Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0984836	05/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Baker Ambulatory Surgery Center	810 Merriman Street, Conway, AR	

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: Through a review of documentation for the two proficiency testing events completed by the laboratory, lack of documentation, and interviews with staff, it was determined the laboratory testing personnel and director failed to sign the attestation statements for two of two proficiency testing events completed by the laboratory. Survey findings include: A. The laboratory performed proficiency testing on the third testing event of 2020 and the first testing event of 2021. The attestation statement for the third testing event of 2020 was signed by employee #2 from the CMS-209 but had no director signature. The attestation statement for the first testing event of 2021 had no signatures of testing personnel or director. B. Laboratory employee #2 confirmed, in an interview at 10:20 on 5/13/2021, that the forms lacked the required signatures.
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: Through a review of the laboratory procedure manual, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to approve, sign, and date the laboratory procedures. Survey findings include: A. During

	a review of the laboratory procedures it was determined the procedure manual and individual procedures lacked the directors approval signature and date of approval. B. In an interview at 10:20 on 5/13/2021, laboratory employee #2 (as listed on the form CMS-209) confirmed the laboratory directors written approval of the laboratory procedures was not available.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory procedure manual, a review of quality control documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform two levels of quality control each day of moderate complexity I-Stat Chem 8+ patient testing on the Abbott I-Stat instrument. Survey findings include: A. A review of the laboratory I-Stat procedure revealed the procedure stated that controls are performed on each new shipment of cartridges. B. During a review of quality control documentation, it was determined that instead of documenting quality control on each day of patient testing, the quality control was only documented on the following days in 2020 and 2021: 10/12/2020, 11/5/2020, 12/8/2020, 12/28/2020, 1/28 /2021, 3/8/2021, and 4/12/2021. C. Laboratory employee #2 (as listed on the form CMS-209) confirmed, at 10:20 a.m. on 5/13/2021, that the laboratory only performs external quality control with each new shipment of cartridges instead of each day of testing. The surveyor asked if the laboratory had developed an IQCP for the I-Stat Chem 8+ cartridges in order to perform testing less frequently that each day of testing. Employee #2 was not familiar with the term "IQCP" and confirmed that the laboratory did not have an IQCP.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of competency assessments for eight of eight laboratory testing personnel and interviews with laboratory staff, it was determined the laboratory failed to rotate testing of control material among all testing personnel. Survey findings include: A. Competency assessments for seven of eight laboratory testing personnel stated that quality control testing was not applicable for the testing personnel. Only the competency assessment for laboratory employee #2 (as listed on the form CMS-209) included competency for quality control testing. B. In an interview at 9:50 a.m., laboratory employee #2 confirmed that she performed all external quality control on new shipments of I-Stat cartridges.

D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel records for eight of eight testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to specify, in writing, the procedures each individual is authorized to perform, and whether supervision is required for reporting patient test results. Survey findings include: A. During a review of personnel records for eight of eight testing personnel, it was determined none of the eight testing personnel had written authorization to perform testing without direct supervision. B. During an interview, at 9:50 a.m. on 5/13/2021, laboratory employee #2 (as listed on the form CMS-209) confirmed that written authorizations to test were not available.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Through a review of competency assessments for eight of eight laboratory testing personnel, a review of laboratory personnel documentation of education, and interviews with laboratory staff, it was determined the employee performing technical consultant duties did not have the required education to meet the qualifications as evidenced by: D6035 - The employee performing the duties of technical consultant did not meet the education requirements for the position
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of

	podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Through a review of competency assessments for eight of eight laboratory testing personnel, a review of laboratory personnel documentation of education, and interviews with laboratory staff, it was determined the employee performing technical consultant duties did not have the required education to meet the qualifications. Survey findings include: A. A review of personnel records for eight of eight testing personnel listed on the form CMS-209 revealed that all competency assessments were signed by laboratory employee #2 (as listed on the CMS-209). B. Through a review of personnel records for laboratory employee #2, it was determined the highest level of education documented in the personnel record was a high school diploma. The minimum acceptable education is a bachelor's degree in a chemical, physical, or biological science or medical technology. C. During an interview, at 9:50 a.m. on 5/13 /2021, laboratory employee #2 confirmed that she documented the competency of all testing personnel.