Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2017670	11/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Westpac Labs, Inc	361 Hospital Rd Ste 222, Newport Beach, 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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 review of the laboratory's proficiency (PT) testing results reports, and interview with the laboratory testing personnel, it was determined that the laboratory failed 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. The findings included: a. The laboratory performed qualitative Mono test for infectious mononucleosis using SURE-VUE COLOR MONO by fisher healthcare. b. The laboratory enrolled with CAP (College of American Pathologists) PT program to meet the evaluation of evaluation of proficiency testing performance. c. The laboratory attained a score of 20%, four out of five PT samples unacceptable, for the S-B 2021 Diagnostic Immunology PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory performed qualitative Mono in approximately 2 patient samples annually. e. The laboratory testing personnel affirmed (11/17/2021 @ 11:35 am) that the laboratory attained a score of 20%, four out of five PT samples unacceptable, for the S-B 2021 Diagnostic Immunology PT event which was unsatisfactory analyte performance for the testing event.
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 review of the laboratory's proficiency (PT) testing results reports, and interview with the laboratory testing personnel, it was determined that the laboratory failed to 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. The findings included: a. The laboratory performed LH (Luteinizing Hormone) test which is not listed in the subpart I of 42 CFR part 493, by Cobas model e411 instrument. b. To meet the evaluation of proficiency testing performance the laboratory must verify, at least twice annually, the accuracy of any test or procedure it performed that is not included in subpart I of 42 CFR part 493. c. The laboratory elected to enroll with CAP (College of American Pathologists) PT program. d. The laboratory attained a score of 0 %, three out of three PT samples unacceptable, for the Y-A 2020 Ligand-Special PT event which was unsatisfactory analyte performance for the testing event. e. The laboratory performed LH in approximately 35 patient samples monthly. f. The laboratory testing personnel affirmed (11/17/2021 @ 11:55 am) that the laboratory attained a score of 0 %, three out of three PT samples unacceptable, for the Y-A 2020 Ligand-Special PT event which was unsatisfactory analyte performance for the testing event.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency (PT) testing results reports, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory, including accurate, and proficiently and for assuring compliance with the applicable regulations and failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: a. To meet the evaluation of proficiency testing performance, the laboratory enrolled with CAP PT programs for qualitative Mono by SURE-VUE COLOR test and quantitively LH by Cobas e411 instrument. b. The laboratory attained a score of 20%, four out of five PT samples unacceptable, for the S-B 2021 Diagnostic Immunology PT event which was unsatisfactory analyte performance for the testing event, see D-2075. c. The laboratory attained a score of 0 %, three out of three PT samples unacceptable, for the Y-A 2020 Ligand-Special PT event which was unsatisfactory analyte performance for the testing event, see D-5217.