

Attachment 6.3
Anniston Community Health Survey: Follow up Study and Dioxin Analyses
Clinical Test Results Report

Dear Participant,

The following tables show the results of clinical tests that we performed in your blood or serum on *mm/dd/yyyy*. The results that are out of normal range are marked red.

These clinical tests are mostly those that your doctor would perform in an office. We would advise you to go over the results with your doctor. If he or she has any questions about some of the more specialized tests we did, he/she can contact us at numbers provided below.

Because we are providing these results _____ months after your blood was collected, the results may be of limited value to you or your physician, especially if you are already under treatment or being followed for a particular chronic condition that the results indicate.

Some individuals will not have the measurements for all tests. You may not have a measurement for some test because your level is lower than the limit of detection. You may also not have a measurement because your blood sample failed one of the laboratory quality control procedures. If the reason for missing measurement is known, that reason will be included with your results.

You or your physician may contact us with questions about your clinical test results by calling ATSDR at 770-488-_____.

Thank you for your understanding and your participation in the study.

Sincerely,

Study investigators.

Table 1. Results of your clinical tests for thyroid hormones, glycemic parameters, lipids, and liver function.

<i>Test name</i>	<i>Your Result</i>	<i>Comparison Values</i>	<i>Comments</i>
Thyroid Hormones and Antibodies			
Clinical Ranges			
Total Triiodothyronine (TT3)		80-180 ng/dL ¹	
Total Thyroxin (TT4)		4.5-12.5 µg/dL ¹	
Thyroid Stimulating Hormone (TSH)		0.30-3.0 mIU/L ¹	
Free T3 Index		80-180 ¹	
Free T4		0.8-2.0 ng/dL ¹	
Free T4 Index		4.5-12.5 ¹	
Thyroxin-Binding Globulin		14-31 µg/mL ¹	
Anti-Thyroglobulin Antibody		<0.4 U/mL ¹	
Anti-Thyroid Peroxidase Antibody		<1.0 IU/mL ¹	
Thyroid Hormone Binding Ratio		0.72-1.24 ¹	
Glycemic Parameters			
Clinical Guidelines and Ranges			
Glucose, fasting, 8-hr		<u>Diabetes Risk</u> ² Hypoglycemic: <70 mg/dL Normal: 70-99 mg/dL Increased Risk Diabetes: 100-125 mg/dL Diabetes: ≥126 mg/dL (confirmation required)	Critical Value: <40 mg/dL ³ Critical Value: >400 mg/dL ³
Insulin		<17 µU/ml ³	
Glycosylated Hemoglobin (HbA1c)		<u>Diabetes Risk</u> ² Normal: <5.7% Increased Risk Diabetes: 5.7-6.4% Diabetes: ≥6.5% (confirmation required)	
Thyrosine Phosphatase-like Protein Autoantibodies (IA 2)		Negative Antibody: DK<5 ³ Positive Antibody: DK≥5	
Glutamate Decarboxylase -65 (anti-GAD 65)		Negative Antibody: DK≤33 ³ Positive Antibody: DK>33	
Lipids			
Clinical Guidelines and Ranges			
Total Cholesterol		<u>Coronary Heart Disease Risk (CHD)</u> ⁴ Desirable: <200 mg/dL Borderline High: 200-239 mg/dL High: ≥240 mg/dL	
Triglycerides		<u>CHD Risk</u> ⁴ Desirable: <150 mg/dL	Critical Value: >1,500 mg/dL ³

		Borderline High: 150–199 mg/dL High: 200–499 mg/dL Very High: ≥500 mg/dL	
Low Density Lipoprotein Cholesterol		<u>CHD Risk</u> ⁴ Desirable: <100 mg/dL Low Risk: 100–129 mg/dL Borderline High: 130–159mg/dL High: 160–189 mg/dL Very High: ≥190 mg/dL	
High Density Lipoprotein Cholesterol		<u>CHD Risk</u> ⁴ Desirable: ≥60 mg/dL Borderline Risk: 40–60 mg/dL At Risk: <40 mg/dL	
Phospholipids		150-250 mg/dL ³	
Free Fatty Acids		0.01–0.6 mEq/L ³	
Liver Tests		Clinical Ranges	
Alanine Aminotransferase (ALT)		15–65 U/L ⁵	
Aspartate Aminotransferase (AST)		5–40 U/L ⁵	
γ-Glutamyl Transferase (GGT)		Female 5–55 U/L; Male 5–85 U/L ⁵	
Alkaline Phosphatase (ALP)		Female: 50–136 U/L; Male: 40–136 U/L ⁵	
Albumin		3.4–5.0 g/dL ⁵	Critical Value: <1.5 g/dL ⁵ Critical Value: >7.9 g/dL ⁵
Direct Bilirubin		0.0–0.3 mg/dL ⁵	NA
Total Bilirubin		0.0–1.0 mg/dL ⁵	Critical Value: >12.9 mg/dL ⁵

Table 2. Results of your clinical tests for heavy metals and trace metals.

