Normalyte™

Chemistry Control Level 1

COMPOSITION

Normalyte is a lyophilized clinical chemistry control based on Human blood material (plasma) and chemical additives, intended for control of accuracy for use with manual and automated analytical procedures.

DESCRIPTION

Normalyte is a clinical chemistry control with adjusted concentrations in or near the normal range. Target values and ranges are supplied for the analytes in the value sheet provided.

CONTENTS

This kit contains 6 lyophilized vials of 3ml each.

STORAGE

Unopened: The lyophilized controls are stable at 2°C to 8°C up to the expiry mentioned on the label.

Opened : Reconstituted control is stable for 12 hours at 15°C to 25°C or 5 days at 2°C to 8°C and 4 weeks when frozen at -15°C to -25°C.

LIMITATIONS

1. Alkaline Phosphatase levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum be allowed to stand for 30 minutes at 15°C to 25°C before measurement.
2. Stability of Total bilirubin in the reconstituted control (when stored protected from light):
   - at 15°C to 25°C 6 hours
   - at 2°C to 8°C 1 day
   - at -15°C to -25°C 2 weeks (when frozen once)
3. Stability of Direct bilirubin in the reconstituted control (when stored protected from light):
   - at 15°C to 25°C 3 hours
   - at 2°C to 8°C 8 hours
   - at -15°C to -25°C 2 weeks (when frozen once)
4. Stability of acid phosphatase and prostatic acid phosphatase in the reconstituted control (criterion: ± 10% of initial value):
   - at 15°C to 25°C 4 hours
   - at 2°C to 8°C 1 day
   - at -15°C to -25°C 2 weeks (when frozen once)
5. The values assigned to the controls are lot specific.
6. The control should not be used as a calibrator.

REAGENT PREPARATION

Normalyte is supplied in a lyophilized state and must be reconstituted prior to use.

1. Reconstitute each vial of the lyophilized control with exactly 3 ml of distilled or deionised water. Allow to stand for 30 minutes with occasional mixing by gentle swirling.
2. DO NOT SHAKE VIGOROUSLY.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

WARNINGS AND PRECAUTIONS

1. The used blood units of European origin have been tested by CE-marked kits and have been found to be non-reactive for HBsAg, Ant-HCV and Anti- HIV-1/ HIV-2. In addition HCV and HIV have been tested by PCR.
2. Normalyte contains biological material and should be handled as potentially infectious and with the same precautions used for patient specimens.

FOR IN VITRO DIAGNOSTIC USE ONLY

Marketed By:
Tulip Diagnostics (P) Ltd.
D3-D4, Dr. Antonio do Rego Bagh,
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Manufactured by:
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