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DIACON P

(Assayed Universal Control Serum Abnormal)

Lyophilized universal control serum for the use in tests for the quantitative in vitro determination of various analytes in human samples on photometric systems.

REF	Content	
D98482	12 x 5 mL	kit
D14482	5 x 5 mL	kit
D98482SV	1 x 5 mL	single vial

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Shelf life 36 months from production date
Storage 2 - 8 °C

INTENDED USE

Lyophilized universal control serum for the use in tests for the quantitative in vitro determination of various analytes in human samples on photometric systems.

REAGENT COMPOSITION

Diacon P is a lyophilized control based on human blood material (serum) and contains drugs, organic and non-organic chemicals and biological material of specified origin. The concentrations are either at pathological or at borderline pathological levels.

Analyte	Origin
Alkaline phosphatase	Calf (Intestine)
Alanine Aminotransferase	Porcine (heart)
Aspartate Aminotransferase	Porcine (heart)
α-Amylase	Porcine (pancreas)
Bilirubin	Porcine/Bovine
Creatine kinase	Human, recombinant
Glutamate dehydrogenase	Bovine (liver)
γ-Glutamyltransferase	Porcine (kidney)
Lactate dehydrogenase	Porcine (heart)
Lipase	Human, recombinant

The concentration of the biological material does not exceed the maximum, lot specific target value concentration of the analyte.

MATERIAL REQUIRED BUT NOT PROVIDED

- Clinical chemistry analyser.

REAGENT PREPARATION

1. The lyophilisate is vacuum sealed, therefore the vial should be opened very carefully to avoid loss of dried material.
2. Add exactly 5 mL of distilled water (inaccurate reconstitution of the control can cause erroneous results.)
3. Close the vial carefully and let the control stand for 30 min.
4. Dissolve contents completely by swirling gently, avoiding the formation of foam. Do not shake!

STORAGE AND STABILITY

Storage: Unopened bottles must be stored at 2 – 8 °C.

Stability:

Unopened: Until the end of the indicated month of expiry.

Once reconstituted, Diacon P can be used within the period reported in the table below if stored tightly closed at the indicated temperature.

Stability after reconstitution:

	+ 4 °C
Bilirubin (in the dark), GOT, GPT	2 days
Other analytes	7 days

	+ 25 °C
GPT	2 hours
CK-NAC, CK-MB	4 hours
Other analytes	8 hours

	-20 °C*
Bilirubin	14 days
Other analytes	30 days

*Freeze only once!

WARNINGS AND PRECAUTIONS

1. Each individual blood donation used for production of Diacon P was found to be non-reactive when tested with approved methods for HbsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the control with the same precautions used for patient specimens.
2. Diacon P contains biological material of specified origin. The controls should be handled as potentially infectious and with the same precatuions used for patient specimens.
3. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
4. For professional use only!

TEST PROCEDURE

Please refer to the reagent package insert for instructions for use.

LOT SPECIFIC ASSAY VALUES AND RANGES

The analyte concentrations contained in Diacon P are specific and only valid for the corresponding lot and thus stated in the value sheet of the lot involved. All assay values have been established within standardized conditions with the method stated in the value sheet. Please refer to table with Lot specific assay values.

Ranges of acceptance were calculated as assigned value ± the maximum tolerable deviation of a single value according to the Guidelines of the German Federal Medical Council (Rilibaek) from 2003 [3]. For analytes not listed in the Guidelines of the German Federal Medical Council (Rilibaek) ranges are indicated with a deviation of ± 20% from the given mean value.

Each laboratory should establish corrective action in case of deviations in control recovery.

WASTE MANAGEMENT

Please refer to local legal requirements.

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. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt 2003; 100:A 3335-38.

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