## Biochemical analytical plan in children and adults: performing laboratories, reference levels, reporting ranges, clinical guidelines, and critical values.

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| **Laboratory and Contact** | **Analyte** | **\* CLIA Cert.** | **Matrix** | **Volume** | **NHANES 1**  **(µg/L)**  **2013 - 2014** | |
| ***Children and Adults*** | | | | | | |
| ***NCEH/Division of Laboratory Sciences\****  *Contact: Dr. Antonia Calafat* | *Per- and Poly-fluoroalkyl Substances (PFAS)* | Yes | Serum | 1 ml (for all PFAS);  1 ml reserve (for future PFAS analyses) | **Age Group (years):** | **50th to 95th %** |
| perfluorooctanoic acid (PFOA)‡ | 3-5:  6-11:  12-19:  20+: | 1.80 – 5.58  1.94 – 3.84  1.67 – 3.47  2.07 – 5.60 |
| n-PFOA - linear isomer | 3-5:  6-11:  12-19:  20+: | 1.72 – 5.32  1.84 – 3.77  1.60 – 3.40  2.00 – 5.40 |
| Sb-PFOA - serum branched isomer | 3-5:  6-11:  12-19:  20+: | < LOD – 0.280  < LOD – 0.230  < LOD – 0.200  < LOD – 0.200 |
| perfluorooctane sulfonic acid, (PFOS)‡ | 3-5:  6-11:  12-19:  20+: | 3.41 – 8.82  4.02 – 12.4  3.60 – 9.30  5.60 – 19.5 |
| n-PFOS – linear isomer | 3-5:  6-11:  12-19:  20+: | 2.11 – 6.19  2.65 – 8.41  2.70 – 7.10  3.70 – 15.1 |
| Sm-PFOS – serum branched | 3-5:  6-11:  12-19:  20+: | 1.00 – 3.60  1.41 – 4.25  1.00 – 2.30  1.60 – 5.30 |

Limit of detection (LOD, see Data Analysis section) for Survey year 13-14 is 0.1. < LOD means less than the limit of detection, which may vary for some chemicals by year and by individual sample.

1 CDC. 2018. 2013-2014 NHANES 50th to 95th percentiles among children 12-19 years and adults 20+ years old from the Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, March 2018. Accessed April 13, 2018 at (<https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Mar2018.pdf>).

‡ See Calculation of PFOS and PFOA as the Sum of Isomers for additional information in March 2018 Updated Tables.

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| **Laboratory and Contact** | **Analyte** | **\* CLIA Cert.** | **Matrix** | **Volume** | **NHANES 1**  **(µg/L)**  **2013 - 2014** | |
| ***Children and Adults*** | | | | | | |
| ***NCEH/Division of Laboratory Sciences\****  *Contact: Dr. Antonia Calafat* | *Per- and Poly-fluoroalkyl Substances (PFAS) (continued)* | Yes | Serum | 1 ml (for all PFAS);  1 ml reserve (for future PFAS analyses) | **Age Group (years):** | **50th to 95th %** |
| perfluorohexane sulfonic acid (PFHxS) | 3-5:  6-11:  12-19:  20+: | 0.740 – 1.62  0.850 – 4.14  1.10 – 6.30  1.40 – 5.50 |
| perfluorooctane sulfonamide (PFOSA) | 3-5:  6-11:  12-19:  20+: | < LOD – 0.110  < LOD - < LOD  n/a ‡  n/a ‡ |
| 2-(N-methyl-perfluorooctane sulfonamido) acetic acid (Me-PFOSAA) | 3-5:  6-11:  12-19:  20+: | 0.110 – 1.02  0.110 – 0.940  0.100 – 0.600  < LOD – 0.600 |
| 2-(N-ethyl-perfluorooctane sulfonamido) acetic acid (Et-PFOSAA) | 3-5:  6-11:  12-19:  20+: | < LOD - < LOD  < LOD - < LOD  n/a ‡  n/a ‡ |
| perfluorobutane sulfonic acid (PFBS) | 3-5:  6-11:  12-19:  20+: | < LOD - < LOD  < LOD – 0.130  < LOD - < LOD  < LOD - < LOD |
| perfluoroheptanoic acid (PFHpA) | 3-5:  6-11:  12-19:  20+: | < LOD – 0.310  < LOD – 0.170  < LOD – 0.200  < LOD – 0.100 |

Limit of detection (LOD, see Data Analysis section) for Survey year 13-14 is 0.1. < LOD means less than the limit of detection, which may vary for some chemicals by year and by individual sample. ‡ Not measured after Survey Years 2011-2012.

1 CDC. 2018. 2013-2014 NHANES 50th to 95th percentiles among children 12-19 years and adults 20+ years old from the Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, March 2018. Accessed April 13, 2018 at (<https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Mar2018.pdf>).

