Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0590252	08/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Salinas Pediatric Medical Group	505 E Romie Ln, Ste K, Salinas, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on observation of the Celldyn Emerald hematology analyzer, review of proficiency testing (PT) reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts) and laboratory proficiency testing records, and interview with Laboratory Personnel (3, 7), the laboratory failed to attain an acceptable score of 80% or better for RBC (Red Bood Cell Count) and Hematocrit for Q1/2022. Findings included: 1. The laboratory reported 2 unacceptable results (*) out of 5 for the score of 60%, signifying unacceptable testing for RBC, as follows: PT sample Lab result Intended Grading Range ---------- 2 *5.99 5.627 5.29 - 5.96 3 *5.06 4.595 4.32 - 4.87 2. The laboratory reported 2 unacceptable results (*) out of 5 for the score of 60%, signifying unacceptable testing for Hematocrit, as follows: PT sample Lab result Intended Grading Range ---------- 2 *58.3 54.77 51.5 - 58.1 3 *45.5 41.01 38.5 - 43.5 3. Laboratory Testing Persons (3, 7) affirmed (8/16/23 at 11:00 am) the aforementioned unacceptable scores for RBC and Hematocrit proficiency testing in 2022/Q1. 4. The reliability and quality of RBC and Hematocrit results reported for 104 pediatric patients during the timeframe January - April 2022 could not be assured (CMS116, 8/15/23). Test records selected from February 2022, are as follows: DATE SEQ ---------- 2/01/22 00006 " 00007 2/02/22 00006 2/03/22 00010 " 00011 " 00012 2/04/22 00005 " 00006 " 00007 2/07/22 00006 " 00007 " 00009 2/08 /22 00006 2/09/22 00006 " 00007 .
D2128	HEMATOLOGY

	CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of 2022/Q1 CMS and AAB PT reports and laboratory PT records, the lack of laboratory document, and interview with Laboratory Personnel (3, 7), the laboratory failed to document investigation, determine the root cause, and corrective action for unacceptable RBC and Hematocrit results. Findings included: 1. CMS and AAB reported unsatisfactory scores of 60% for RBC and Hematocrit for 2022/Q1. See D2121. 2. Review of laboratory PT records revealed no documents for investigating the unacceptable results, identifying the root cause for the errors, implementing corrective action, and affect on patients results. 3. Laboratory Personnel (3, 7) affirmed (8/15/23 at 12:30 pm) the aforementioned unsatisfactory testing for RBC and Hematocrit and the lack of documented investigation and follow up. .
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 observation of the Celldyn Emerald hematology analyzer, review of laboratory records, the lack of a laboratory manual, and interview with laboratory personnel (3, 7), the laboratory failed to provide for review a laboratory manual of written policies and procedures including, but not limited to, training and competency assessments, preanalytic patient identification, specimen identification, handling, and criteria for rejection; analysis with quality control materials of specified levels, frequency, and ranges of acceptabillity; postanalysis reporting; proficiency testing; and quality assessment/assurance. Findings included: 1. The Celldyn Emerald, serial number 030321-010064, was installed and laboratory records verified tests performance specifications on 1/21/21. 2. The laboratory tested 313 patients specimen annually and reported 1,878 hematology results including RBC (Red Blood Cell Count), WBC (White Blood Cell Count), Hematocrit, Hemoglobin, Platelet Count, and Automated WBC Differential (form 144A, Laboratory Testing Declaration, 8/07 /23; form CMS116 CLIA Application, 8/15/23). 3. The Laboratory Personnel Report (CLIA), (form CMS209, 8/07/23), named 8 testing persons. 4. The laboratory failed to provide for review a laboratory manual of written policies and procedures for all staff to follow. 5. Laboratory personnel (3, 7) affirmed (8/16/23 at 1:00 pm) the aforementioned findings. 6. The reliability and quality of testing performed preanalytically, analytically, and postanalytically could not be assured in the absence of a manual of written policies and procedures for all staff to follow. .

D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on observation of the Celldyn Emerald hematology analyzer, review of laboratory records, the lack of data/results records, and interview with laboratory personnel, the Laboratory Director is herein cited for deficient practice in ensuring that trainees demonstrate the entire routine testing process from preanalytic specimen handling to operating the Celldyn Emerald with quality control materials to postanalytic reporting. Findings included: 1. The Laboratory Personnel Report (CLIA), [CMS209, 8/07/23] named eight testing persons performing moderate complexity testing. 2. Training records for Testing Person-5 failed to include Cellydyn Emerald results records documenting demonstrated hematology testing. 3. Laboratory Personnel (3, 7) affirmed (8/15/23 at 1:00 pm) that upon completion of training, trainees weren't required to demonstrate routine hematology testing from beginning to end with preanalytic specimen handling to operating the Celldyn Emerald, the use of quality control materials, to postanalytic reporting of results. 4. That all personnel received appropriate training on the Celldyn Emerald prior to testing patients specimen could not be assured in the absence of demonstrated testing with documents of reliable and accurate results.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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: Based on the lack of a laboratory manual of written policies and procedures, the Laboratory Director is herein cited for deficient practice in ensuring that an approved procedure manual is available for all staff to follow. See D5401.