

Liquid Reagents – ready to use

## Lyophilized Serum Control

# DIACON N (Assayed Universal Control Serum Normal)

Single Reagent

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

| Ref.No.   | Kit Size  | Content     |
|-----------|-----------|-------------|
| DIA030012 | 1 x 5 ml  | Single Vial |
| DIA030010 | 3 x 5 ml  | Kit         |
| DIA030011 | 5 x 5 ml  | Kit         |
| DIA030014 | 10 x 5 ml | Kit         |
| DIA030015 | 12 x 5 ml | Kit         |
| DIA030016 | 15 x 5 ml | Kit         |
| DIA030017 | 20 x 5 ml | Kit         |

### COMPOSITION

Diacon N is a lyophilized control based on human blood material (serum) and contains purified human and animal components, purified drugs and non-organic components. The concentrations are either at normal or at borderline pathological levels.

### 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 dist. water (inaccurate reconstitution of the control and error in assay technique 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!

### TEST PROCEDURE

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

### STABILITY AND STORAGE

**Storage:** at 2 – 8°C  
**Stability:** until date of expiration

### Stability after reconstitution:

|                          | 25°C    | 2 - 8°C | -20°C   |
|--------------------------|---------|---------|---------|
| Bilirubin (in the dark): | -       | 2 days  | 14 days |
| GPT                      | 2 hours | 2 days  | 30 days |
| GOT                      | 8 hours | 2 days  | 30 days |
| CK-NAC, CK-MB            | 4 hours | 7 days  | 30 days |
| Other Analytes:          | 8 hours | 7 days  | 30 days |

Close immediately after use. Store the vials tightly closed at the indicated temperature. \*Freeze only once! Improper handling and/or storage of the control can affect results.

### LOT SPECIFIC ASSAY VALUES AND RANGES

Values and Expiry Date are LOT specific. Please refer to table with Lot specific assay values. Assay values for analytes for which approved reference methods are available were determined according to Guidelines of the German Federal Medical Council from 1987 (reference method values) [3]. 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 from 2003 [4]. Assay values may slightly vary depending on different reagents and methodologies used.

### WARNINGS AND PRECAUTIONS

Each individual blood donation used for production of DIACON N Control 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.

### WASTE MANAGEMENT

Please refer to local legal requirements.