Test name	Your Result	Comparison Values	Comments
Heavy Metals		Agency Guidelines, Standards, and NHANES Reference Ranges	
Lead (Pb)		1.34–3.90 µg/L ⁶ Desirable: <5.0 µg/dL ⁷ Elevated (Current or Potentially Pregnant or Lactating Women): 5.0–9.9 µg/dL ⁷ Elevated (All Adults): ≥10.0 µg/dL ^{9,10,11} (a.)	
Mercury (Hg)		0.89–5.32 µg/L ⁶ Desirable: <5.8 µg/L ¹³ *Elevated (Current or Potentially Pregnant, Lactating Women): 5.8–10.0 µg/L ¹³ *Elevated (All Adults): >10.0 µg/L ^{14,15} (b.)	
Cadmium (Cd)		0.33–1.70 µg/L ⁶ [Nonsmokers: 0.3–1.2 µg/L ¹⁸] [Smokers: 0.6–3.9 µg/L ¹⁸] Desirable: ≤5 µg/L ^{19,20, 21} Elevated: >5 µg/L ^{19,20, 21} (c.)	
Trace Metals			
Manganese		4.7–18.3 µg/L ²⁴ (d.)	
Selenium		97.3–176.9 µg/L ²⁵ (e.)	

ADDITIONAL COMMENTS, INCLUDING DETAILED REFERENCES WILL BE A PART OF THE REPORT TO THE PARTICIPANT ONLY IF ANY MEASUREMENTS ABOVE CRITICAL/ACTION LEVELS ARE FOUND TO BE PRESENT OR IF MORE DETAIL IS REQUESTED BY THE PARTICIPANT OR HIS/HER PHYSICIAN

Additional comments related to elevated levels of heavy metals and trace metals for you or your physician.

a. Elevated Lead levels

Action Level for women who are or might become pregnant or lactating: 5.0–9.9 µg/dL (CDC advisory level exceeded; discuss health risks; seek medical advice; reduce exposure; breastfeed with infant BLL monitoring)^{7,8}

Action Level All Adults: 10.0–39.9 µg/dL (CDC advisory threshold exceeded; seek medical evaluation; removal from exposure for women who are or might become pregnant or lactating; reduce exposure all others; breastfeed with infant BLL monitoring)^{7,8,9,10,11}

Action Level All Adults: ≥40.0 µg/dL (OSHA threshold exceeded; prompt medical evaluation; reduce exposure; pump breast milk and discard until BLL <40 µg/dL)^{7,8,12}

Action Level All Adults: ≥50.0 µg/dL (OSHA threshold exceeded; prompt medical evaluation; removal from exposure; ; pump breast milk and discard until BLL <40 µg/dL)^{7,8,12}

Action Level All Adults: ≥80.0 µg/dL (OSHA threshold exceeded; immediate medical evaluation; removal from exposure; pump breast milk and discard until BLL <40 µg/dL)^{7,8,11,12}

b. Elevated Mercury levels

Action Level for women who are or might become pregnant or lactating: 5.8–10.0 µg/dL¹³

Action Level All Adults: >10.0 µg/L^{14,15,16,17}

Action Level All Adults: ≥50 µg/L (immediate medical evaluation)¹⁸

c. Elevated Cadmium levels

Action Level All Adults: >5 µg/L (OSHA threshold exceeded; medical monitoring among workers; discretionary medical removal)^{19,20,21}

Action Level All Adults: >15 µg/L: (OSHA threshold exceeded; medical removal from exposure)^{19,20,21}

Toxic Range: 100–3,000 µg/L²²

d. Elevated Manganese levels²³

Critical Value: >37 µg/L²⁴

e. Elevated Selenium levels²³

Critical Value: <50 µg/L²⁵

Critical Value: >300 µg/L²⁵

References:

