



**PHOENIX
DIAGNOSTICS**
BILIRUBIN CONTROL NORMAL
CAT. No. PH6001 10 X 1ML

INTENDED USE:

Bilirubin Controls are intended for in vitro diagnostic use in calibrating automated, semi-automated and manual chemistry systems. The analytes are Direct Bilirubin (DBIL) and Total Bilirubin (TBIL).

Bilirubin Controls are designed to be compatible with all popular chemistry analyzers. Each kit we manufacture comes with 10 ampules of 1mL each.

SUMMARY:

Bilirubin Controls contain purified bilirubin stabilized within a bovine albumin solution. This calibrator can also be used to troubleshoot problems with chemistry systems, reagents, and / or calibration anomalies.

INGREDIENTS:

Purified Bilirubin from bovine source is stabilized and preserved in a bovine albumin solution.

STORAGE AND STABILITY:

Bilirubin Controls materials are stable until the expiration date printed on the ampule when stored at 2-8° C, and away from light. Opened ampules **must be used within the same working day** or else discarded. Dispose if gross contamination is visible.

INSTRUCTIONS FOR USE:

Bilirubin Controls are ready-to-use, and require no reconstitution. Materials contained herein should be treated in the same manner as patient samples. If additional dilutions or pre-treatment are required as part of your testing procedure, please consult the instructions of your instrument manufacturer.

Before actual use, hold ampule by the top and shake gently. Then with light tapping, restore all liquid to the bottom. Break open carefully to avoid cutting of fingers – using the complementary ampule snapper provided with this test set. With pipette, aspirate liquid from ampule and transfer to one or more sample cups (duplicate or triplicate runs are advised when performing calibration verification).

EXPECTED VALUES:

Actual results obtained may vary depending upon instrumentation and methodology used, as well as assay temperature. Results may also depend upon the accuracy of instrument and reagent calibration. The degree of acceptable non-linearity is an individual judgment based upon a test analyte's methodology, clinical significance and medical decision levels.

Technicians are advised to consult the analytical limits defined by the Clinical Laboratory Improvement Act of 1988 (CLIA '88). These criteria specify the *total error allowed* for most analytes in question, and they can be referenced at the following web address:

http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.931

Analyte	Target Value
Direct Bilirubin (DBIL)	0.5mg/dL
Total Bilirubin (TBIL)	1.0mg/dL

REORDERING INFORMATION:

BILIRUBIN CONTROL NORMAL
CAT. No.: PH6001
CONFIGURATION: 10 X 1mL (AMPULES)

For technical assistance or to place an order, please call:

Tel: 508-655-8310
Fax: 508-655-8273
Email: sales@phoenixdiagnostics.com

Please allow 3-7 days for delivery.

Phoenix Diagnostics, Inc.
8 Tech Circle, Natick, MA 01760.