Statement of Work

Memorandum of Need (MON) for custom synthesis of a peptide library derived from AAV2 capsid

Part I: General Information

A. Introduction

FDA CBER Gene Transfer Immunogenicity Branch requires a peptide library spanning the entire sequence of AAV2 VP1. This has a direct relevance for the review of Gene Therapy vectors and products involved in emerging gene therapy strategies. The success of gene therapy is often determined by the immune response it induces. These peptides will be used to identify the T cell epitopes in AAV2 and develop new methods to detect and mitigate the immunogenicity of AAV vectors used in gene therapy vectors.

B. Background

We study the immune response to gene therapy product. The AAV2 derived peptide library will be used to stimulated human white blood cell samples and help identify T cell epitopes in AAV2.

C. Scope

We analyzed the sequence of AAV2 capsid protein and designed a list of 241 overlapping peptides, spanning the entire amino acid sequence of AAV2 VP1 capsid protein. The list is attached as appendix 1. Each of the peptides in the library will be used to stimulate T cells and map the immune response against peptide fragments derived from the capsid protein**.** Cells from various donors will be expanded with the peptide library. Each peptide-stimulated sample will be analyzed and studies for a cytokine immune response to each of the peptides in the library.

D. Period of Performance

Delivery shall occur 50-100 days from date of award at a time determined by the requesting lab.

E. Delivery

All peptides will be supplied on a single delivery 50-100 days from date of award at a time determined by the requesting lab.

Contractor shall deliver 241 peptides in 96 format vials and QC reports in a USB drive or paper. All peptides shall be delivered in a single delivery. Peptide tubes shall be labeled with peptide name as described in appendix 1.

Peptide shall be in accordance with he below requirements.

purity	**QC Report**
>95%	COA, RP-HPLC and MS