



CERTIFICATE OF ANALYSIS
(BATCH RELEASE)

1. PRODUCT NAME: **GLYCOHEMOGLOBIN**
 NORMAL CONTROL LOT#: 102091 EXP. DATE: 10/2012
 ELEVATED CONTROL LOT#: 102092 EXP. DATE: 01/2012
2. METHOD/PROCEDURE: CATION EXCHANGE RESIN
3. DESCRIPTION: LIQUID RESIN AND LYSING
 LYOPHILIZED STANDARD
4. KEY INGREDIENTS: RESIN: CATION EXCHANGE RESIN
 LYSING: POTASSIUM CYANIDE
 STANDARD: GLYCOHEMOGLOBIN STANDARD
5. CONTROL MANUFACTURER: TECO

TOLERANCE LEVELS OF CONTROLS

<u>CONTROL OR STANDARD</u>	<u>LOT #</u>	<u>EXP. DATE</u>	<u>TOLERANCE RANGE</u>	<u>TARGET</u>
Standard	121291	12/2012	8.5 – 11.5	10.0
Normal	011881	10/2012	5.9 – 8.1	7.0
Elevated	102092	01/2012	11.9 – 16.1	14.0

TEST VALUES/RESULTS

<u>CONTROL OR STANDARD</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>MEAN</u>	<u># PASS</u>
Standard	7.7	7.7	8.1	7.7	7.8	7.7	7.7	6/6
Normal	10.3	9.7	10.2	9.7	10.3	10.2	10.0	6/6
Elevated	15.8	13.4	13.8	13.7	14.0	14.2	14.6	6/6

COMMENTS: VISUAL CHECK OK

APPROVED BY: *V. Bassey* DATE: 05/03/2010
 Quality Control