National Health and Nutrition Examination Survey

August 2021-August 2023 Data Documentation, Codebook, and Frequencies

High-Sensitivity C-Reactive Protein (HSCRP_L)

Data File: HSCRP_L.xpt

First Published: September 2024

Last Revised: NA

Component Description

C-reactive protein (CRP) is an acute phase protein synthesized in the liver. It is involved in the activation of complement, enhancement of phagocytosis, and detoxification of substances released from damaged tissue. It is one of the most sensitive, though nonspecific, indicators of inflammation. CRP levels may rise within six hours of an inflammatory stimulus. Measurement of CRP concentrations by this highly sensitive method is performed primarily to ascertain the level of cardiovascular disease risk in individuals who have no existing inflammatory conditions. Increases in CRP concentration are non-specific and should be used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes.

Eligible Sample

Examined participants aged 1 year and older were eligible.

Description of Laboratory Methodology

This is a two-reagent, immunoturbidimetric system. The specimen is first combined with a Tris buffer, then incubated. The second reagent (latex particles coated with mouse anti-human CRP antibodies) is then added. In the presence of circulating CRP the latex particles aggregate, forming immune complexes. These complexes cause an increase in light scattering that is proportional to the CRP concentration. The light absorbance resulting from this light scatter is read against a stored CRP standard curve. The concentration of CRP is determined from this line. Turbidity is measured at a primary wavelength of 546 nm (secondary wavelength 800 nm).

Refer to the Laboratory Method Files section for a detailed description of the laboratory methods used.

There were no changes to the lab method or lab site for this component in the NHANES August 2021-August 2023 cycle. During the cycle, the laboratory equipment changed from the Cobas 6000 Analyzer to the Cobas 8000.

Laboratory Method Files

HS-CRP Laboratory Procedure Manual (September 2024)

Laboratory Quality Assurance and Monitoring

Serum specimens are processed, stored, and shipped to the University of Minnesota – Advanced Research Diagnostics Laboratory (ARDL), Minneapolis, MN for analysis.

Detailed instructions on specimen collection and processing are discussed in the NHANES Laboratory Procedures Manual (LPM). Vials were stored under appropriate frozen (–30°C) conditions until they were shipped to the University of Minnesota for testing.

The NHANES quality control and quality assurance protocols (QA/QC) meet the 1988 Clinical Laboratory Improvement Amendments mandates. Detailed QA/QC instructions are discussed in the NHANES LPM.

Mobile Examination Centers (MECs)

Laboratory team performance is monitored using several techniques. NCHS and contract consultants use a structured competency assessment evaluation during visits to evaluate both the quality of the laboratory work and the QC procedures. Each laboratory staff member is observed for equipment operation, specimen collection and preparation; testing procedures and constructive feedback are given to each staff member. Formal retraining sessions are conducted annually to ensure that required skill levels were maintained.

Analytical Laboratories

NHANES uses several methods to monitor the quality of the analyses performed by the contract laboratories. In the MEC, these methods include performing blind split samples collected during "dry run" sessions. In addition, contract laboratories randomly perform repeat testing on 2% of all specimens.

NCHS developed and distributed a QC protocol for all CDC and contract laboratories, which outlined the use of Westgard rules (Westgard, et. al., 1981) when running NHANES specimens. Progress reports containing any problems encountered during shipping or receipt of specimens, summary statistics for each control pool, QC graphs, instrument calibration, reagents, and any special considerations are submitted to NCHS quarterly. The reports are reviewed for trends or shifts in the data. The laboratories are required to explain any identified areas of concern.

Data Processing and Editing

The data were reviewed. Incomplete data or improbable values were sent to the performing laboratory for confirmation.

Analytic Notes

There are over 800 laboratory tests performed on NHANES participants. However, not all participants provided biospecimens or enough volume for all the tests to be performed. The specimen availability can also vary by age or other population characteristics. Analyst should evaluate the extent of missing data in the dataset related to the outcome of interest as well as any predictor variables used in the analyses to determine whether additional re-weighting for item non-response is necessary.

Please refer to the NHANES Analytic Guidelines and the on-line NHANES Tutorial for details on the use of sample weights and other analytic issues.

Phlebotomy Weights

For the August 2021-August 2023 cycle, analysis of nonresponse patterns for the phlebotomy component in the MEC examination revealed differences by age group and race/ethnicity, among other characteristics. For example, approximately 67% of children aged 1-17 years who were examined in the MEC provided a blood specimen through phlebotomy, while 95% of examined adults aged 18 and older provided a blood specimen. Therefore, an additional phlebotomy weight, WTPH2YR, has been included in this data release to address possible nonresponse bias. Participants who are eligible but did not provide a blood specimen have their phlebotomy weight assigned a value of "0" in their records. The phlebotomy weight should be used for analyses that use variables derived from blood analytes, and is included in all relevant data files.

