

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0903343	(X3) Date Survey Completed 06/12/2019
Name of Provider or Supplier Regal Medical Group Inc	Street Address, City, State 117 E Live Oak Ave, Ste 101, Arcadia, 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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on observations of the laboratory facility, review of the laboratory's patient test result reports and quality assessment (QA) in analytic system, and interview with the laboratory testing personnel, it was determined that the laboratory failed to follow written QA policies and procedures provided by the vendor. The findings included: a. The laboratory performed hematology analyzer, Horiba Micro 60 and established its quality control policies and procedures (P&P) in their QA program which was provided by a commercial vendor. c. The Quality Control and Assessment indicates that Daily Decision for Instrument Quality Control, a Westgard Multi-Rules was used. b. Interview with the testing personnel, the laboratory accepted daily control when all three QC levels within 2SD. c. The laboratory testing personnel acknowledge that she was not familiar Westgard rules.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

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's patient test result reports, and interview with the laboratory testing personnel, it was determined that the laboratory test reports failed to expressly and clearly indicate and include, but not limited to the following, reference values and the test report date. The findings included: a. The laboratory used Horiba Micro 60 hematology analyzer to perform complete blood cell counts (CBC) and report cell counts test results including, but not limited to hemoglobin and hematocrit. b. The laboratory used laboratory information system (LIS) LiteDM for their laboratory reporting. c. Reviewed patient CBC test results, Medical #s 718423 (M 06/11/2019), 718426 (F 06/11/2019), 38352 (F 06/11/2019), 54226 (F 06/11/2019). d. The laboratory's reference values for both male and females were between 11-16.5 g/dL and hematocrit between 35 to 50 % , which were inappropriate and should have the gender difference. e. Review of the final patient test reports, the laboratory did not expressly and clearly indicate that the test result report date, but a "Verified" date and time, and by a name of the testing personnel. c. Review of the laboratory's test result reports including male and female patients, the laboratory provided identical normal ranges for male and female patients for hemoglobin and hematocrit result. f. The CLIA regulations 42 CFR part 493. 1291 (c) (3) and (6) states: the Test report must indicate that (3) the test report date and (6) the test result and, if applicable, the units of the measurement or interpretation, or both. g. The testing personnel affirmed (6/13/19 @ 10:45 AM) that there were no differences in normal ranges for both hemoglobin and hematocrit and nether clearly and expressly a test result report date but "Verified".

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory facility, review of the laboratory test result reports and quality control records, and interview with the testing personnel, it was determined that the laboratory director failed to be responsible for overall operation and failed to ensure that quality assessment programs were maintained and follow the written policies and procedures provided by the vendor. The findings included: a. The laboratory failed to ensure that the patient test result reports must expressly and clearly include and indicate 1) the test result report date and 2) appropriate reference values for hemoglobin and hematocrit between male and female. See D-5805 b. The laboratory failed to assure the consistency of the daily acceptance of quality control rules for Horiba Micro 60 analyzer with the vendor Westgard rules. see D-5791