Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0860502	(X3) Date Survey Completed 04/22/2019
Name of Provider or Supplier Allan Kurtz Do / Warner Medical Center	**Street Address, City, State** 6325 Topanga Canyon Blvd, Ste 501, Woodland 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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 reviews second quarter (Q2-2018) of the American Proficiency Institute (API) proficiency testing performance summary records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Creatinine. The findings included: a. Q2-2018, API reported a score of 40% for Creatinine analyte. b. For ten (10) out of ten (10) random patient sampling test results reviewed covering period from 10/2/2017 to 4/2/2019, the laboratory analyzed and reported Creatinine tests during the approximate time the laboratory received the failed proficiency score. c. The technical consultant confirmed (4/22/2019, 1245) that the laboratory received that above unsatisfactory proficiency testing score.
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 reviews second quarter (Q2-2018) of the American Proficiency Institute (API) proficiency testing performance summary records, random patient sampling test results, and interview with the technical consultant, it was determined that the

	laboratory failed to attain a score of at least 80 percent of acceptable responses for Free Thyroxine. The findings included: a. Q2-2018, API reported a score of 0% for Free Thyroxine analyte. b. For two out of two (2) random patient sampling test results reviewed covering period from 10/1/2018 and 1/2/2019, the laboratory analyzed and reported Free Thyroxine approximately during the time the laboratory received the failed proficiency testing score. c. The technical consultant confirmed (4/22/2019, 1245) that the laboratory received that above unsatisfactory proficiency testing score.
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 reviews third quarter (Q3-2017) of the American Proficiency Institute (API) proficiency testing performance summary records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Monocytes. The findings included: a. Q3-2017, API reported a score of 60% for Monocytes analyte. b. For eleven (11) out of eleven (11) random patient sampling test results reviewed covering period from 10/2/2017 to 4/2/2019, the laboratory analyzed and reported Complete Blood Count (CBC) tests which included Monocytes. c. The technical consultant confirmed (4/22/2019, 1245) that the laboratory received that above unsatisfactory proficiency testing score.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on reviews of the American Proficiency Institute (API) proficiency testing performance summary records, and interview with the technical consultant, it was determined that the laboratory failed to least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: a. API reported the following unsatisfactory proficiency testing scores. Hematology Analyte: Score: Event/Year ESR 50% Q1-2017 MCHC 40% Q1-2018 MCV 0% Q1-2018 RDW-SD 0% Q1-2018 RDW-SD 0% Q2-2018 Endocrinology Analyte: Score: Event/Year SHBG 20% Q1-2018 Testo 20% Q1-2018 (SHB) Testo, Free 0% Q1-2018 Testo, Free 0% Q2-2018 Abbreviation: ESR= Erythrocyte Sedimentation Rate MCHC= Mean Corpuscular Hemoglobin Concentration MCV= Mean Corpuscular Volume RDW= Red Cell Distribution SHBG= Sex Hormone Binding Globulin Testo= Testosterone b. Based on the laboratory's annual test volume submitted, the laboratory analyzed and reported approximately 200 ESR tests and 200 Testosterone and SHBG tests during the approximately time that the laboratory received the above unsatisfactory proficiency testing scores. c. The technical consultant confirmed (4/22/2019, 1245) that the laboratory received the above unsatisfactory proficiency testing scores.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on reviews of the American Proficency Institute (API) proficiency performance summary records, random patient sampling test results, and interview with the technical consultant it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2087, D 2098, D 2121, and D5217.
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 reviews of the laboratory's random patient sampling test orders, and the lack of test results, and interview with the technical consultant it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 6070.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on reviews of the random patient sampling test orders, test results, and interview with the technical consultant it was determined that the laboratory failed to follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. The findings included: a. Patient #12712 had an order for Urinalysis on 8/2/2018, reviews of the patient test results revealed that the laboratory failed to result the Urinalysis test order. b. The technical consultant confirmed (4/22/2019, 1245) that the laboratory failed to results the above patient test order.