

DiaPharma Streptokinase

Data Sheet

Catalog #: B811111

Item Description: Streptokinase (Approximately 0.866 MIU)

Lot #: B-121901

Reassay Date: 01/31/2028

All units of plasma have been tested for absence of HB_sAg (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 866,000 IU (0.866 MIU) per vial

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Title: Scientific Director

1.0 Purpose

This report describes the results of a chromogenic streptokinase potency assay to assign the client sample a potency utilizing the NIBSC international standard for streptokinase.

2.0 Principle of the Analytical Test Method

The method assigns a streptokinase potency to an unknown sample relative to the NIBSC streptokinase international standard. A seven point curve is made of the streptokinase standard and any samples. Each standard or sample level is then incubated with glu-plasminogen in a 96-well plate at 37°C in order to catalyze the activation of plasminogen to plasmin. After the incubation the S-2251 substrate is added to each standard and sample level and the rate of the absorbance at 405 nm is monitored. An increased rate of change correlates to an increased level of plasmin and therefore increased level of streptokinase activity.

3.0 Results

The results of the chromogenic streptokinase potency assay are shown below in Table 1 and Figure 1.

Table 1. Streptokinase Potency Assay Results

Sample	R ²	Potency
NIBSC Streptokinase International Standard	0.996	100%
DiaPharma Streptokinase Lot B-121901	0.994	86.6%

Figure 1. Streptokinase Potency Assay Results

