

# CLINICAL CHEMISTRY CALIBRATOR

REF. 6002/8

1x3 ml



DNV CERTIFIED COMPANY  
UNI EN ISO 9001:2008  
UNI EN ISO 13485:2012



## PRODUCT CHARACTERISTICS

Is a human multiparameter calibration serum. The concentration and the activities have been selected to ensure optimum calibration of automatic analyzers. Particularly, these values were determined in our laboratory on BT 2000 plus.

## REAGENTS

Human serum with chemical additives and tissue extract of human and animal origin. The origin of biological additives is as follow:

AST/GOT, ALT/GPT; LDH:	porcine heart
ALBUMIN, CHOLESTEROL:	bovine plasma
ALDOLASE, CREATINE KINASE:	rabbit muscle
TOTAL AMYLASE, LIPASE:	porcine pancreas
CHOLINESTERASE:	human serum
ACID PHOSPHATASE:	human prostate, potato
ALKALINE PHOSPHATASE:	placenta (human, recombinant)
GAMMA-GT:	porcine kidney
TRANSFERRIN:	human Cohn IV fraction
TRIGLYCERIDES:	chicken egg yolk

The concentrations and the activities are lot specific. The exact values are in the enclosed values sheet.

## PRECAUTIONS AND WARNING

For in vitro diagnostic use only.



*The product is obtained using only blood of donors tested by an FDA method and found non-reactive for HbsAg and negative for antibodies to HIV 1/2 and HCV. However as no test method can rule out the potential risk of infection with absolute certainty, the material should be handled as potentially infectious, just as carefully as a patient sample.*

## WASTE DISPOSAL

Please consult local regulations for a correct waste disposal.

S56: Dispose of this material and its container at hazardous or special waste collection point.

S57: Use appropriate container to avoid environmental contamination.

S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.

## PREPARATION

Carefully open one bottle of calibrator avoiding the loss of lyophilizate, and pipette exactly 3.0 ml of bidistilled water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 15 minutes. Avoid the formation of foam.

## STORAGE AND STABILITY

Store at 2 - 8 °C. Lyophilized calibrator is stable at 2 - 8 °C until the stated expiration date.

Stability of the components in the reconstituted calibrator:

at 15 - 25 °C	8 hours
at 2 - 8 °C	2 days
at -25° / - 15°C	2 weeks (when frozen once)

Stability of Bilirubin in the reconstituted calibrator: (when stored protected from light):

at 15 - 25 °C	4 hours
at 2 - 8 °C	1 day
at -25° / - 15°C	2 weeks (when frozen once)

Stability of acid phosphatase in the reconstituted calibrator:

at 15 - 25 °C	4 hours
at 2 - 8 °C	1 day
at -25° / - 15°C	2 weeks (when frozen once)

Store the reconstituted calibrator tightly capped when not in use.

## REQUIRED MATERIALS NOT PROVIDED

Automatic micropipette, distilled water, general laboratory equipment.

## ASSAY

Dispense the required volume into a sample cup and use as advice.

## RESULTS

The calibration values were determined using the method mentioned in the enclosed value sheet. Determinations were performed under strictly standardized conditions on Roche/Hitachi analyzers using Roche system reagents and Roche master calibrators. The calibration value specified is the median of the values obtained. Giesse Diagnostics calibration takes place in own laboratory on BT2000 plus analyzers and with own reagents.

## REFERENCES

1. Department of Labor, Occupational Safety and Health Administra 29 CFR Part 1910.1930 Federal Register. Juli 1, 1998; 6: 267-280.
2. Council Directive 90/679/EEC. Official journal of the European directives n°. L. 374 from Dec. 31,1990:1-12

Giesse Diagnostics srl

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600207  
Ed. 2014/11 rev. 01