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| **Laboratory and Contact** | **Analyte** | **\* CLIA Cert.** | **Matrix** | **Volume** | **NHANES 1**  **(µg/L)**  **2013 - 2014** | | |
| ***Children and Adults*** | | | | | | | |
| ***NCEH/Division of Laboratory Sciences\****  *Contact: Dr. Antonia Calafat* | *Per- and Poly-fluoroalkyl Substances (PFAS) (continued)* | Yes | Serum | 1 ml (for all PFAS);  1 ml reserve (for future PFAS analyses) | **Age Group (years):** | | **50th to 95th %** |
| perfluorononanoic acid (PFNA) | 3-5:  6-11:  12-19:  20+: | | 0.620 – 3.49  0.750 – 3.19  0.500 – 2.00  0.700 – 2.00 |
| perfluorodecanoic acid (PFDA) | 3-5:  6-11:  12-19:  20+: | | 0.100 – 0.370  < LOD – 0.350  0.100 – 0.400  0.193 – 0.800 |
| perfluoroundecanoic acid (PFUnDA) | 3-5:  6-11:  12-19:  20+: | | < LOD – 0.370  < LOD – 0.250  < LOD – 0.200  < LOD – 0.500 |
| perfluorododecanoic acid (PFDoA) | 3-5:  6-11:  12-19:  20+: | | < LOD - < LOD  < LOD - < LOD  < LOD – 0.200  < LOD – 0.200 |
| **Laboratory and Contact** | **Proposed Biospecimen Bank for Future Analytes** | **\* CLIA Cert.** | **Matrix** | **Volume** | **NHANES TBD**  **(µg/L)**  **20xx – 20xx** | | |
| ***Children and Adults*** | | | | | | | |
| ***NCEH/Division of Laboratory Sciences\****  *Contact: Dr. Antonia Calafat* | *Per- and Poly-fluoroalkyl Substances (PFAS)* | Yes | Spot Urine (morning void) | 1 ml (for PFAS);  15 ml for creatinine/or specific gravity) | **Age Group:** | **50th to 95th %** | |
| To be determined (TBD) when analytical methods are developed  (Including but not limited to the following 18 analytes: PFOA  [n-PFOA;, Sb-PFOA], PFOA [n-PFOS, Sm-PFOS], PFHxS, PFBS, PFHpA, PFNA, PFDA, PFUnDA, PFPrS, PFHpS, PFBA, PFPeA, PFHxA, HFPO-DA (GenX), DONA, 9Cl-PF3ONS) | 3-5:  6-11:  12-19:  20+: | TBD  TBD  TBD  TBD | |
| Creatinine (for urinary creatinine correction; may be contracted) | TBD | | |

Limit of detection (LOD, see Data Analysis section) for Survey year 13-14 is 0.1. < LOD means less than the limit of detection, which may vary for some chemicals by year and by individual sample. ‡ Not measured after Survey Years 2011-2012.

1 CDC. 2018. 2013-2014 NHANES 50th to 95th percentiles among children 12-19 years and adults 20+ years old from the Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, March 2018. Accessed April 13, 2018 at (<https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Mar2018.pdf>).

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| **Laboratory and Contact** | **Analyte** | **\* CLIA Cert.** | **Matrix** | **Volume** | **Reportable Range, Guidelines,**  **Critical Values**  *Reference ranges will be updated when commercial lab is selected.* |
| ***Children and Adults*** | | | | | |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Lipids* | Yes | Serum | 0.5 ml  (for all) |  |
| Total cholesterol, fasting | Coronary Heart Disease Risk (CHD)[[1]](#footnote-1)  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 | CHD Risk1  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 (LDL), fasting | CHD Risk1  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 (HDL), fasting | CHD Risk1  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 |

