Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2144896	09/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Arcpoint Labs Of West Palm Beach	5601 Corporate Way Ste 108, 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 unannounced complaint survey for #2020014037 was conducted on 9/30/20 at Arcpoint Labs of West Palm Beach, a clinical laboratory in West Palm Beach, Florida. The complaint contained one allegation which was substantiated with a deficiency. Arcpoint Labs of West Palm Beach is not in compliance with 42 Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories. The following is a description of the noncompliance.
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: Based on record review and staff interview with laboratory personnel, the laboratory was conducting waived testing without a valid CLIA certificate. The findings included: Review of the laboratory history revealed that the certificate expired on 2/25 /20 due to nonpayment of the certificate of waiver fee. On 9/30/20 at 1:45 p.m., the clinical manager said that they were performing waived testing and that she had been

	attempting to contact someone to find out how to renew their certificate. The surveyor gave her the notice of unlicensed activity letter and instructed them to cease testing.