Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0531371	07/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Community Hospital Association Inc Dba	520 Rose Ln, Wickenburg, AZ	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation for the Abbott Architect chemistry analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration verification procedures as required during 2019 and 2020. Findings include: 1. The laboratory began using two Abbott Architect chemistry analyzers (serial# C402511 and #C402512) in January 2019 to conduct patient testing in the specialty of Routine Chemistry, with an approximate annual test volume of

	277,364. 2. No documentation was presented for review to indicate the laboratory performed calibration verification procedures at least once every six months from January 2019 through the date of the survey conducted on July 28, 2021, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. 3. The facility personnel confirmed that the laboratory failed to perform calibration verification procedures every six months as required for testing performed on the analyzers indicated above.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of patient test records and interview with the testing personnel it was determined that the laboratory failed to document duplicate cell counts using a hemacytometer. Findings include: 1. The laboratory performs body fluid counts using a hemacytometer. It is the practice of the laboratory to perform each patient cell count and each control cell count in duplicate. 2. No documentation was presented for review to indicate the patient specimens and quality control material are counted in duplicate by testing personnel. 3. The laboratory performs approximately 20 body fluid cell counts annually. 4. The testing personnel confirmed that patient specimens and control material are tested in duplicate but the laboratory failed to document both counts.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test worksheets, review of patient test reports in the Laboratory Information System (LIS) and interview with the facility personnel, the laboratory failed to include the gram stain result for testing performed in the specialty of Microbiology. Findings include: 1. The laboratory performs blood culture testing, including a gram stain on any blood culture bottle flagged as positive. It is the practice of the laboratory to utilize a 'Blood Culture Card' (worksheet) to record the gram stain test result. The test information is then manually transcribed from the worksheet to the LIS. 2. Review of the blood culture test report in the LIS for patient# 1022815 performed on 04/16/2021 revealed the gram stain test result was not entered into the LIS. 3. Review of the Blood Culture Card for the patient referenced above indicated the Gram Stain test result as "Gram Positive Cocci (GPC)", performed on 04/16/21. 4.

	The facility personnel confirmed that the testing personnel failed to document the gram stain test result in the LIS for the patient indicated above.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation, review of patient test reports and interview with the General Supervisor, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. It is the practice of the laboratory to electronically transmit patient test results from the instruments to the Laboratory Information System (LIS) for the following test systems: Abbott Architect chemistry analyzers, Sysmex XN-2000 hematology analyzers, Medtox toxicology analyzer, Stago Satellite coagulation analyzers, Rapid Point 500 blood gas analyzer, Aution Hybrid Arkray Urine analyzer and Cepheid Microbiology analyzer. 2. It is the practice of the laboratory to manually input test results into the LIS for the following tests: Serum hCG, Bactec, Blood bank, manual cell counts, and urine microscopic testing. 3. No documentation was presented for review during the survey conducted on 07/28/2021 to indicate the laboratory established a policy or procedure regarding the laboratory's audit process for checking the accuracy and timeliness of electronically transmitted test results and manually entered test results into the LIS. 4. The general supervisor indicated that the laboratory performs an audit to check the accuracy and timeliness of test results interfaced or manually entered into the LIS as part of the laboratory's QA processes but failed to establish a policy or procedure describing the audit process.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview with the facility personnel, the laboratory failed to document the competency evaluation of five testing personnel in 2020. Findings include: 1. No 2020 annual competency evaluation was presented for review for five out of five testing personnel. 2. The facility personnel confirmed the testing personnel indicated above were missing annual competency evaluations for 2020.