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| **Laboratory and Contact** | **Analyte** | **\* CLIA Cert.** | **Matrix** | **Volume** | **Reportable Range, Guidelines,**  **Critical Values**  *Reference ranges will be updated when commercial lab is selected.* |
| ***Children and Adults*** | | | | | |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Uric Acid* | Yes | Serum | 1 ml | Males[[2]](#footnote-2)  ≤ 8.0 mg/dL  Females  ≤ 6.1 mg/dL |
| *Creatinine (to estimate glomerular filtration rate [eGFR])* | Males[[3]](#footnote-3)  1-2 years: 0.1-0.4 mg/dL  3-4 years: 0.1-0.5 mg/dL  5-9 years: 0.2-0.6 mg/dL  10-11 years: 0.3-0.7 mg/dL  12-13 years: 0.4-0.8 mg/dL  14-15 years: 0.5-0.9 mg/dL  > or =16 years: 0.8-1.3 mg/dL  Reference values have not been established for patients that are <12 months of age.    Females  1-3 years: 0.1-0.4 mg/dL  4-5 years: 0.2-0.5 mg/dL  6-8 years: 0.3-0.6 mg/dL  9-15 years: 0.4-0.7 mg/dL  > or =16 years: 0.6-1.1 mg/dL  Reference values have not been established for patients that are <12 months of age.    ESTIMATED GFR  >60 mL/min/BSA  **Note:** eGFR results will not be calculated for patients <18 or >70 years old. |
| **Laboratory and Contact** | **Analyte** | **\* CLIA Cert.** | **Matrix** | **Volume** | **Reportable Range, Guidelines,**  **Critical Values**  *Reference ranges will be updated when commercial lab is selected.* |
| ***Children and Adults*** | | | | | |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Thyroid Hormones* | Yes | Serum | 0.5 ml |  |
| Thyroid Stimulating Hormone (TSH) | 0.30-3.0 mIU/L [[4]](#footnote-4) |
| Free Total Thyroxine (Free T4) | 0.8-2.0 ng/dL |
| Total Thyroxine (TT4) | 4.5-12.5 µg/dL |
| Total Triiodothyronine (TT3) | 80-180 ng/dL |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Liver Tests* | Yes | Serum | 0.5 ml standard tests;  1 ml CK18 |  |
| Alanine transaminase (ALT) | 15-65 U/L [[5]](#footnote-5) |
| Aspartate transaminase (AST) | 5-40 U/L |
| Alkaline phosphatase (ALP) | Female: 50-136 U/L;  Male: 40-136 U/L |
| Gamma-glutamyltransferase (GGT) | Female 5-55 U/L;  Male 5-85 U/L |
|  |  |
| *Albumin (Alb)* | 3.4-5.0 g/dL  **Critical Value: <1.5 g/dL**  **Critical Value: >7.9 g/dL** |
| *Total bilirubin (TBIL)* | 0.0 – 1.0 mg/dL  **Critical Value: >12.9 mg/dL** |
| *Direct bilirubin (Conjugated Bilirubin)* | 0.0-0.3 mg/dL |
|  |  |
| *Non-alcoholic fatty liver disease (NAFLD)/steatohepatitis* |  |
| Cytokeratin 18 M30 (CK-18 M30)  Cytokeratin 18 M65 (CK-18 M65) | No evident liver disease: M30 <200 U/L and M65 <300 U/L  TASH: M30<200 U/L and M65 >300 U/L  Other liver disease: M30: >200 U/L |
| **Laboratory and Contact** | **Analyte** | **\* CLIA Cert.** | **Matrix** | **Volume** | **Reportable Range, Guidelines,**  **Critical Values**  *Reference ranges will be updated when commercial lab is selected.* |
| ***Children and Adults*** | | | | | |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Sex Hormones* | Yes | Serum | 1 ml |  |
| Testosterone | Males[[6]](#footnote-6)  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  17-18 years: 20-75 ng/dL  ≥19 years: 8-60 ng/dL |
| Estradiol | CHILDREN[[7]](#footnote-7)  Males   |  |  | | --- | --- | | **Tanner Stages** | **Reference Range** | | Stage I (>14 days and prepubertal) | <LOD-13 pg/mL | | Stage II | <LOD-16 pg/mL | | Stage III | <LOD-26 pg/mL | | Stage IV | <LOD-38 pg/mL | | Stage V | 10-40 pg/mL |   Females   |  |  |  | | --- | --- | --- | | **Tanner Stages** | **Mean Age** | **Reference Range** | | Stage I (>14 days and prepubertal) | 7.1 years | Undetectable-20 pg/mL | | Stage II | 10.5 years | Undetectable-24 pg/mL | | Stage III | 11.6 years | Undetectable-60 pg/mL | | Stage IV | 12.3 years | 15-85 pg/mL | | Stage V | 14.5 years | 15-350 pg/mL\*\* |   ADULTS  Males: 10-40 pg/mL  Females  Premenopausal: 15-350 pg/mL\*\*  Postmenopausal: <10 pg/mL  \*\*E2 levels vary widely through the menstrual cycle. |
| Sex hormone-binding globulin (SHBG) | CHILDREN[[8]](#footnote-8)  Males   |  |  | | --- | --- | | Tanner Stages | Reference Range | | Stage I | 31-167 nmol/L | | Stage II | 49-179 nmol/L | | Stage III | 5.8-182 nmol/L | | Stage IV | 14-98 nmol/L | | Stage V | 10-57 nmol/L |   Females   |  |  | | --- | --- | | Tanner Stages | Reference Range | | Stage I | 43-197 nmol/L | | Stage II | 7.7-119 nmol/L | | Stage III | 31-191 nmol/L | | Stage IV | 31-166 nmol/L | | Stage V | 18-144 nmol/L |   ADULTS  Males: 10-57 nmol/L  Females (non-pregnant): 18-144 nmol/L |
| Follicle stimulating hormone (FSH) | Males[[9]](#footnote-9)  4-6 years: < or =6.7 IU/L  7-8 years: < or =4.1 IU/L  9-10 years: < or =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  16 years: < or =9.7 IU/L  17 years: 2.2-12.3 IU/L  ≥18 years: 1.0-18.0 IU/L  Females  15 days-6 years: < or =3.3 IU/L  7-8 years: < or =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  ≥18 years:  Premenopausal  Follicular: 3.9-8.8 IU/L  Midcycle: 4.5-22.5 IU/L  Luteal: 1.8-5.1 IU/L  Postmenopausal: 16.7-113.6 IU/L |
| Insulin-like growth factor (IGF-1) |  |

