Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2103860	03/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Newport Children's Medical Group	31862 Coast Hwy, Ste 302, Laguna Beach, CA	

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
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the hematology automated analyzer testing records and interview with the testing personnel and technical consultant on 03/21/2024 at 11:00 AM, the laboratory failed to establish a corrective action policy and procedure as necessary for reporting analytes when hematology analyzer generates a flag. The finding include: 1) The laboratory performed complete blood count (CBC) testing using Sysmex XP-300 Hematology Analyzers. The laboratory did not establish a corrective action policy for the hematology analyzer when analyzer generates a flag. On 3/18/2024, the analyzer generated a flag for WBC for accession #139300. The test result with the flag was reported for the patient without any corrective action. Therefore, the accuracy and reliability of the laboratory's test result cannot be assured and might have had harmed patient. 2) On 03/21/2024 at 11:00 AM, the laboratory testing personal and technical consultant confirmed the laboratory did not have any corrective action policy for hematology analyzer when the analyzer generates a flag. 3) The laboratory's testing declaration form, signed by the laboratory director on 03/12 /2024 stated that the laboratory performed approximately 3435 tests in hematology, annually.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on surveyor review of the hematology automated analyzer testing records and interview with the laboratory staff on 03/21/2024 at 11:00 AM, the laboratory director failed to assure compliance with the applicable regulations and potentially may have harmed patients. The finding include: See D5779
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on surveyor review of the hematology automated analyzer testing records and interview with the technical consultant on 03/21/2024 at 11:00 AM, the technical consultant failed to assure compliance with the applicable regulations and potentially may have harmed patients. The finding include: See D5779