Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2207489	01/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Immufood Laboratory	201 W Main St, Ste 101, Jenks, OK	

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
D0000	The initial survey was performed on 01/27/2022. The findings were reviewed with the laboratory director, technical supervisor, and testing person #1 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, and interview with the technical supervisor, the laboratory failed to establish the performance specifications of analytical sensitivity, analytical specificity, and reportable range for 91 of 91 new analytes not cleared or approved by the FDA. Findings include: (1) On 01/27/2022 at 09:45 am, the technical supervisor stated to surveyor #2 a 91 food panel sensitivity testing was performed using the Ridascreen Specific IgG Foodscreen and the Tecan reader beginning 12/16/2021; (2) Surveyor #2 attempted to verify the classification of the analytes using the Ridascreen Specific IgG Foodscreen Reagents and Tecan reader on the FDA (Food and Drug Administration) test classification database, since classification of test systems are performed by the FDA. The database did not include

	a classification for the analytes/analyzer combination (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (3) Surveyor #2 reviewed the implementation records for the analyzer. There was no evidence the analytical sensitivity, analytical specificity, and reportable range had been established for the 91 food panel sensitivity testing using the Ridascreen Specific IgG Foodscreen and the Tecan reader; (4) Surveyor #2 reviewed the validation records with the technical supervisor who stated on 01/27/2022 at 01:40 pm analytical sensitivity, analytical specificity, and reportable ranges had not been documented as established.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical supervisor and general supervisor, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) On 01 /27/2022 at 09:45 am, the technical supervisor stated to surveyor #2 a 91 food panel sensitivity testing was performed using the Ridascreen Specific IgG Foodscreen and the Tecan reader beginning 12/16/2021. The Biotek EL 406 washer was used to wash the microplates used for the testing; (2) Surveyor #1 reviewed the maintenance requirements contained in the operator's manual for the Biotek EL 406 washer on pages 110 and 111. The requirements for the weekly maintenance were as follows: (a) Remove Protein Residuals and Fungi Growth, if necessary (b) Clean Plate Carrier System (c) Clean Exterior Surfaces and Mist Shield (3) Surveyor #1 reviewed maintenance records from 12/16/2021 through 01/27/2022 and identified the Clean Plate Carrier System had not been performed between 12/29/2021 and 01/19/2022; (4) Surveyor #1 reviewed the findings with the general supervisor who stated on 01/27 /2022 at 02:40 pm, the maintenance had not been performed as stated above.
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 a review of records and interview with the technical supervisor, the laboratory failed to ensure patient test reports included the name of the laboratory location for 1 of 1 patient report. Findings include: (1) On 01/27/2022 at 09:45 am, the technical supervisor stated to surveyor #2 a 91 food panel sensitivity testing was

	performed using the Ridascreen Specific IgG Foodscreen and the Tecan reader beginning 12/16/2021; (2) Surveyor #1 reviewed a patient test report with the results reported on 12/30/2021 and identified the name of the laboratory on the report did not match the name on the Clia certificate. The name on the patient report was "Immufood Laboratory" and the name on the Clia certificate was "Calvary Analytical Laboratory, LLC"; (3) Surveyor #1 reviewed the report with the technical supervisor, who stated on 01/27/2021 at 02:10 pm, the laboratory name on the patient report did not match the name on the Clia certificate.