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| **Laboratory and Contact** | **Analyte** | **\* CLIA Cert.** | **Matrix** | | **Volume** | | **Reportable Range, Guidelines,**  **Critical Values**  *Reference ranges will be updated when commercial lab is selected.* |
| ***Children and Adults*** | | | | | | | |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Immune Function* | Yes | Serum | | 2 ml | |  |
| Ig A, Ig G, Ig M, Ig E |  |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Glycemic Parameters* | Yes |  | |  | |  |
| Glycosylated hemoglobin (HbA1c) | Whole Blood EDTA | | 1 ml;  plus 1 ml reserve | | Diabetes Risk[[10]](#footnote-10)  Normal: <5.7%  Increased Risk Diabetes: 5.7-6.4%  Diabetes: ≥6.5% (confirmation required) |
| Glucose, fasting, 8-hour | Serum | | 1 ml Glucose/  Insulin;  1 ml antibodies | |  |
| Insulin | <17 µU/ml 8 |
| Pro-insulin | 3.6-22 pmol/L8 |
| C-peptide | 1.1-4.4 ng/mL8 |
| Glutamate Decarboxylase -65 (Anti-GAD 65) | Negative Antibody: DK≤33 8  Positive Antibody: DK>33 |
| Thyrosine Phosphatase-like Protein Autoantibodies (Anti-IA2) | Negative Antibody: DK<5 8  Positive Antibody: DK≥5 |
| ***Children Only*** | | | | | | | |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Antibodies to measles, mumps, rubella, tetanus, and diphtheria* | Yes | | Serum | | 1 ml |  |
| **Child Total** | | | | | | **Serum - 11ml Whole Blood – 2 ml Urine – 16 ml**  **Red Top 3 x10 ml EDTA Lavender Top 3 ml** | |

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| ***Adults Only*** | | | | | |
| ***Commercial Laboratory (to be determined)\****  *Contact:* | *Autoimmune Parameters* | Yes | Serum | 2 ml (for all) |  |
| Rheumatoid Factor (RF) | < 15 IU/mL[[11]](#footnote-11) |
| Antinuclear Antibody (ANA) screen | < or =1.0 U (negative)[[12]](#footnote-12)  1.1-2.9 U (weakly positive)  3.0-5.9 U (positive)  > or =6.0 U (strongly positive) |
| Antinuclear Antibody (ANA) titer |  |
|  |  |  |  |  |  |
|  | *Inflammatory Cytokines* |  |  |  |  |
|  | Interleukin 1-β (IL-1β), IL-4, IL-6, IL-8, IL-12, monocyte chemotactic protein-1 (MCP-1), tumor necrosis factor α (TNFα), leptin, adiponectin, resistin, plasminogen activator inhibitor-1 (PAI-1)*.* | No | Serum | 2 ml | Clinical reference levels not established. |
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| **Adult Total** | | | | **Serum – 15 ml Whole Blood – 2 ml Urine – 16 ml**  **Red Top 4 x 10 ml EDTA Lavender Top 3 ml** | |

1. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8320> [↑](#footnote-ref-1)
2. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8440> [↑](#footnote-ref-2)
3. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8472> [↑](#footnote-ref-3)
4. University of Southern California Clinical Laboratories Endocrine Services. [↑](#footnote-ref-4)
5. University of Louisville Department of Medicine, Gastroenterology (updated 14 October 2015). [↑](#footnote-ref-5)
6. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/83686> [↑](#footnote-ref-6)
7. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/81816> [↑](#footnote-ref-7)
8. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/9285> [↑](#footnote-ref-8)
9. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8670> [↑](#footnote-ref-9)
10. American Diabetes Association. Standards of Medical Care in Diabetes - 2011. Diabetes Care. January 2011;34(Supplement 1):S11-S61 (subject to periodic update). [↑](#footnote-ref-10)
11. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/9060> [↑](#footnote-ref-11)
12. <https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/9026> [↑](#footnote-ref-12)