

	UTAK Laboratories, Inc.	FM-75-05-02
	Certificate of Analysis	Revision: C Date: 11/18/15

CERTIFICATE OF ANALYSIS

Product Information

Product Name: Metals Level 2
Product Number: 44522
Manufacture Date: 03/15
Lot Number: A4230
Expiration Date: 09/17
Intended Use: In vitro diagnostic
Homogeneity: Sufficiently homogeneous for analytical testing

Precautions

Matrix: Normal Human Whole Blood
Form: Lyophilized
Anticoagulant: Potassium Oxalate
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°C (35-46°F)
Open Bottle Stability: 30 days *
Volume Per Bottle: 3 mL ± 0.1%

* Whole Blood can be aliquoted and refrozen; multiple freeze/thaw cycles are not recommended

Origin of Raw Material

Whole Blood: Biological Specialty Corp., Donor Units LS8818587-818963, LS8818702-TU08913
Sodium Fluoride: Spectrum Chemical, Lot CB10569, 100% purity
EDTA Sodium Salt: Sigma-Aldrich, Lot 100K0283, 100% purity
Arsenic: Sigma-Aldrich, Lot 63C-0510, ≥99% purity
Cadmium: Sigma-Aldrich, Lot 96F-05251, ≥98% purity
Chromium: Sigma-Aldrich, Lot STBC8008V, ≥98% purity
Lead: Sigma-Aldrich, Lot BCBD0769, 100% purity
Manganese: Sigma-Aldrich, Lot 117F-0304, ≥99% purity
Mercury: Sigma-Aldrich, Lot 74K-0015, 99.5% purity
Selenium: Sigma-Aldrich, Lot 28F-0497, ≥98% purity
Thallium: Spectrum, Lot TF1024, 100% purity

ICP/MS Reference Value

Arsenic: 29.2 ng/mL

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Cadmium: 5.1 ng/mL
Chromium: 15.2 ng/mL
Lead: 40.7 µg/dL
Manganese: 31.4 ng/mL
Mercury: 14.9 ng/mL
Selenium: 210 ng/mL
Thallium: 12.2 ng/mL

Approved by: *Kevin Kopp*

Quality Assurance

CE