Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1040918	11/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
South County Kidney & Endocrine Center	23141 Moulton Pkwy Ste 102, Laguna Hills, 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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory patient complete blood cell count (CBC) test result reports, and interview with the technical consultant (TC) and the testing personnel, it was determined that the laboratory failed to provide the test result and, if applicable, with proper interpretations of reference intervals/Ref Range depending upon different gender. The findings included: a. The laboratory used Medonic hematology analyzer to perform CBC and reported the following parameters including, but are not limited to the followings: Red blood cell (RBC), Hemoglobin (Hgb), Hematocrit (Hct). b. Review of the patient CBC testing result reports along with Ref Range for RBC, Hgb, and Hct. c. The laboratory failed to provide proper Ref Range for each of the RBC, Hgb, and Hct results based on the gender (female or male). d. The laboratory provided the following Ref Range for female and male were identical as follows: RBC Hgb Hct All 4.20 - 6.00 11.0 to 16.0 35.0 - 55.0 e. The TC provided a "TEST DEMOGRAPHICS" sheet, which indicated that the laboratory information system (LIS), Labdaq, was set to have RBC Ref Range for female is 3.80 - 5.22. f. the "TEST DEMOGRAPHICS" sheet indicates that the LIS was set to have Hgb Ref Range for male is 14.0 - 18.0 and female is 12.0 - 16.0. g. The "TEST DEMOGRAPHICS" sheet indicates that the LIS was set to have Hct Ref Range for male is 38.0 - 52.0 and

	female 35.0 - 47.0. h. The TC affirmed (11/25/2019 @12:20 PM) that the laboratory failed to quality assess and correct the inconsistent settings of "Ref Range" between the LIS and the hematology analyzer parameters.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of the laboratory patient testing result reports, and interview with the technical consultant (TC) and the testing personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for CBC testing result reports with proper interpretations with reference intervals/Ref Range. The findings included: a. The laboratory performed CBC with Medonic hematology analyzer to report RBC, Hgb, Hct, and other parameters. b. There are inconsistent reference intervals/Ref Range setting among the LIS, Labdaq, and Medonic analyzer, see D-5805.