Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2118087	05/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Maverick Labs Llc	4601 N Congress Ave, West Palm Beach, FL	

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	An announced recertification survey was conducted on 5/24/22 at Maverick Labs LLC, a clinical laboratory in West Palm Beach, Florida. Maverick Labs LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory was not in compliance with Federal licensure requirements to perform testing for the analyte "Lactoferrin" for two of two years reviewed. (2020-2022) The findings include: The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) obtained during survey showed the laboratory performs testing in the following specialty/subspecialties: Bacteriology, Parasitology, Virology, and Histopathology. The CLIA certificate provided at the time of survey confirmed the same specialties were on the license. Review of the laboratory test menu showed the laboratory performs testing for the analyte Lactoferrin using the Abbott Techlab Leuko EZ Vue test kit. Review of the FDA (Food and Drug Administration) web site for CLIA testing complexity showed that since 2007, the FDA has classified the testing system "Techlab Leuko EZ Vue" for the analyte "Lactoferrin" to be "Moderate Complexity" under the specialty of General Chemistry. The interview with the Technical Consultant on 5/24/22 at 9:40 am confirmed the laboratory was not licensed for General Chemistry. .
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 record review and staff interview, the laboratory failed to send Histopathology patient slides twice annually for peer review for two of two years reviewed (2020 - 2022). Findings include: There was no documented peer review for Histopathology slides read by the Clinical Consultant/Technical Supervisor between June 2020 and May 2022. The interview with the Technical Consultant on 5/24/22 at 9:30 am confirmed that laboratory was not performing twice annual verification of accuracy of Histopathology slides. .