SPECTRUM

The Creative Approach to Bioscience

SP-PATHOTROL

REF: 327 001 (1 vial) 1 x 5 ml
REF: 327 002 (5 vials) 5 x 5 ml
REF: 327 003 (6 vials) 6 x 5 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Control serum pathological, for Control of Accuracy and Precision in quantitative In vitro Diagnostics

Description

SP-PATHOTROL is a lyophilized human-based control serum.

Preparation

Reconstitute carefully by adding exactly 5 ml of distilled water. Allow the vial to stand for 30 minutes ,with occasional swirling. Avoid foaming i.e. do not shake!
For alkaline phosphatase the control serum should stand for 2 hours at +25 °C before use .

Storage and stability

Unopened bottles must be stored at 2 - 8°C and are stable up to the expiration date printed on the labels

After reconstitution it is stable for:
12 hours at 15 -25ºC , 5 days at 2 - 8ºC , 28 days at -25ºC to -15ºC (when frozen once).

-Bilirubin and Acid Phosphatase (stored protected from light) :
8 hours at 15-25ºC , 24 hours at 2 - 8°C, 2 weeks at -25ºC to -15ºC (when frozen once).

-ALT:
12 hours at 15-25ºC , 5 days at 2 - 8°C , 2 weeks at -25ºC to -15ºC (when frozen once)

-CK is stable for 3 days at < -20°C .

Warnings and Precautions

Each individual blood donation used for this serum was found negative when tested with FDA-approved methods on HBsAg, anti-HIV 1+2 and anti-HCV. Nevertheless the serum should be treated for safety reasons always as a potentially infectious material .

Procedure

Refer to the package inserts of the reagent kits

Assay Values and Ranges

Assay values for analytes for which approved reference methods are available were determined according to Guidelines of the German Federal Medical Council [Bundesaerztekammer] from 1987 (reference method values) [3].
Ranges of acceptance were calculated as assigned value ± three times the maximum tolerable deviation of a single value according to the Guidelines of the German Federal Medical Council [4].

Expected Values

1. The expected value of specific assays are provided on the assay value sheet accompanying each kit, and are lot specific.
2. The expected values are obtained using replicate assay of each manufactured lot of SP-Pathotrol.
3. The individual laboratory values should fall within the expected values.
4. It must however be noted that each laboratory should establish its own normal values and reference range according to GLP.

Literature

1. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt:TH-Books Verlagsgesellschaft; 1998. p. 1393-1401

2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).

3. Richtlinien der Bundesärztekammer zur Qualitätssicherung in medizinischen Laboratorien. Deutsches Ärzteblatt 1988;85: B519–B532.

4. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt 2002;98:A 2747-59.

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