- ¹ University of Southern California Clinical Laboratories Endocrine Services.
- ² American Diabetes Association . Standards of Medical Care in Diabetes - 2011. Diabetes Care. January 2011;34(Supplement 1):S11-S61 (subject to periodic update).
- ³ Northwest Lipid Metabolism And Diabetes Research Laboratories.
- ⁴ NHLBI. 2004. [Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults \(Adult Treatment Panel III\)](http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm) (<http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm> - subject to periodic update).
- ⁵ Jacksonville Medical Center Clinical Biochemistry Laboratory (updated 25 July 2012)
- ⁶ CDC. 2012. 2007-2008 NHANES 50th to 95th percentiles from the Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, February 2012 (http://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Feb2012.pdf).
- ⁷ CDC. 2010. Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women (<http://www.cdc.gov/ncchd/lead/publications/LeadandPregnancy2010.pdf>).
- ⁸ Kosnett MJ, Wedeen RP, Rothenberg SJ, Hipkins KL, Materna BL, Schwartz BS, Hu H, Woolf A. Recommendations for medical management of adult lead exposure. Environ Health Perspect. 2007;115(3):173-181.
- ⁹ CDC. 2012. Nationally Notifiable Non-Infectious Conditions Case Definition (http://www.cdc.gov/nndss/document/2012_Case%20Definitions.pdf).
- ¹⁰ CDC. 2011. NIOSH Adult Blood-Lead Epidemiology and Surveillance Program (ABLES) 2009 Case Definition Update (http://intranet.cdc.gov/osels/phspo/bc/bc_registry_profiles/profile_adult_bloodlead_epidemiology_and_surveillance_program_ables.pdf).
- ¹¹ Henretig FM. Lead. Chapter 91 in Goldfrank's Toxicologic Emergencies, 8th Edition. Flomenbaum N, Goldfrank L, Hoffman R, Howland MA, Lewin N, Nelson L, eds. McGraw-Hill Professional: New York, NY.
- ¹² OSHA General Industry and Construction Lead Standard Medical Surveillance Guidelines (29 CFR 1910.1025 App C and 29 CFR 1926.62 App C, respectively).
- ¹³ US EPA. 2001. Integrated Risk Information System: Methylmercury (MeHg) (CASRN 22967-92-6) (<http://www.epa.gov/iris/subst/0073.htm>). Recommended maternal blood methylmercury =5.8 µg/L, below which exposures are considered to be without adverse effects. This estimate is based on recommendations in 2000 by the National Research Council. See *Toxicological Effects of Methylmercury* at http://books.nap.edu/catalog.php?record_id=9899. Assume: total blood mercury ≈ methylmercury in blood.
- ¹⁴ CDC. 2006. Emergency Preparedness and Response: Case Definitions for Chemical Poisoning – Mercury (Elemental, Inorganic, Organic) (<http://emergency.cdc.gov/agent/mercury/>).
- ¹⁵ Sue YJ. Mercury. Chapter 92 in Goldfrank's Toxicologic Emergencies, 8th Edition. Flomenbaum N, Goldfrank L, Hoffman R, Howland MA, Lewin N, Nelson L, eds. McGraw-Hill Professional: New York, NY.
- ¹⁶ ACGIH. 2007 TLVs and BEIs. Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati (OH): Signature Publications. ACGIH recommends that the blood levels due to inorganic mercury exposure in workers not exceed 15 µg/L. Information about the biological exposure indices is provided here for comparison, not to imply a safety level for general population exposure.
- ¹⁷ HSDB. 2012. Blood levels of 10–15 µg/L are common in patients eating several fish meals per week (Accessed 26 July 2012).
- ¹⁸ ATSDR. 2011. Medical Management Guidelines for Mercury (Hg): CAS 7439-97-6; UN 2024 (liquid compounds) (<http://www.atsdr.cdc.gov/MHMI/mmg46.pdf>).
- ¹⁹ Tietz NW (ed). 1995. Clinical Guide to Laboratory Tests. 3rd Ed. WB Saunders Co.: Philadelphia, PA.
- ²⁰ OSHA. 1993. Substance Safety Data Sheet for Cadmium – Medical Surveillance Program (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10036).
- ²¹ ATSDR. 2011. Case Studies in Environmental Medicine – Cadmium. Elevated blood cadmium levels confirm recent acute exposure, but do not correlate with body burden or clinical outcome, and should not be used to determine the need for treatment.
- ²² Traub SJ, Hoffman RS. Cadmium. Chapter 87 in Goldfrank's Toxicologic Emergencies, 8th Edition. Flomenbaum N, Goldfrank L, Hoffman R, Howland MA, Lewin N, Nelson L, eds. McGraw-Hill Professional: New York, NY.
- ²³ No NHANES reference ranges are available for blood manganese.

²⁴ Mayo Clinic Medical Laboratories. Test ID: MNB for Manganese, Blood (<http://www.mayomedicallaboratories.com/test-catalog/Overview/89120>; accessed 24 July 2012). Value greater than twice the upper limit of normal correlates with disease.

²⁵ Laclaustra M, Navas-Acien A, Stranges S, Ordovas JM, Guallar E. Serum selenium concentrations and diabetes in U.S. adults: National Health and Nutrition Examination Survey (NHANES) 2003-2004. *Environmental Health Perspect.* 2009;117(9):1409-1413. Restricted to adults 40+ years of age.

²⁶ CDC. 2004. Laboratory Procedure Manual (Selenium, Serum by Inductively Coupled Plasma-Dynamic Reaction (http://www.cdc.gov/nchs/data/nhanes/nhanes_03_04/l39_c_met_selenium.pdf) performed by NYS DOH Wadsworth Center Trace Elements Laboratory.