Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0903538	07/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cossio Pediatrics	334 Stephenson Avenue, Savannah, GA	

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
D0000	On August 30, 2021 an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and staff interview, the laboratory failed to establish a written quality assessment (QA) to monitor, assess, and correct problems in the general laboratory system for quality assessment. The laboratory did not have a written quality assessment policy that encompasses all facets of the laboratory's technical and non-technical functions. 1. The laboratory failed to have a QA that assess patient confidentially, specimen integrity and identification, complaint, corrective actions, proficiency test performance, and personnel competency. 2. The laboratory does not have a written QA policy or any records of QA being performed from 2019, 2020, and 2021(January-July). 3. During an interview with Testing Personnel #1(CMS 209) on July 29, 2021 at approximately 4:30 PM in the sick patient area, confirmed that the laboratory did not have a written and established QA policy for the laboratory.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the

	effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist documentation for 2019, 2020 and 2021(January- July 2021). 2. During an interview with Testing Personnel #1(CMS 209) on July 27, 2021 at 4:35 PM, confirmed the lack of QA checklist documentation for 2019, 2020 and 2021(January-July 2021).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. QC document review revealed the lack of Levey-Jennings charts for the following time periods: 2019, 2020, and 2021(January-July 2021), the Levey-Jennings charts for the Medonic M Series. 2. During an interview with Testing Personnel #1(CMS 209) in the laboratory on July 25, 2021 at 4:45 PM, confirmed the laboratory failed to print Levey-Jennings for 2019, 2020, and 2021(January-July).
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of personnel records and staff interview, the Laboratory Director failed to assess the six competency assessment criteria for testing personnel for the specialty of Hematology. The findings include: 1. A review of testing

	personnel records revealed that a comprehension assessment was performed for laboratory procedures and skills evaluation, but the assessment did not address the six competency assessment criteria for their hematology testing. 2. During an interview with the Laboratory Director over the phone, in the sick patient room area on July 27, 2021 at 4:50 PM, confirmed that annual competencies did not contain the six competency assessment criteria for testing personnel for the specialty of Hematology for 2019, 2020, and 2021(January-July 2021).