

Pease Study Clinical Test Results Report

Dear [NAME/NAME OF PARENT OR GUARDIAN],

The following tables show the results of clinical tests that we performed in [your/your child's] blood or serum on |_|_|/|_|_|/|_|_|. 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 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 or she can contact us at the number provided below.

Because we are providing these results |_|_| months after ATSDR collected [your/your child's] blood, the results may be of limited value to you or your doctor, especially if you are already under treatment or being followed for a particular chronic condition that the results indicate.

Some people will not have results for all chemicals. [You/Your child] may not have a result for a chemical test if [your/his/her] level is lower than the lab's limit of detection (<LOD). [You/Your child] may also not have a result if the blood sample did not pass a lab quality control check. If the reason for missing results is known, it will be included with [your/your child's] results.

You or your physician may contact us with questions about [your/your child's] clinical test results by calling ATSDR at [*study telephone number*].

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

Sincerely,

Marian Pavuk, MD, PhD

Frank Bove, DSc

Co-Principal Investigators
Pease PFAS Health Study

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

* NOTE: the displayed clinical ranges will be updated when the contract labs are selected.

Test name	Your Result	Adult Comparison Values	Child Comparison Values
Thyroid Hormones and Antibodies			
Clinical Ranges			
Thyroid Stimulating Hormone (TSH)		18-19 years: 0.5-4.3 mIU/L ¹ >20 years: 0.3-4.2 mIU/L	4-5 years: 0.7-6.0 mIU/L 6-10 years: 0.6-4.8 mIU/L
Total Thyroxin (TT4)		18 -19 years: 5.9-13.2 mcg/dL ² ≥20 years): 4.5-11.7 mcg/dL ≥50 years: ≥6.0 ng/dL (check units) ³	4-5 years: 6.0-14.7 mcg/dL 6 -10 years: 6.0-13.8 mcg/dL 11 -17 years: 5.9-13.2 mcg/dL
Free T4		18-19 years: 1.0-1.6 ng/dL ² ≥20 years of age: 0.9-1.7 ng/dL	4-5 years: 1.0-1.8 ng/dL 6-10 years: 1.0-1.7 ng/dL 11-17 years: 1.0-1.6 ng/dL
Total Triiodothyronine (TT3)		18-19 years: 91-218 ng/dL ⁴ (> or =20 years): 80-200 ng/dL	4-5 years: 92-248 ng/dL 6-10 years: 93-231 ng/dL 11-17 years: 91-218 ng/dL
Other Hormones			
Total Testosterone		Males: ⁵ 18 years: 300-1,200 ng/dL ≥19 years: 240-950 ng/dL Females: 18 years: 20-75 ng/dL ≥19 years: 8-60 ng/dL	Males: 4-9 years: <7-20 ng/dL 10-11 years: <7-130 ng/dL 12-13 years: <7-800 ng/dL 14 years: <7-1,200 ng/dL 15-16 years: 100-1,200 ng/dL 17-18 years: 300-1,200 ng/dL ≥19 years: 240-950 ng/dL Females: 4-9 years: <7-20 ng/dL 10-11 years: <7-44 ng/dL 12-16 years: <7-75 ng/dL 17 years: 20-75 ng/dL

¹ <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8939>² <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/36108>³ <https://www.mayomedicallaboratories.com/test-catalog/appendix/criticalvalues/view.php?name=Critical+Values%2FCritical+Results+List>⁴ <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8613>⁵ <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/83686>

Attachment 23

Estradiol		<p>Males: ⁶ 10-40 pg/mL</p> <p>Females: Premenopausal: 15-350 pg/mL** Postmenopausal: <10 pg/mL **E2 levels vary widely through the menstrual cycle.</p>	<p>Males: Tanner Stage I <LOD-13 pg/mL Tanner Stage II <LOD-16 pg/mL Tanner Stage III <LOD-26 pg/mL Tanner Stage IV <LOD-38 pg/mL Tanner Stage V 10-40 pg/mL</p> <p>Females: Tanner Stage I <LOD-20 pg/mL Tanner Stage II <LOD-24 pg/mL Tanner Stage III <LOD-60 pg/mL Tanner Stage IV 15-85 pg/mL Tanner Stage V 15-350 pg/mL</p>
Sex hormone-binding globulin (SHBG)		<p>Males: 10-57 nmol/L ⁷ Females (non-pregnant): 18-144 nmol/L</p>	<p>Males: Tanner Stage I 31-167 nmol/L Tanner Stage II 49-179 nmol/L Tanner Stage III 5.8-182 nmol/L Tanner Stage IV 14-98 nmol/L Tanner Stage V 10-57 nmol/L</p> <p>Females: Tanner Stage I 43-197 nmol/L Tanner Stage II 7.7-119 nmol/L Tanner Stage III 31-191 nmol/L Tanner Stage IV 31--166 nmol/L Tanner Stage V 18-144 nmol/L</p>
Follicle stimulating hormone (FSH)		<p>Males: ⁸ ≥18 years: 1.0-18.0 IU/L</p> <p>Females: ≥18 years: Premenopausal Follicular: 3.9-8.8 IU/L Midcycle: 4.5-22.5 IU/L Luteal: 1.8-5.1 IU/L</p>	<p>Males: 4-6 years: ≤6.7 IU/L 7-8 years: ≤4.1 IU/L 9-10 years: ≤4.5 IU/L 11 years: 0.4-8.9 IU/L 12 years: 0.5-10.5 IU/L 13 years: 0.7-10.8 IU/L 14 years: 0.5-10.5 IU/L 15 years: 0.4-18.5 IU/L</p>

