Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0531371	12/28/2018
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for the following test systems: (A) Gene Expert Cepheid, (B) Cardinal Serum hCG, (C) Acceava Mono test and (D) Medtox Drug Screen. Findings include: A1. The laboratory performs the following tests on the Gene Expert Cepheid test system under the specialty of Microbiology: C. Diff, MRSA, and CT/NG (Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG). On the date of the survey, December 28, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, once per month, with each new lot and/or each shipment. A2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016. B1. The laboratory performs serum hCG testing using the Cardinal Serum pregnancy test kit under the sub-specialty of Endocrinology. On the date of the survey, December 28, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, with each new QC shipment or each new lot of test kit. B2. No QC documentation was provided for review during the survey to indicate the

	laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016. C1. The laboratory performs Mono testing using the Acceava Mono test kit under the sub-specialty of General Immunology. On the date of the survey, December 28, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, monthly and/or with each new shipment or each new lot of test kit. C2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016. D1. The laboratory performs urine drug screen testing using the Medtox test system under the sub-specialty of Toxicology. On the date of the survey, December 28, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, weekly and/or with each new shipment or each new lot of test kit. D2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016. 3. During the survey, review of QC records from January 1, 2016 through December 28, 2018 indicated the laboratory performed and documented QC with the number and frequency as described in their policy above for each test system, and as of January 1, 2016, the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for any test systems listed above. 4. The facility personnel confirmed that the laboratory did not perform and document controls as required since January 1, 2016 and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for the test systems referenced above. 5. The number of patients tested on each test system during the time period indicated above could not be determined at the time of the survey.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation, review of the laboratory's QC procedures and interview with the facility personnel, the laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Bacteriology, with an annual approximate test volume of 1,890. 2. The laboratory utilizes BD Bactec Lytic /10 Anaerobic and BD Bactec Aerobic media for blood culture testing performed on the Bactec FX40 test system. 3. No QC documentation was presented for review on the day of the survey, December 28, 2018, to indicate the laboratory checked each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms prior to using the media for patient testing. 4. The facility personnel confirmed that the laboratory was not checking each batch of media used in the Bactec test system for its ability to support and/or inhibit growth.

D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. 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 blood bank temperature documentation and interview with the facility personnel, the laboratory failed to perform and document inspection of the audible alarm system used to monitor proper blood and blood product storage. Findings include: 1. The laboratory performs patient testing in the specialty of Immunohematology with an approximate annual test volume of 786. 2. It is the policy of the laboratory to perform quarterly audible alarm checks on the refrigerator and freezer used to store blood and blood products. 3. No documentation was presented for review during 2018 to indicate the alarm checks were performed and documented on a quarterly basis. The laboratory's records indicated an alarm check was documented on 12/12/17, 7/13/18 and 12/26/18. 4. The facility personnel confirmed the laboratory failed to perform and document the audible alarm check during 2 quarters of 2018.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of test comparison results and interview with the facility personnel, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship of test results using two separate Bactec FX40 instruments. Findings include: 1. The laboratory utilizes two separate Bactec FX40 instruments to perform blood culture testing on patient specimens. The two instruments are used interchangeably. 2. No documentation was presented for review to indicate the laboratory had a system in place to evaluate and define the relationship between the test results from each Bactec FX40 instrument 3. The facility personnel confirmed that the laboratory did not document a test result comparison between the two Bactec FX40 instruments.
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 corrective action presented for review and interview with the facility personnel, the laboratory failed to document corrective actions taken for humidity measurements that were outside the laboratory's established ranges. Findings include: 1. The laboratory performs patient testing in the specialties of Microbiology, General Immunology, Hematology, Chemistry, Immunohematology, and Pathology, with an approximate annual test volume of 282,447. The laboratory's established humidity range is 30-45%. 2. Review of the laboratory's temperature logs from January 2017 through December 2018 indicated that the documented humidity was not within the laboratory's established humidity range on several dates. 3. No corrective action documentation was presented for review for the out of range humidity measurements, to indicate the laboratory resolved the problem and the steps taken to prevent reoccurrence of the problem. 4. The facility personnel confirmed that the laboratory did not document any corrective action for the humidity measurements that were outside the laboratory's established temperature ranges during 2017 and 2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) documentation, Quality Control (QC) records and interview with the facility personnel, the laboratory failed to identify errors found in the analytic systems. Findings include: 1. The laboratory performs serum hCG testing and Mono testing under the sub-specialties of Endocrinology and General Immunology. 2. Review of QC records for the Mono test indicated the laboratory performed and documented QC on 1/19/17, however the facility personnel verified that the date was documented incorrectly and the correct date the QC was performed was 1/19/18. 3. Review of QC records for the hCG test indicated the laboratory performed and documented QC on 12/9/18, however the facility personnel verified that the date was documented incorrectly and the correct date the QC was performed was 12/9/17. 4. No corrective action documentation was presented for review to indicate the laboratory identified the error of listing the incorrect QC test date for both tests indicated above. 5. The facility personnel confirmed that the laboratory's review of quality control information for the Mono and hCG test failed to identify errors found in the analytic systems.
D5801	TEST REPORT CFR(s): 493.1291(a)

	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the laboratory's information system (LIS). Findings include: 1. The laboratory performs approximately 282,477 patient tests annually under the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology, Immunohematology and Pathology. The laboratory's test results interface from each analyzer to the Laboratory Information System (LIS). 2. It is the practice of the laboratory to annually perform and document a check of the interfaced results from the analyzer to the LIS for each test system used. 3. No documentation was presented for review during the survey from 2017 and 2018 to indicate the laboratory performed an annual check of interfaced test results. 4. The facility personnel confirmed that the laboratory failed to perform an annual check to verify the accuracy of the patient test results that are sent from the analyzer to the LIS.
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 test reports and interview with the facility personnel, the test reports issued by the laboratory for Mono testing failed to include the specimen source. Findings include: 1. The laboratory performs the Acceava Mono test in the sub-specialty of Diagnostic Immunology, with an approximate annual test volume of 10. 2. The laboratory uses either whole blood or serum as the specimen source for the Mono test. 3. One out of one test reports reviewed during the survey (for patient# 473743 on 2/09/18) failed to indicate the specimen source. 4. The facility personnel confirmed that the laboratory's test report format for Mono testing failed to include the specimen source.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established

	and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control records and control procedures, the laboratory director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445, D5477 and D5791 for findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of acceptable education records for one out of one testing personnel and interview with the technical supervisor, the laboratory director failed to ensure that all testing personnel have the appropriate education prior to testing patients' specimens. Findings include: 1. During the survey, documentation of foreign transcripts were presented for review for one out of one testing personnel hired in 2018. 2. No documentation was presented for review during the survey to indicate the laboratory had the transcript of the testing personnel indicated above evaluated by a foreign transcript evaluation agency. 3. The technical supervisor confirmed that the laboratory did not complete the process of having the foreign transcript evaluated for the testing personnel indicated above, prior to individual testing patient specimens.