Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0965626	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kindred Hospital	700 High Street Ne, Albuquerque, NM	

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
D0000	An onsite validation survey conducted on April 9, 2025 at Kindred Hospital Albuquerque found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) 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. This STANDARD is not met as evidenced by: Based on review of laboratory's Calibration & Calibration Verification policy, Calibration Verification records for the Nova Prime CCS, lack of documentation, and interview with Testing Personnel 2 (TP2); the laboratory failed to follow their own procedure requiring calibration verification for the Nova Prime CCS `be performed at least every six months in 2023 and 2024. Findings include: 1. Review of laboratory's Calibration & Calibration Verification policy stated calibration verification must be performed "At least every six months." 2. Review of laboratory's calibration verification records for the Nova Prime CCS for 2023 and 2024 revealed calibration verification was performed once in 2023 (4/4/2023) and once in 2024 (7/22/2024). 3. A request was made for calibration verification records demonstrating the six-month minimum requirement was met, none were provided. 4. Interview with TP2 on 4/9 /2025 at 1:45 pm confirmed the above findings. 5. The laboratory reports 2000 Routine Chemistry tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(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. This STANDARD is not met as evidenced by: Based on lack of documentation, review of Nova Prime CCS operation manual found online, Kindred Hospital Albuquerque Lab Refrigerator Temp, Room Temp, and Room Humidity log, and interview with Testing Personnel 2 (TP2); the laboratory failed to document corrective actions for monitoring being outside of the manufacturer specified range for the Nova Prime CCS analyzer for 42 days of 5 months reviewed in 2023. Findings include: 1. A request was made for a policy covering documentation of corrective actions for out of manufacturer specified ranges for ambient temperature and humidity, none was provided. 2. Review of the Nova Prime CCS operation manual found online determined ambient humidity requirements of 20-85%. 3. Review of Kindred Hospital Albuquerque Lab Refrigerator Temp, Room Temp, and Room Humidity log determined humidity was below the required range of 20-85% for 1 of 30 days in June 2023, 17 of 31 days in August 2023, and 24 of 31 days in October 2023. Humidity was not recorded for 1 of 30 days in June 2023. No corrective actions were documented for humidity monitoring being outside the manufacturer's specified range for the Nova Prime CCS Analyzer during June 2023, August 2023, and October 2023 4. An interview with TP2 on 4/9/2025 at 11:43 am confirmed the above findings. 5. The laboratory reports performing 2000 Routine Chemistry tests annually.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation, review of personnel competency records, and interview with Testing Personnel (TP) 2; the Technical Consultant failed to ensure competency evaluations were performed twice during the first year of patient testing, once for TP16 in 2023 and once for TP18 in 2024. Findings include: 1. A request was made for a policy covering competency assessment requirements, none was provided. 2. Review of personnel competency records revealed the following: - TP16 initial training performed 7/13/2022 - TP16 annual competency evaluation performed 3/25/2024 - TP18 initial training performed 2/23/2024 - TP 18 annual competency evaluation performed 3/5/2025 3. A request was made for documentation demonstrating competency evaluations were performed twice during the first year of testing for TP16 and TP18, none was provided. 4. An interview with TP2 on 4/9/2025 at 10:19 am confirmed the above findings.