

Dept: Quality Assurance Issue Date: 5/20/2013

## CERTIFICATE OF ANALYSIS

## **Product Information**

**Product Name:** Metals Level 2

Product Number: 44522
Manufacture Date: 01/12
Lot Number: 7985
Expiration Date: 07/14

**Intended Use:** In vitro diagnostic

**Homogeneity:** Sufficiently homogeneous for analytical testing

**Precautions** 

Matrix: Normal human whole blood

Form: Lyophilized

**Residual Moisture Content:** < 1% **Anticoagulant:** EDTA

**Preservative:** Sodium Fluoride

**pH:** 6-7

**Virology:** Non-reactive for HBsAg, HCV, and HIV **Microbial Growth:** < 100 colony-forming units per milliliter

**Storage and Stability** 

**Storage Condition:**  $2-8^{\circ}\text{C} (35-46^{\circ}\text{F})$ 

**Reconstituted Stability:** 30 days **Volume Per Vial:** 3 mL

**Vial-to-Vial Variability:**  $3 \text{ mL} \pm 0.1\%$ 

**Origin of Raw Material** 

Whole Blood: Interstate Blood, Donor Units IM045180-UM014363

**Sodium Fluoride:** Mallinckrodt Baker, Lot H05168, 100% purity Sigma-Aldrich, Lot 63C-0510, ≥99% purity Arsenic: **Cadmium:** Sigma-Aldrich, Lot 96F-05251, ≥98% purity Sigma-Aldrich, Lot 96F-0471, ≥98% purity **Chromium:** Sigma-Aldrich, Lot 05009PC, 100% purity Lead: Manganese: Sigma-Aldrich, Lot 117F-0304, ≥99% purity **Mercury:** Sigma-Aldrich, Lot 74K-0015, 99.5% purity Sigma-Aldrich, Lot 28F-0497, ≥98% purity Selenium: Thallium: Spectrum, Lot TF1024, 100% purity

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## **ICP/MS Reference Value**

21 ng/mL **Arsenic:** 4.9 ng/mL **Cadmium: Chromium:** 12 ng/mL Lead:  $40.3 \,\mu g/mL$ 25 ng/mL Manganese: Mercury: 14 ng/mL Selenium: 206 ng/mL 9.3 ng/mL Thallium:

Approved by: Kevín Kopp

**Quality Assurance** 

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