Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0531824	06/27/2019
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2018 and 2019 and interview with the facility personnel, the laboratory director failed to sign the PT attestation statements for Hematology and Chemistry. Findings include: 1. The laboratory participates in PT for testing performed in the specialties of Hematology and Chemistry. The laboratory's approximate annual test volume for these specialties is 308,777. 2. The PT attestation statement presented for review for the second event of 2019 for Hematology lacked the director's signature. 3. The PT attestation statement presented for review for the second event of 2019 for Chemistry lacked the director's signature. 4. The PT attestation statements presented for review for Blood Gas testing for the 3rd event of 2018 and 1st event of 2019 lacked the director's signature.** 5. The facility personnel confirmed that the PT attestation statements indicated above were not signed by the laboratory director. ** - This is a repeat deficiency from the previous survey conducted on June 21, 2017.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty,

	subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2018 and 2019 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the regulated analyte, PTT, under the specialty of Hematology. Findings include: 1. The laboratory's PT performance was unsatisfactory for the 3rd event of 2018 for the regulated analyte, PTT, with a score of 40%. 2. The laboratory's PT performance was unsatisfactory for the 1st event of 2019 for the regulated analyte, PTT, with a score of 20%.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve satisfactory performance for the regulated analyte, PTT, for the 3rd event of 2018 and 1st event of 2019 resulting in unsuccessful PT performance. See D2016 for findings.
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 lack of manufacturer's assay information sheets for review for quality control (QC) material used and interview with the facility personnel, the laboratory failed to retain the records described above for body fluid testing performed. Findings include: 1. The laboratory performs body fluid counts using a Hemacytometer in the specialty of Hematology. It is the practice of the laboratory to perform 2 levels of Strek Cell-Chex QC each day of patient testing. 2. No manufacturer's package insert or assay information sheet was presented for review for the QC lot currently in use at the time of the survey that was performed on June 27, 2019. 3. The facility personnel confirmed that the laboratory could not produce evidence of the manufacturer's

