Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0300348	(X3) Date Survey Completed 09/12/2019
Name of Provider or Supplier Pinson Medical Office	**Street Address, City, State** 4338 Main St, Pinson, AL	

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
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and an interview with Testing Personnel (TP) #1 and #2, the surveyor determined the laboratory director (new director since February of 2019) failed to sign the policy and procedure manual, to indicate his review and approval of the policies and procedures to be used by the laboratory testing personnel. This affected the survey review period from February - September 12, 2019. The findings include: 1. A review of the policy and procedure manual revealed the Laboratory Director (LD), new since February 2019, failed to review and sign the manual, which would indicate his approval of the policies and procedures to be used in the laboratory. 2. In an interview at approximately 12:30 PM on 9/12/2019, the surveyor asked TP #1 and #2 when the laboratory changed directors (a different name for LD was noted on the previous CLIA Laboratory Personnel Report). TP #2 stated the physician became the LD in February of 2019, when he took the director's course and submitted the documents to CLIA. The surveyor asked the testing personnel to review the manual to clarify if the laboratory director had signed the manual to ensure his review and approval of the polices and procedures to be used in the laboratory. TP #1 reviewed the manual and confirmed the new laboratory director had not signed.
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:
Based on a review of the CLIA Laboratory Personnel Report (CMS Form #209), a review of the personnel records, and an interview with Testing Personnel (TP) #1 and #2, the surveyor determined the employee listed on the Personnel Report as Technical Consultant (TC-B) did not present with documentation to ensure he had obtained the necessary laboratory training and/or experience to serve as TC. This affected one of two listed technical consultants. The findings include: 1. The laboratory staff listed two individuals on the CLIA laboratory Personnel Report as technical consultants. TC-A had previously qualified. A review of the personnel records revealed the individual, listed as TC-B, presented with the appropriate educational credentials but not the necessary documentation to verify professional training and/or experience as a laboratorian. 2. In an interview on September 12, 2019 at approximately 12:30 PM the surveyor discussed the above noted findings with TP #1 and #2. The surveyor inquired when TC-B started employment with the laboratory and when the individual offered technical consultation. The testing personnel stated TC-B started around February 2019, and had visited the laboratory about two times, with June being the last visit. At the time of his visits, TC-B reviewed the laboratory's books/documents and offered technical advice to testing personnel. The surveyor noted during the

	review, TC-B had signed proficiency testing and quality control records.