Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2192197	05/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Auburn Pediatric And Adult Medicine	560 Devall Drive, Suite 201, Auburn, 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
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Emerald Cell-Dyn and an interview with the technical consultant, the surveyor determined the laboratory director failed to review and approve of the validation studies and use of the instrument in the laboratory, prior to beginning patient testing, as evidenced by lack of signature. The laboratory director has a responsibility to review and approve of policies, procedures and validation studies, prior to instruments being used in the laboratory. This affected one of one instrument installed to perform non-waived testing. The findings include: 1. During the tour of the laboratory on May 25, 2021 at 9:15 AM, the technical consultant stated the Emerald Cell-Dyn was used to perform Complete Blood Count (CBC) testing. At 9:47 AM, the technical consultant stated the testing began in October of 2020. 2. The surveyor noted the laboratory director had not signed the installation and validation records for the Emerald, upon review of the carryover, precision, calibration report, quality control testing post-calibration, reportable range study (dated 10/21/2020) and method comparison. The surveyor noted the technical consultant signed (dated 2/21/2021) the first page of the method comparison. 3. On May 25, 2021 at 10:30 AM, the technical consultant reviewed the manual with the validation studies, and confirmed she had signed the first page of the method comparison, not until 2/21/2021 (testing began in October, 2020). The

	technical consultant stated the signature was representative of her review/approval of the entire validation study. The surveyor asked if the laboratory director had reviewed the validation studies and given approval for use. The technical consultant stated she did not believe the laboratory director had reviewed the validation, and added she believed the laboratory director took the staff's word that it was done. Further, the technical consultant reviewed the manual, and stated she did not see where the laboratory director had signed.