	package insert to coincide with the Strek Cell-Chex QC that was in use at the time of the survey. 4. The facility personnel confirmed that the manufacturer's QC information sheets were not being retained by the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the laboratory's policy and procedure manual presented for review for Blood Gas testing and interview with the facility personnel, the laboratory failed to indicate panic or alert values prior to initiating patient testing performed under the specialty of Chemistry. Findings include: 1. The laboratory began testing patient specimens on the ABL90 Flex Plus Blood Gas analyzer in April 2019. 2. No documentation of panic or alert values existed in the policy and procedure manual or any other location in the laboratory. 3. The facility personnel acknowledged that panic or alert values for Blood Gas testing were not documented in the procedure manual prior to patient testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's Blood Gas test procedure for the ABL90 Flex Plus analyzer and interview with the facility personnel, the laboratory failed to have the current laboratory director approve and sign the test procedure before use. Findings include: 1. The laboratory began testing on the ABL90 Flex Plus Blood Gas analyzer in April 2019. 2. The Blood Gas procedure manual presented for review during the survey conducted on June 27, 2019 was not approved, signed and dated by the current laboratory director. 3. The facility personnel confirmed that the procedure manual indicated above was not approved, signed and dated by the current laboratory director before use.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 document the acceptability of staining materials used for testing performed in the specialty of Hematology. Findings include: 1. The laboratory performs patient testing in the specialty of Hematology, with an approximate annual test volume of 91,771. It is the practice of the laboratory to perform a manual differential on blood smears using the Hema 3 Stat Pack Stain, if the specimen meets certain criteria established in the laboratory's procedure manual. 2. No documentation was presented for review during the survey to indicate the laboratory tested the differential stain for its intended reactivity each day of patient testing. 3. The facility personnel confirmed that the laboratory did not have a system in place at the time of the survey to evaluate and document the acceptability of the stain 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 count in duplicate. 2. No documentation was presented for review in the test record to indicate the body fluid counts are counted in duplicate by testing personnel. 3. The testing personnel confirmed that the counts are performed in duplicate but the laboratory failed to document both counts.
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 from 2017 and 2018 and interview with the facility personnel, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results for testing performed in the specialties of Microbiology and Chemistry. Findings include: 1. The laboratory utilizes the following molecular instruments for testing performed in the specialty of Microbiology: Luminex Verigene and Luminex Aries . The Luminex Verigene has 4 separate modules that are used interchangably to perform testing for Blood Culture ID, respiratory panel, C. Difficile, and Stool ID. The Luminex Aries has two separate modules that are used interchangably to perform testing for C. Difficile, Flu, and Strep A. 2. No documentation was presented for review to indicate the laboratory had a system in place that twice a year evaluates and defines the relationship between the test results generated by each module for each test system indicated above and also between test systems for C. Difficile testing, which is performed on both analyzers. 3. The laboratory performs Troponin I testing on the Architect chemistry analyzer and on the I-stat analyzer. 4. No documentation was presented for review to indicate the laboratory had a system in place that twice a year evaluates and defines the relationship between the Troponin I test results performed on the Architect analyzer and the I-stat analyzer as indicated above. 5. The laboratory's approximate annual test volume for Microbiology is 3176. The laboratory's approximate annual test volume for Routine Chemistry is 205,957, however the facility personnel stated the I-stat analyzer is only used as a back up to perform Troponin I testing, with an approximate annual test volume of 10. 6. The facility personnel confirmed that the laboratory did not have a system in place at the time of the survey to evaluate and document a comparison of test results between the instruments mentioned above.
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 Innovin reagent information entered into the Coagulation analyzer, review of the manufacturer's package insert for the Innovin reagent and interview with the facility personnel, the laboratory failed to identify errors found with the lot number and expiration date maintained in the analyzer. Findings include: 1. The laboratory performs Coagulation testing on the Sysmex CA-560 analyzer and utilizes the Dade Innovin thromboplastin reagent. Each new lot of Innovin must be entered into the analyzer with lot-specific data including the lot number, expiration date and ISI value. 2. Review of the lot-specific information contained in the analyzer on the date of the survey, June 27, 2019 revealed the current lot number and expiration date were incorrect. 3. Review of the manufacturer's package insert for Innovin for the current lot in use at the time of the survey was lot# 549722, expiration date of 10/26/2020. Direct observation of the lot # progammed into the analyzer at the time of the survey was lot# 539393, expiration date 8/10/2019. The ISI value from the current lot was correctly entered into the analyzer according to the package insert. 4. The facility personnel acknowledged that the ISI value was updated correctly, but the lot number and expiration date were not updated in the analyzer for the current lot of Innovin in use at the time of the survey.

D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of patient test results for Blood Gas testing and interview with the facility personnel, the laboratory failed to immediately alert the individual or entity requesting the test when the test result indicates an imminently life-threatening condition, or panic or alert values. Findings include: 1. Review of patient test results in the Laboratory Information System (LIS) for patient ID# 354913 on 06/13/19 at 19: 43 indicated two critical low test results, PCO2 = 23 mmhg and PO2(T) = 23 mmhg. When reviewed in the LIS, the two test results were highlighted in red to indicate a panic or alert value. 2. No documentation was presented for review to indicate the laboratory recorded the date, time, test results and person to whom the test results were reported for the critical low test results indicated above. 3. The facility personnel stated that critical test results are verbally reported to the ordering physician in person and the laboratory does not document that information.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6016 - ensuring that the proficiency testing samples are tested as required under Subpart H.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated analyte, PTT. See D2016 and D6000 for findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on lack of documentation presented for review and interview with the facility personnel, the technical consultant failed to evaluate the annual competency assessment of 7 out of 7 testing personnel that perform Troponin testing on the i-Stat analyzer. Findings include: 1. The laboratory performs Troponin testing on the i-Stat analyzer as a backup method, with an approximate annual test volume of 10. 2. The annual competency evaluations presented for review for 2017 and 2018 failed to include an evaluation for testing performed on the i-Stat analyzer. 3. The facility personnel acknowledged that the competency evaluations performed for each testing personnel in 2017 and 2018 did not include an evaluation specific to testing performed on the i-Stat analyzer.
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 records and interview with the facility personnel, the laboratory failed to document the competency evaluation for one out of one testing personnel for 2018. Findings include: 1. No 2018 competency evaluation was presented for review for one testing personnel who performs testing in the general laboratory. 2. The facility personnel confirmed the testing personnel indicated above was missing a competency evaluation for 2018.