Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2132305	05/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ummc - Gulf Coast Pediatrics	1721 Medical Park Drive, Biloxi, MS	

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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) results for the Ortho Clinical Diagnostics Vitros 350 chemistry system from 3/1/2023 through 4/28/2023, manufacturer's instructions for Performance Verifier I, Lot #D8955, and Performance Verifier II, Lot #K9589, put in use on 3/1/2023, the patient test log for glucose, and interview with the technical consultant on 5/11/2023 at 11:30 a.m., the laboratory failed to ensure results for at least two levels of control materials met the laboratory's criteria for acceptability for glucose testing for 32 of 37 testing days, during this timeframe, when a total of 79 patient glucose tests were performed and reported. Findings include: 1. In an interview on 5/11/2023 at 11:30 a.m., the technical consultant stated the laboratory's policy for establishing an acceptable range for Performance Verifier (PV) I and Performance Verifier (PV) II, used for quality control testing on the Vitros 350 chemistry system, is to calculate the mean for each analyte after repeated testing and to establish a range of two standard deviations above and below the mean with the manufacturer's suggested standard deviation from the package insert for each lot of PV I and PV II. 2. Review of QC results for the Ortho Clinical Diagnostics Vitros 350 chemistry system from 3/1/2023 through 4/28/2023, manufacturer's instructions for Performance Verifier I, Lot #D8955, and Performance Verifier II, Lot #K9589, put in use on 3/1/2023, and the patient test log for glucose revealed at least one of two levels of control materials failed to meet the laboratory's acceptable range of two standard deviations above and below the established mean for glucose testing for the following 32 of 37 testing days, during this timeframe, when a total of 79 patient glucose tests were performed and reported: 3/2/23--1 patient result reported. 3/3/23--1 patient result

	reported. 3/7/23--5 patient results reported. 3/8/23--1 patient result reported. 3/13/23--3 patient results reported. 3/14/23--4 patient results reported. 3/15/23--2 patient results reported. 3/16/23--2 patient results reported. 3/17/23--2 patient results reported. 3/20/23--6 patient results reported. 3/21/23--4 patient results reported. 3/23/23--2 patient results reported. 3/24/23--2 patient results reported. 3/27/23--2 patient results reported. 3/28/23--2 patient results reported. 3/29/23--2 patient results reported. 3/30/23--2 patient results reported. 4/4/23--5 patient results reported. 4/5/23--2 patient results reported. 4/10/23--1 patient result reported. 4/11/23--4 patient results reported. 4/12/23--1 patient result reported. 4/14/23--1 patient result reported. 4/17/23--3 patient results reported. 4/18/23--3 patient results reported. 4/20/23--1 patient result reported. 4/21/23--2 patient results reported. 4/24/23--2 patient results reported. 4/25/23--3 patient results reported. 4/26/23--2 patient results reported. 4/27/23--3 patient results reported. 4/28/23--3 patient results reported.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of quality control (QC) results for the Ortho Clinical Diagnostics Vitros 350 chemistry system from 3/1/2023 through 4/28/2023, manufacturer's instructions for Performance Verifier I, Lot #D8955, and Performance Verifier II, Lot #K9589, put in use on 3/1/2023, the patient test log for glucose, and interview with the technical consultant on 5/11/2023 at 11:30 a.m., the technical consultant failed to ensure acceptable levels of analytic performance were maintained throughout the entire testing process when at least one of two levels of control materials failed to meet the laboratory's criteria for acceptability for glucose testing for 32 of 37 testing days, during this timeframe, when a total of 79 patient glucose tests were performed and reported. Refer to D5481 (Failure to ensure two levels of control met criteria for acceptability each day of patient testing.)