Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0899231	05/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Beaumont Internal Medicine & Geriatric Associates	755 N 11th St Suite P5200, Beaumont, TX	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observations, review of policies and procedures and interview of facility personnel found the laboratory did not have a written procedure for testing patient specimens using the Alcor miniised erythrocyte sedimentation analyzer. The laboratory had tested 7839 patient specimens using the miniised erythrocyte sedimentation analyzer in 2022. The findings included: 1. Observations made during the inspection found the laboratory was currently using the Alcor miniised sedimentation analyzer (serial number 00165) to test patient specimens. 2. Review of policies and procedures found no written procedure for the use of the miniised erythrocyte sedimentation analyzer. During interview of testing person one conducted May 1, 2023 at 10:58 AM confirmed the laboratory did not have a written procedure for performing sedimentation rates using the miniised sedimentation analyzer and did not hove the manufacturer's instructions.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observations, review of verification studies, patient test records and interview of facility personnel, the laboratory failed to verify the reportable range of the erythrocyte sedimentation rate using the Alcor miniiSED erythrocyte sedimentation analyzer prior to testing 7839 patient specimens. The findings included: 1. Observations made during the inspection found the laboratory was using the miniiSED erythrocyte sedimentation analyzer (serial number 00165) to test patient specimens for sedimentation rates. 2. Review of the verification study provided by the laboratory found no documentation of the laboratory verifying the accuracy, precision and reportable range for the miniiSED erythrocyte sedimentation analyzer, or verify the reference range was acceptable for it's patient population. The laboratory offered a comparison study as the verification of the analyzer 3. During interview of testing person one on May 1, 2023 at 10:58 AM, she confirmed that the laboratory had not verified the accuracy, precision and reportable range for the miniiSED erythrocyte sedimentation analyzer, or verify the reference range was acceptable for it's patient population.
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 observations, review of verification studies, patient test records and interview of facility personnel, the laboratory director failed to ensure verification procedures were adequate to verify the accuracy, precision, reportable range and suitability of reference ranges for the Alcor miniiSED erythrocyte sedimentation analyzer prior to testing 7839 patient specimens. (see D 5421)
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: The laboratory director failed to ensure that an approved written procedure for

	sedimentation rate testing was available to all testing personnel outlining the step by step performance when using the Alcor miniised sedimentation analyzer. (see D 5401)