DiaPharma Streptokinase

Data Sheet

Catalog #: B811111

Item Description: Streptokinase (Approximately 0.91 MIU)

Lot #: B-121901

Expiration Date: 12/31/2024 (Re-assay Date: 1

All units of plasma have been tested for absence of HB₅Ag (third generation test), anti-HIV (FDA licensed test) and found to be negative. This material should be handled as if capable of transmitting disease.

CAUTION:

NOT SUITABLE OR INTENDED FOR USE IN HUMANS OR FOOD ANIMALS

NOT FOR STERILE USE OR INJECTION.

IN VITRO USE ONLY.

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES

Product:

Streptokinase (purified preparation of a bacterial protein elaborated by group C b-hemolytic streptococci). Supplied as white, water-soluble, lyophilized powder (non-sterile)

Material contains 11 mg sodium L-glutamate and 13.0 mg albumin (human) per 1,000,000 IU

(1 MIU) of Streptokinase. Contains no preservatives.

Amount:

per vial:

Approximately 912,000 IU (0.91 MIU) per vial

Printed Name:

Jennifer J. Kiblinger

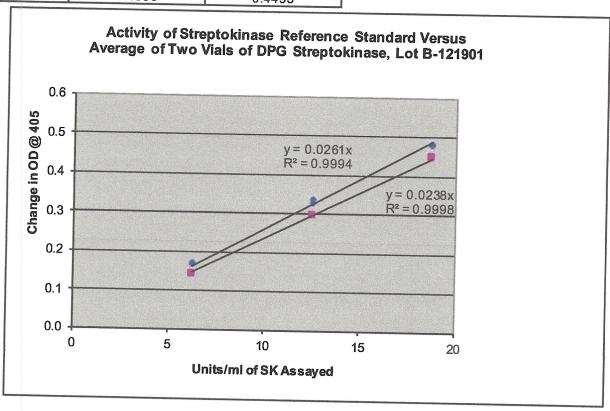
Title: Scientific Director Assay Results of DPG Streptokinase Lot B-121901 vs. 4th Int. Reference Standard (21 February 2022)

Experimental:

Two separate vials of lot B-121901 of DPG Streptokinase were assayed vs. the 4th Int. SK Ref. Standard (RS Lot 16/358) following BioCascade SOP AP-30. Three concentrations of the RS and of two separate vials of Lot B-121901 were assayed in duplicate and the average of the duplicates was used to construct the concentration curves shown below. Using slope comparison methods, the average potency (activity) of each vial of DPG SK Lot B-121901 was calculated. The results showed that these vials contained 0.912 MIU per vial.

Results:

	Change in OD @ 405 nm over 14 minutes	
IU/ml	Ref. Std	Vial 1 and 2
6.25	0.1690	0.1430
6.25	0.1730	0.1415
12.5	0.3300	0.2970
12.5	0.3380	0.2955
18.75	0.4800	0.4490
18.75	0.4830	0.4495



Calculations: Based upon the above slope comparison, the average number of Units contained in these vials was 911,877 IU/vial or about 91% of the labeled potency.