⁶ <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/81816>

⁷ <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/9285>

⁸ <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8670>

Attachment 23

		Postmenopausal: 16.7-113.6 IU/L	<p>16 years: ≤ 9.7 IU/L 17 years: 2.2-12.3 IU/L</p> <p>Females 4-6 years: 3.3 IU/L 7-8 years: ≤ 11.1 IU/L 9-10 years: 0.4-6.9 IU/L 11 years: 0.4-9.0 IU/L 12 years: 1.0-17.2 IU/L 13 years: 1.8-9.9 IU/L 14-16 years: 0.9-12.4 IU/L 17 years: 1.2-9.6 IU/L</p>
Insulin-like growth factor (IGF-1)		<p>Males:⁹ 18-22 years: 91-442 ng/mL 23-25 years: 66-346 ng/mL 26-30 years: 60-329 ng/mL 31-35 years: 54-310 ng/mL 36-40 years: 48-292 ng/mL 41-45 years: 44-275 ng/mL 46-50 years: 40-259 ng/mL 51-55 years: 37-245 ng/mL 56-60 years: 34-232 ng/mL 61-65 years: 33-220 ng/mL 66-70 years: 32-209 ng/mL 71-75 years: 32-200 ng/mL 76-80 years: 33-192 ng/mL 81-85 years: 33-185 ng/mL 86-90 years: 33-179 ng/mL >91 years: 32-173 ng/mL</p> <p>Females: 18-22 years: 85-370 ng/mL 23-25 years: 73-320 ng/mL 26-30 years: 66-303 ng/mL 31-35 years: 59-279 ng/mL 36-40 years: 54-258 ng/mL 41-45 years: 49-240 ng/mL</p>	<p>Males: 4 years: 30-236 ng/mL 5 years: 39-250 ng/mL 6 years: 47-275 ng/mL 7 years: 54-312 ng/mL 8 years: 61-356 ng/mL 9 years: 67-405 ng/mL 10 years: 73-456 ng/mL 11 years: 79-506 ng/mL 12 years: 84-551 ng/mL 13 years: 90-589 ng/mL 14 years: 95-618 ng/mL 15 years: 99-633 ng/mL 16 years: 104-633 ng/mL 17 years: 107-615 ng/mL</p> <p>Females: 4 years: 33-237 ng/mL 5 years: 36-234 ng/mL 6 years: 39-246 ng/mL 7 years: 44-279 ng/mL 8 years: 51-334 ng/mL 9 years: 61-408 ng/mL 10 years: 73-495 ng/mL 11 years: 88-585 ng/mL</p>

⁹ <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/62750>

Attachment 23

		46-50 years: 44-227 ng/mL 51-55 years: 40-217 ng/mL 56-60 years: 37-208 ng/mL 61-65 years: 35-201 ng/mL 66-70 years: 34-194 ng/mL 71-75 years: 34-187 ng/mL 76-80 years: 34-182 ng/mL 81-85 years: 34-177 ng/mL 86-90 years: 33-175 ng/mL ≥91 years: 25-179 ng/mL	12 years: 104-665 ng/mL 13 years: 120-719 ng/mL 14 years: 136-729 ng/mL 15 years: 147-691 ng/mL 16 years: 153-611 ng/mL 17 years: 149-509 ng/mL
Glycemic Parameters		Clinical Guidelines and Ranges	
Glucose, fasting, 8-hr		Normal: <100 mg/dL ¹⁰ Prediabetes: 100–125 mg/dL Diabetes: ≥126 mg/dL Critical Value: <40 mg/dL ¹¹ Critical Value: ≥400 mg/dL ¹⁰	
Insulin		<17 µU/ml ³	
Glycosylated Hemoglobin (HbA1c)		<u>Diabetes Risk</u> ¹² Normal: <5.7% Prediabetes: 5.7-6.4% Diabetes: ≥6.5%	<18 years: Criteria for diagnosing diabetes have not been established.
Thyrosine Phosphatase-like Protein Autoantibodies (IA 2)		Negative Antibody: DK<5 ³ Positive Antibody: DK≥5	Store for later
Glutamate Decarboxylase -65 (anti-GAD 65)		Negative Antibody: DK≤33 ³ Positive Antibody: DK>33	Store for later

