Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0531824	05/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Benson Hospital	450 S Ocotillo, Benson, 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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) records and interview with the technical supervisor, it was determined the laboratory failed to document corrective actions taken to resolve problems associated with unsatisfactory Proficiency Testing (PT) scores. Findings include: 1. The laboratory performs patient testing in the specialty of Chemistry, with an approximate annual test volume of 205,139. 2. The laboratory participates in PT under the specialty of Chemistry for the regulated analyte 'Iron' and received an unsatisfactory score of 0% for the 3rd testing event of 2020. 3. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and resolved the problem of the unsatisfactory PT score indicated above. 4. During the survey conducted on May 10, 2022 at approximately 12:15pm, the facility personnel confirmed the laboratory failed to document corrective action for the unsatisfactory PT score indicated above.
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 review of Quality Control (QC) documentation for Microbiology plated media and interview with the facility personnel, the laboratory failed to check each batch of media for sterility. Findings include: 1. The laboratory performs culture and sensitivity testing under the sub-specialty of bacteriology, with an approximate annual test volume of 3,000. 2. No documentation was presented for review during the survey conducted on May 10, 2022 to indicate the laboratory performed and documented sterility checks for the media used to perform culture testing on patient specimens. 3. The facility personnel confirmed that the laboratory failed to document sterility checks on each batch of media used for culture testing.
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 body fluid Quality Control (QC) documentation, review of the QC package insert and interview with the facility personnel, the laboratory failed to correctly document the acceptable ranges for body fluid control material tested with each patient test. Findings include: 1. The laboratory performs manual body fluid counts on patient specimens in the specialty of Hematology. 2. It is the practice of the laboratory to test two levels of body fluid QC in duplicate with each patient test performed. The laboratory utilizes the Cell-Chex Body Fluid Count Control which includes the 'CSF W1' control for White Blood Cells (WBC) and the 'CSF R1' control for Red Blood Cells (RBC). The control ranges from the manufacturer's package insert are manually entered by laboratory personnel in the laboratory's electronic Laboratory Information System (LIS) for each lot of control material used. 3. During the survey conducted on May 10, 2022, QC ranges were reviewed in the LIS for the lot currently in use at the time of the survey (lot#13190412, opened on 11/19/2021). The QC ranges for lot# 13190412 entered into the LIS indicated the CSF W1 (WBC) mean as 8, with a Standard Deviation of 2.5, and the low value of 3.0 and the high value of 13.0. According to the data entered into the LIS, the acceptable range for the WBC control was 3-13. 4. During the survey conducted on May 10, 2022, QC ranges were reviewed in the LIS for the lot currently in use at the time of the survey (lot#13190412). The QC ranges for lot# 13190412 entered into the LIS indicated the CSF R1 (RBC) mean as 11, with a Standard Deviation of 2.5, and the low value of 6.0 and the high value of 16.0. According to the data entered into the LIS, the acceptable range for the RBC control was 6-16. 5. The manufacturer's package insert for lot# 13190412 reviewed during the survey indicated the RBC control (L1-UC) mean as 9, with a standard deviation of +/- 5, resulting in an acceptable range of 4-14. 6. The manufacturer's package insert for lot# 13190412 reviewed during the survey indicated the WBC control (L1-UC) mean as 11, with a standard deviation of +/- 5, resulting in an acceptable range of 6-16. 7. The laboratory failed to enter the correct range values

	in the LIS for the WBC and RBC controls from lot# 13190412 by reversing the values input for each control from the values listed on the manufacturer's package insert, as indicated above. 8. The laboratory failed to calculate the correct acceptable range for the RBC control (in addition to the reversing the control values as indicated above in #7). 9. No Quality Assessment (QA) documentation was presented for review during the survey to indicate the laboratory monitored, identified and corrected the errors referenced above. 10. The facility personnel interviewed on May 10, 2022 at approximately 3:25pm acknowledged that the body fluid QC values were incorrectly listed in the LIS and also acknowledged the laboratory failed to provide QA documentation to monitor, identify and correct the issue. 11. The number of patient Body Fluid tests performed using control lot# 13190412 from 11/19/2021 through the date of the survey could not be determined at the time of the survey.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review and interview with the technical consultant, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on May 10, 2022, no 2021 annual competency evaluation documentation was presented for review for six out of six testing personnel who perform Arterial Blood Gas (ABG) testing on patients' specimens. 2. The technical consultant confirmed the laboratory failed to provide documentation of annual competency evaluations from 2021 for the testing personnel indicated above.
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 education records for two out of two 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 performed on May 10, 2022, documentation of a foreign diploma was presented for review for one out of one testing personnel hired in April 2020. 2. No documentation was presented for review during the survey to indicate the laboratory had the diploma and corresponding transcripts of the testing personnel indicated above evaluated by a foreign transcript evaluation agency to ensure the equivalent education requirements. 3. No documentation of education credentials was presented for review during the survey for one out of one testing personnel hired in

	January 2022. 4. The technical supervisor confirmed the laboratory failed to complete the process of having the foreign transcript evaluated for the testing personnel indicated above hired in April 2020, prior to the individual testing patients' specimens, and confirmed the laboratory failed to have documentation of education credentials for the testing personnel hired in January 2022