ChemCAL™

Chemistry Calibrator

COMPOSITION

ChemCal is a lyophilized clinical chemistry calibrator based on Human blood material (plasma) and chemical additives. The concentrations of the analytes have been selected so as to ensure optimum calibration for use in semi-automated and fully-automated analyzers .

DESCRIPTION

The concentrations of the analytes are lot specific and are provided with the kit.

CONTENTS

This kit contains 6 lyophilized vials of 3ml each.

STORAGE

Unopened: The lyophilized calibrator is stable at 2°C to 8°C up to the expiry mentioned on the label when stored tightly closed.

Opened : Reconstituted control is stable for 8 hours at 15°C to 25°C or 2 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 calibrator (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 calibrator (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 calibrator (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 calibrators are lot specific.

REAGENT PREPARATION

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

1. Reconstitute each vial of the lyophilized calibrator with exactly 3 ml of distilled or deionised water. Allow to stand for 30 minutes with occasional mixing by gentle swirling.
3. DO NOT SHAKE VIGOROUSLY.
2. 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. ChemCal 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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CHE/08320/VER- 01