¹⁰ <http://www.diabetes.org/diabetes-basics/diagnosis/?loc=db-slabnav>

^{11,10} <https://www.mayomedicallaboratories.com/test-catalog/appendix/criticalvalues/view.php?name=Critical+Values%2FCritical+Results+List>

¹² <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/82080>

Attachment 23

Lipids		Clinical Guidelines and Ranges	
Total Cholesterol, fasting		<u>Coronary Heart Disease Risk (CHD)¹³</u> Adult, 18+ years: Desirable: <200 mg/dL Borderline High: 200-239 mg/dL High: ≥240 mg/dL	Child, 2-17 years: Acceptable: <170 mg/dL Borderline high: 170-199 mg/dL High: ≥200 mg/dL
Triglycerides, fasting		<u>CHD Risk¹²</u> Adult, 18+ years: Normal: <150 mg/dL Borderline High: 150-199 mg/dL High: 200-499 mg/dL Very High: ≥500 mg/dL Critical Value: >1,000 mg/dL	Child, 2-9 years: Acceptable: <75 mg/dL Borderline high: 75-99 mg/dL High: ≥100 mg/dL Child, 10-17 years: Acceptable: <90 mg/dL Borderline high: 90-129 mg/dL High: > or =130 mg/dL
Low Density Lipoprotein Cholesterol (LDL), fasting		<u>CHD Risk¹²</u> Adult, 18+ years: Desirable: <100 mg/dL Above Desirable: 100-129 mg/dL Borderline high: 130-159 mg/dL High: 160-189 mg/dL Very high: ≥190 mg/dL	Child, 2-17 years: Acceptable: <110 mg/dL Borderline high: 110-129 mg/dL High: ≥130 mg/dL
High Density Lipoprotein Cholesterol (HDL), fasting		<u>CHD Risk¹²</u> Adult, 18+ years: Males: ≥40 mg/dL Females: ≥50 mg/dL	Child, 2-17 years: Low: <40 mg/dL Borderline low: 40-45 mg/dL Acceptable: > 45 mg/dL
VLDL			
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	

¹³ <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8320>

Attachment 23

Albumin (ALB)		3.4–5.0 g/dL ⁵ Critical Value: <1.5 g/dL ⁵ Critical Value: >7.9 g/dL ⁵	
Total Bilirubin (TBIL)		0.0–1.0 mg/dL ⁵ Critical Value: >12.9 mg/dL ⁵	
Direct Bilirubin (Conjugated Bilirubin)		0.0–0.3 mg/dL ⁵	
Cytokeratin 18 M30 (CK-18 M30)		<u>No evident liver disease</u> ⁽²⁷⁻²⁸⁾	
Cytokeratin 18 M65 (CK-18 M65)		M30: <200 U/L and M65: <300 U/L <u>TASH</u> (toxicant associated steatohepatitis; consistent with necrosis) M30: <200 U/L and M65: >300 U/L <u>Other liver disease</u> (consistent with apoptosis) M30: >200 U/L	

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/nceh/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://wwwn.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 1910.1025App 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.

Attachment 23

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.

²⁷ Cave, M., Falkner, K. C., and McClain, C. J. (2011). Occupational and Environmental Liver Disease. In Zakim and Boyer's *Hepatology: A Textbook of Liver Disease* (T. Boyer, M. Manns, and A. Sanyal, Eds.) 6 ed., pp. 476-492. Elsevier Saunders, Philadelphia.

²⁸ Feldstein, A. E., Wieckowska, A., Lopez, A. R., Liu, Y. C., Zein, N. N., and McCullough, A. J. Cytokeratin-18 fragment levels as noninvasive biomarkers for nonalcoholic steatohepatitis: a multicenter validation study. 2009; *Hepatology* 50(4), 1072-8.