ALPHA DIAGNOSTIC INTERNATIONAL

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Product Specification Sheet

PLGA Combo Trial Pak-1

□ **Cat. #** AV-2000-PK-1 PLGA Combo Trial Pak-1 (Contains 100 mg each of AV-2010-1; AV-2020-1 and AV-2030-1) **SIZE**:1 PK

General Information: The word '**adjuvant'** is derived from the Latin word '*adjuvare*' which means '**to help'**. Therefore, Immunologic Adjuvants are added to vaccines to stimulate the immune system's response to the target antigen, but do not in themselves confer immunity. Adjuvants act in various ways in presenting an antigen to the immune system. Adjuvants can act as a depot for the antigen, presenting the antigen over a long period of time, thus maximizing the immune response before the body clears the antigen. Examples of depot type adjuvants are oil emulsions. Adjuvants can also act as an irritant which causes the body to recruit and amplify its immune response. A tetanus, diphtheria, and pertussis vaccine, for example, contains minute quantities of toxins/toxoids produced by each of the target bacteria. The body's immune system develops an antitoxin to the bacteria's toxins, not to the aluminum, but would not respond enough without the help of the aluminum adjuvant**.** Adjuvants have also evolved as substances that can aid in stabilizing formulations of antigens, especially for vaccines administered for animal health.

Adjuvants augment the effects of a vaccine by stimulating the immune system to respond to the vaccine more vigorously, and thus providing increased immunity to a particular disease. Adjuvants accomplish this task by mimicking specific sets of evolutionarily conserved molecules, so called PAMPs, which include liposomes, lipopolysaccharide (**LPS**), molecular cages for antigen, components of bacterial cell walls (e.g., **flagellins**), and endocytosed nucleic acids such as double-stranded RNA (**dsRNA**), single-stranded DNA (**ssDNA**), and unmethylated CpG dinucleotide-containing DNA (**ODNs**). Natural proteins such as **ovalbumin** or OVA-peptides and key hole limpet hemocyanins (**KLH**) are also being explored not only serve as carrier protein but also as adjuvants. Because immune systems have evolved to recognize these specific antigenic moieties, the presence of an adjuvant in conjunction with the vaccine can greatly increase the innate immune response to the antigen by augmenting the activities of dendritic cells (DCs), lymphocytes, and macrophages by mimicking a natural infection. Furthermore, because adjuvants are attenuated beyond any function of virulence, they pose little or no independent threat to a host organism.

For human vaccines, aluminum hydroxide (Alum) based adjuvants (Aluminum hydroxide or Alhydrogel; Aluminium phosphate or Adjuphos) are the only **FDA-approved adjuvants**.. Vaccine components that are formulated in Alum are called "Adsorbed Vaccines". The effectiveness of each salt as an adjuvant depends on the characteristics of the specific vaccine and how the manufacturer prepares the vaccine

Not all vaccines contain Alum because an adjuvant may not have been needed, was not expected to increase the desired immune response, or was going to cause an imbalance in the immune response. For example, **inactivated Polio Virus** (IPV/IPOL) vaccine, measles, mumps and rubella vaccine (**MMR/MMRII/MMRV**), **Varicella or chickenpox vaccine** (Varivax/Proquad/MMRV), **Meningococcal conjugate** (MCV4/Menomune/Menactra) vaccine, and **influenza vaccines** (Fluzone/Flulaval/Flumist/Fluvirin etc) do not contain aluminum salts.

Product Information

Aliphatic polyesters such as polylactide, poly(lactide-co-glycolide) and polycaprolactone, as well as their copolymers, represent a diverse family of synthetic biodegradable polymers that have been widely explored for medical uses and are commercially available. These polymers have been approved by the United States Food and Drug Administration (FDA) and European Medicine Agency (EMA) for many biomedical applications such as drug delivery devices, sutures and implants.
By combining emulsion/solvent evaporation and miniemulsion techniques, it is possible to produce biodegradable nanoparticles with a controlled size and narrow size distribution

PLGA-Trial Pak-1 Contains 100 mg each of the 3 common PLGA Contains 100 mg each of AV-2010-1; AV-2020-1 and AV-2030-1) Designed to provide various formulations of PLGA for testing adjuvantcy with a given antigen)

Storage and Stability: Shipped at room temperature and it should be stored at room temp. DO NOT FREEZE. Stable for 6 months.

Suggested Usage: Adsorption of most proteins can be achieved by mixing equal volume of antigen and adjuvant. Protein left in the supernatant can be measured by protein assay or specific ELISA.

Related items :

Catalog#	ProdDescription
AV-2000-PK-1	PLGA Combo Trial Pak-1 (Contains 100 mg each of AV-2010-1; AV-2020-1 and AV-2030-1)
AV-2010-1	PLGA poly(lactic-co-glycolic) acid); synthetic; (50% lactic and 50% glycolic acid, ~30-60 Kda)
AV-2020-1	PLGA poly(lactic-co-glycolic) acid); synthetic; (65% lactic and 35% glycolic acid, ~ 40-75 Kda)
AV-2030-1	PLGA poly(lactic-co-glycolic) acid); synthetic; (75% lactic and 25% glycolic acid, ~ 65-105 Kda)
AV-2040-1	PLGA poly(lactic-co-glycolic) acid); synthetic (75% lactic and 25% glycolic acid; Ester capped, , MW 75-115 Kda)
AV-2050-1	Poly(lactide-co-glycolide) star, glucose core, hydroxyl terminated vaccine adjuvant
AV-2060-1	Poly(lactide-co-glycolide)-block-poly(ethylene glycol)-block-poly(lactide-co-glycolide)
AV-2070-1	Poly(ethylene glycol) methyl ether-block-poly(lactide-co-glycolide)

Complete list is available at:
http://4adi.com/objects/catalog/product/extras/Vaccine_Adjuvants_flr.pdf

AV-2000-PK-1 140520P

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