed</b>  05/04/2022
<b>Name of Provider or Supplier</b>  Southern Nh Medical Center	<b>Street Address, City, State</b>  8 Prospect St, Laboratory Services, Nashua, NH	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 record review and staff interview, the laboratory (lab) personnel failed to follow the lab's written procedure for performing quality control (QC) testing on the Hemochron Jr. for Activated Clotting Time (ACT) in 2020, 2021 and 2022. Findings include: 1) Review on 5/4/2022 of the lab's "Activation Clotting Time Policy and Procedure" revealed on page 3 instruction to perform external QC testing with each new lot and shipment of Hemochron test cartridges as well as every 31 days. 2) Review on 5/4/2022 of the package insert for "Hemochron Jr. ACT-LR" [Low Range] test cartridges revealed external QC must be performed every 30 days. 3) Review on 5/4/2022 of QC logs from February 2020 to May 4, 2022 revealed no documentation of lot numbers for Hemochron test cartridges. The lab could not demonstrate that it performed external QC for each new lot/shipment of Hemochron test cartridges and every 31 days thereafter for each lot/shipment. Further review of these QC logs revealed QC was not always performed every 31 days according to the lab's procedure: QC for Hemochron Jr serial #SE7956 revealed 5 occurrences of QC being performed greater than 31 days apart. QC for Hemochron Jr serial #SE6698 revealed 7 occurrences of QC being performed greater than 31 days. Days between QC runs range from 32 days to 51 days. 4) Interview on 5/4/2022 at 11:45 a.m. with testing personnel revealed external QC was to be performed monthly and the lab did not check to ensure it was performed every month or every 31 days according to the procedure. 5) Interview on 5/4/2022 at 11:45 a.m. with the Technical Consultant (TC) confirmed the lab did not document lot numbers with external QC testing. The TC</p>

revealed external QC was not performed with each new lot and shipment of Hemochron test cartridges. The lab's annual test volume for ACTs is 300.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory (lab) failed to verify performance specifications for Activated Clotting Time (ACT) on the Hemochron Jr. for 2 out of 2 devices after receiving them back from the manufacturer for servicing in 2020 and 2021. Findings include: 1) Review on 5/4/2022 of quality control and service logs from February 2020 to May 2022 revealed Hemochron Jr. serial # SE7956 was sent out to service in October 2020 through December 2021 and again in October 2021 through November 2021. Hemochron Jr. serial # SE6698 was sent out for service in May 2021. 2) Interview on 5/4/2022 at 12:00 p.m. with the Technical Consultant revealed the lab did not verify performance specifications for accuracy and precision when the devices were received back at the lab from the manufacturer. The lab's annual test volume for ACTs is 300.