Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2105249	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ksb Hospital Cath Lab	403 E First St, Dixon, IL	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #1; the laboratory failed to retain all quality control (QC), patient run result, and manufacturer's electronic simulator printouts for Activated Clotting Time (ACT) testing on the i-Stat analyzer for six of six testing dates in 2022 through the survey date of 03/12/2024. Findings include: 1. Review of the laboratory's "I-Stat Celite Activated Clotting Time's Individualized Quality Control Plan" (IQCP), under "Final QCP - iSTAT", it's stated, "Testing of appropriate external QC every thirty (30) days, or new lot number or shipment of reagent kits." 2. Upon a tour of the facility on 03/12 /2024, at 08:10 am, TP #1 stated external electronic simulator checks were performed upon instruments updates mailed to the facility by the manufacturer. 3. Review of QC, patient run results, and electronic stimulator performance records for ACT testing on the i-Stat analyzer found no instrument QC, patient result, or electric stimulator printout records were retained for six of six testing dates (06/22/2022, 11/10/2022, 02 /22/2023, 05/30/2023, 09/05/2023, 01/24/2024) reviewed from 2022 through the survey date of 03/12/2024. 4. An interview on 03/12/2024, at 08:17 am, with TP #1 confirmed that the laboratory did not print QC, patient run result, or electronic simulator printouts performed on the i-Stat analyzer for ACT testing.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, College of American Pathologists (CAP) proficiency testing (PT) records, and interview with laboratory technical consultant (TC); the laboratory a) failed to ensure Activated Clotting Time (ACT) PT results were evaluated and b) failed to ensure corrective action was taken for unacceptable PT performance for the years of 2022 and 2023. a) Findings include: 1. Review of the laboratory's policy and procedure manual identified the policy "i-STAT Celite Activated Clotting Time Proficiency Testing" which stated the following under "Procedure:", "After results are graded and a report is sent back to the [Point of Care Coordinator] POCC they will be looked over and signed off by the POCC, Cath Lab Director, and MD and filed in the POCC office for 2 years." 2. Review of the CAP PT records for 2022 and 2023 revealed the laboratory failed to review ACT PT results for one of four events (Event 1 of 2023). 3. On survey date 03/12/2024, at 12:10 pm, the above findings were confirmed by the TC. b) Findings include: 1. Review of the laboratory's policy and procedure manual identified the policy "i-STAT Celite Activated Clotting Time Proficiency Testing" which stated the following under "Notes:", "Any unacceptable results will have a CAP Proficiency Test Result Remedial Action Form filled out along with any supporting documents signed by POCC, Cath Lab Director, and MD and kept for 2 years in POCC office." 2. Review of the CAP PT records for 2022 and 2023 revealed that CAP Proficiency Testing Result Remedial Action Forms were not filled out for two of four unacceptable PT events (Event 1 in 2022 and Event 1 in 2023). 3. On survey date 03/12/2024, at 12:10 pm, the above findings were confirmed by the TC.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient Cardiac Cath Lab Procedural Reports and interview with the laboratory representative; the laboratory failed to include all the required components of a laboratory test report including a) the facility's address for six of six i-Stat Activated Clotting Time (ACT) test reports and b) the reference range for six of six i-Stat ACT test reports reviewed for the years of 2022 through the survey date of 03/12/2024. a) Findings Include: 1. Review of Cardiac Cath Lab Procedural Reports revealed six of six patient reports (43579, 91436, 138039, 176262, 263326, 267458) for ACT testing on the i-Stat analyzer found the laboratory failed to indicate the testing facility's address on the laboratory's test report. 2. Review of Cardiac Cath Lab Procedural Reports revealed six of six patient reports (43579, 91436, 138039, 176262, 263326, 267458) for ACT testing for the i-Stat analyzer found the laboratory failed to indicate the result interpretation / reference range on the laboratory's test report. 3. On

	survey date 03/12/2024, at 12:10 pm, the TC confirmed the patient test reports failed to include all the required components of a laboratory test report on six of six test reports.