Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D2265506	**(X3) Date Survey Completed** 05/06/2024
Name of Provider or Supplier Alabama Institute For Sleep Health	**Street Address, City, State** 1803 Park View Dr Ne, Cullman, 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**
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the Accutest/One World Accuracy proficiency testing (PT) records and an interview with the Laboratory Director, the laboratory failed to meet the condition of enrollment and testing of blood gas PT samples in 2022, 2023, and 2024. The findings include: Refer to D 2001. .
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on a review of the CMS 0155 and 0096 CASPER report, CMS-116 application,

	Accutest/One World Accuracy proficiency testing (PT) records and an interview with the Laboratory Director (LD), the laboratory failed to ensure enrollment in an approved PT program for moderate complexity blood gas samples. This was noted for six out of six Accutest PT Cycles from 2022 through 2024. The findings include: 1. Review of the CMS 0155 and 0096 CASPER report revealed no evidence of PT scores from 2022 through 2024 due to PT performed and resulted. 2. Review of CMS-116 application provided by the laboratory included moderate complexity blood gas analytes, paCO2 (Partial pressure of carbon dioxide) and PaO2 (arterial oxygen pressure), which are performed on the Opti-Medical CCA-TS2 blood gas analyzer. 3. During an interview on 5/6/2024 at 8:20 AM, the LD confirmed the laboratory was not enrolled in PT under this CLIA number.
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: Based on a review of the CMS 0155 and 0096 CASPER report, CMS-116 application, laboratory records, and an interview with the Laboratory Director (LD), the LD failed to meet the condition to ensure the laboratory was enrolled in an approved PT program for moderate complexity blood gas samples. The findings include: Refer to D 6015. .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of the CMS 0155 and 0096 CASPER report, CMS-116 application, laboratory records, and an interview with the Laboratory Director (LD), the LD failed to ensure the laboratory was enrolled in an approved PT program for moderate complexity blood gas samples. The findings include: Refer to D 2001. .