Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0970561	02/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Metrolab, Inc	16550 Ventura Blvd Ste 402, Encino, 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
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 touring the laboratory, review of the laboratory written policies and procedures (P&P) for Complete Blood Counts (CBC), and interview with the laboratory testing consultant, and the testing personnel, it was determined that the laboratory failed to follow by the laboratory personnel. The findings included: a. The laboratory's written P&P for CBC had indicated "Date Revised and Date Adopted" in 07-2016 for the subject of "COMPLETE BLOOD COUNTS (CBC). b. A "Date Revised" and "Date Adopted" should indicate the exact "Date" with year, not in "month" with year. c. The laboratory indicated in the CBC P&P that "The instrument is use reports only a three-part differential of the White blood cells. Test orders for a five-part WBC differential will be sent to a reference laboratory." d. The laboratory uses PENTRA XL 80 instrument to perform CBC and report 5 parts WBC differential, NOT three parts. e. The laboratory failed to update the CBC P&P including "Microscopic Exam" and show inconsistence of the laboratory operations in reporting.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's "QUALITY ASSESSMENT REVIEW" records, and interview with the testing personnel, it was determined that the laboratory failed to follow written policies and procedures (P&P) for on ongoing mechanism to monitor, assess and to ensure the accuracy and reliability of the patient test result reports. The findings included: a. The laboratory establish a written policies and procedures for its quality assessment (QA) in a format of "QUALITY ASSESSMENT REVIEW" and listed several tasks or markers to QA its laboratory operations under the following titles: "PATIENT TEST MANAGEMENT", "QUALITY CONTROL ASSESSMENT", "PROFICIENCY TESTING", and "PATIENT INFORMATION /RESULTS COMPARISON" b. Reviewed a record identified as "REVIEW PERIOD 4 /1/18 to 6/30/18" c. Either a check "mark" or a "N/A" was noted and indicated for each of the tasks listed. d. There are 13 tasks to be assessed by the laboratory personnel for accuracy or reliability of the patient result reports under "PATIENT TEST MANAGEMENT". e. A check mark was made to indicate the following tasks been assessed, but no definition to indicate what a check mark means: acceptable or noted or verified? Example of some tasks listed: 1. "Patient prep for specified testing was performed following approval protocol." 2. All panic values were documented, reviewed, and phoned to authorized personnel in a timely manner" 3. "All test records are maintained for required time period. All documentation is filed according policy." 4. "Referral specimens conformed to acceptable turnaround times. No noted problems with requisitions or reports." e. The laboratory personnel was not able to answer clearly or accurately what a "check" mark indicates for the patient test reports assessed when the surveyor questioned at the time of 2/18/2021 @ 12:10 PM. f. The laboratory personal cannot answer for: 1. did the patient follow approval protocol? when the patient sample received from outside drawing station. 2. there was no manic values for the patient test report picked for QA. 3. the CLIA's retention time of the records generally is at least 2 years, 4. there was no patient test report picked for QA was a referral specimen g. A "N/A", not applicable, should be a better answer for most of the above QA questionnaires.
D6020	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 the quality control program is 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, review of the laboratory written policies and procedures (P&P) and patient test report management quality assessment (QA), and interview with the laboratory technical consultant, and the testing personnel, it was determined that the laboratory director failed to be responsible for the overall operation, and failed to ensure that the quality assessment program was established and maintained to be effective and to assure the quality of laboratory services provided. The findings included: a. The laboratory's written P&P for CBC was not updated, reviewed, approved and signed by the current laboratory director and

	inconsistent with the current CBC instrument, see D-5401. b. The laboratory failed to follow the established written P&P properly to effectively assess its overall laboratory operations to ensure the accuracy of the testing result reports. The tasks the laboratory listed were not followed and indicated properly for the effectiveness of the QA procedures, see D-5891.