

TECO DIAGNOSTICS



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CERTIFICATE OF ANALYSIS
(BATCH RELEASE)

1. PRODUCT NAME: **GLYCOHEMOGLOBIN**
NORMAL CONTROL LOT#: 050491 EXP. DATE: 05/2012
ELEVATED CONTROL LOT#: 050492 EXP. DATE: 05/2012
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	102381	10/2011	8.5 – 11.5	10.0
Normal	050491	05/2012	5.9 – 8.1	7.0
Elevated	050492	05/2012	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	10.0	9.8	10.3	10.2	10.0	9.8	10.0	6/6
Normal	6.2	7.1	6.4	7.4	6.6	7.7	6.9	6/6
Elevated	14.1	12.4	12.7	13.6	12.4	13.6	13.1	6/6

COMMENTS: VISUAL CHECK OK

APPROVED
BY:



Quality Control

DATE: 8/3/2009