Demographic and Other Related Variables

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The NHANES August 2021-August 2023 Demographics File contains demographic data, health indicators, and other related information collected during household interviews as well as the sample design variables. The recommended procedure for variance estimation requires use of stratum and PSU variables (SDMVSTRA and SDMVPSU, respectively) in the demographic data file.

The Fasting Questionnaire File includes auxiliary information, such as fasting status, length of fast and the time of venipuncture.

This laboratory data file can be linked to the other NHANES data files using the unique survey participant identifier (i.e., SEQN).

Detection Limits

The detection limit was constant for the analyte in the data set. Two variables are provided for this analyte. The variable name ending in "LC" (ex., LBDHRPLC) indicates whether the result was below the limit of detection: the value "0" means that the result was at or above the limit of detection, "1" indicates that the result was below the limit of detection. For the analyte with analytic results below the lower limit of detection (LBDHRPLC=1), an imputed fill value was placed in the analyte results field. This value is the lower limit of detection divided by the square root of 2 (LLOD/sqrt [2]). The variable prefixed LBX (ex., LBXHSCRP) provides the analytic result for that analyte.

The lower limit of detection (LLOD, in mg/L) for High-Sensitivity C-Reactive Protein:

Variable Name	Analyte Description	LLOD
LBXHSCRP	High Sensitivity C-Reactive Protein (mg/L)	0.15

High Sensitivity C-Reactive Protein (HSCRP) regression equations to compare August 2021-August 2023 and 2017-March 2020 data:

A method validation (bridging) study was performed to compare results from results from a laboratory instrument change that occurred during the August 2021–August 2023 survey cycle. The Cobas 6000 Chemistry Analyzer was upgraded to the Cobas 8000 Chemistry Analyzer during the cycle. Randomly selected serum samples (n=150) from previously NHANES were measured using both instruments and the results were used to conduct the analysis. On average, HSCRP values measured with the Cobas 6000 (2017-March 2020 instrument) were 14.28% higher than values measured with the Cobas 8000 (August 2021-August 2023 instrument) ($p = 0.0001$). Data from the bridging study indicated the correlation coefficient (r) between the measurements was 0.996. Regression analyses were performed using Analyse-it, v4.30.4. Given that the data showed proportional differences in variability, a weighted Deming

regression was chosen to describe the relation between the HSCRP results (mg/dL) from the two instruments as below:

Forward: Cobas 8000 = -0.08653 + 0.9672 * (Cobas 6000); 95% CI of slope (0.9388 to 0.9956) and intercept (-0.1157 to -0.05737).

Backward: Cobas 6000 = 0.08946 + 1.034 * (Cobas 8000); 95% CI of slope (1.003 to 1.065) and intercept (0.06146 to 0.1175).

These regression equations are provided for analytic use and should be applied according to the analytic aims and interests. The backwards equation can be used to ensure comparability between the August 2021-August 2023 cycle and previous years that were measured using the Cobas 6000 Analyzer values (2017-March 2020). The forward equation may be used if the interest is ensuring comparability with data collected using the Cobas 8000 Analyzer (August 2021-August 2023 and later) when comparing or combining the August 2021-August 2023 values with other years of data. Please note that HSCRP was first measured in the continuous NHANES in the 2015-2016 cycle, and it was not measured with the Cobas 6000 Analyzer then. For analysis involving 2015-2016 data, please refer to the documentation accompanying the 2017-2018 data (HSCRP_J) for additional adjustments.

References

- Westgard J.O., Barry P.L., Hunt M.R., Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem (1981) 27:493-501.

Codebook and Frequencies

SEQN - Respondent Sequence Number

Variable Name:	SEQN
SAS Label:	Respondent Sequence Number
English Text:	Respondent Sequence Number
Target:	Both males and females 1 YEARS - 150 YEARS

WTPH2YR - Phlebotomy 2 Year Weight

Variable Name: WTPH2YR

SAS Label: Phlebotomy 2 Year Weight

English Text: Phlebotomy 2 Year Weight

Target: Both males and females 1 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
4391.8220579 to 253478.77765	Range of Values	7626	7626	
0	No blood sample provided	1101	8727	
.	Missing	0	8727	

LBXHSCRP - HS C-Reactive Protein (mg/L)

Variable Name: LBXHSCRP

SAS Label: HS C-Reactive Protein (mg/L)

English Text: High-Sensitivity C-Reactive Protein (hs-CRP) (mg/L)

Target: Both males and females 1 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0.11 to 165.63	Range of Values	7282	7282	
.	Missing	1445	8727	

LBDHRPLC - HS C-Reactive Protein Comment Code

Variable Name: LBDHRPLC

SAS Label: HS C-Reactive Protein Comment Code

English Text: High-Sensitivity C-Reactive Protein (hs-CRP) Comment Code

Target: Both males and females 1 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0	At or above detection limit	7096	7096	
1	Below lower detection limit	186	7282	
.	Missing	1445	8727	