

# XL MULTICAL

For *in-vitro* Diagnostic use only.

## INTENDED USE

XL Multical is a lyophilized calibrator based on human serum. The concentrations and activities are suitable for calibration of clinical chemistry assays on automated clinical chemistry analyzers.

## STORAGE AND HANDLING

Unreconstituted lyophilized calibrator is stable till the expiry date mentioned on the label when stored at 2-8°C. The reconstituted calibrator is stable for 8 hours at 15 - 25°C, 2 days at 2-8°C and 2 weeks when frozen once at (-15) - (-25)°C.

\* **Exceptions** : See below

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

at 15 - 25°C	4 hours
at 2 - 8°C	1 day

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

at 15 - 25°C	3 hours
at 2 - 8°C	8 hours

Store calibrator tightly capped and protected from light when not in use.

Store vials upright to avoid spills and leakage. Seal the vials tightly after use to prevent evaporation.

## WARNING

Human source material used in the manufacturing of this product has been tested by FDA - approved methods and found non reactive for hepatitis B, surface antigen(HbsAg), antibody to Hepatitis C (HCV) and antibody to HIV1/2.

The test procedures do not guarantee that all infectious agents will be detected. Because no test method can offer complete assurance that Hepatitis B virus, Hepatitis C virus and HIV 1/2 or other infectious agents are absent, the material should be handled as potentially infectious.

## RECONSTITUTION

1. Remove the screw cap and rubber stopper from the vial to be used. Avoid loss of lyophilizate.
2. Add exactly 3.0ml of distilled/deionized water using a volumetric pipette.
3. Replace the stopper and cap for each vial and dissolve the contents on a roller mixer completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

## VALUE ASSIGNMENT

The calibrator values were determined using the method mentioned in the enclosed value sheet. The calibrator values were obtained via single determination performed in different laboratories and the values assigned by a consensus of the results obtained by these laboratories.


## LIMITATIONS


Erroneous results can occur from reconstitution inaccuracies and technical errors associated with the assay procedure. Do not use the reconstituted calibrator if there is visible evidence of microbial growth in the vial.

## SYMBOLS:


The following symbols are used in the labelling of ERBA Mannheim kits:


 Catalogue No

 CE Mark - Device comply with the Directive 98/79/EC


 Batch Code

 In Vitro Diagnostics

 Expiry Date  
(Last day of the month)

 Consult Instruction for Use

 Manufactured By

 Storage temperature

 Product Name  Content

Parameter	Methodology	Value
Albumin	BCG	3.5 g/dl
ALP	AMP - 37°C	220 U/l
ALAT / SGPT	IFCC without Pyridoxal phosphate 37°C	88.4 U/l
ASAT / SGOT	IFCC without Pyridoxal phosphate 37°C	88.68 U/l
Amylase	CNPG3	179 U/l
Bilirubin Direct	Diazo with Sulphanilic Acid	3.21 mg/dl
Bilirubin Total	Diazo with Sulphanilic Acid	5.93 mg/dl
Calcium	Arsenazo III	10.3 mg/dl
Chloride	Colorimetric	104 mmol/l
Cholesterol	CHOD - PAP	164.5 mg/dl
CK	DGKC substrate start 37°C	346 U/l
Creatinine	Jaffe / Kinetic	3.5 mg/dl
GGT	Glupa 37°C / IFCC 37°C	102.2 U/l
Glucose	GOD-POD	197.7 mg/dl
LDH-P	DGKC 37°C	496.5 U/l
Magnesium	Calmagite	3.23 mg/dl
Phosphorus	Phosphomolybdate UV	5.23 mg/dl
Total Protein	Biuret, End Point	5.2 g/dl
Triglycerides SR	GPO - PAP	137.6 mg/dl
Urea	Urease - GLDH kinetic	105.2 mg/dl
Uric Acid SR	Uricase - POD	5.05 mg/dl

### Conventional Units

The conversion factors and significant digits places to be used in reporting the mean values and ranges (for both SI and conventional units) are presented in Table 1.

**Table : 1**

Analyte	S.I.Units	Significant Digits	Conversion Factor	Significant Digits	Conventional Units
Albumin	g/l	XX	0,1	X.X	g/dl
Bilirubin	µmol/l	XXX	0,059	X.XX	mg/dl
Calcium	mmol/l	X.XX	4	XX.X	mg/dl
Chloride	mmol/l	XXX	1	XXX	mEq/l
Cholesterol	mmol/l	X,X	38,7	XXX	mg/dl
Creatinine	mmol/l	X.XX	11,3	X,X	mg/dl
Glucose	mmol/l	XX.X	18	XXX	mg/dl
Magnesium	mmol/l	X.XX	2,43	X.XX	mg/dl
Phosphorus	mmol/l	X.XX	3,1	X.XX	mg/dl
Total Protein	g/l	XX	0,1	X.X	g/dl
Triglycerides	mmol/l	X,X	87,5	XXX	mg/dl
Urea	mmol/l	XX.X	6,01	XX	mg/dl
Uric Acid	mmol/l	X.XX	16,8	X,X	mg/dl

**Lot No.: 1041047B**

**Expiry : 11/2011**

### PACK PRESENTATION

PRODUCT CODE : XSYS034

PACK SIZE : 4 x 3 mL

Revision No.: 19-14062010XLM