

# National Health and Nutrition Examination Survey

## 2015-2016 Data Documentation, Codebook, and Frequencies

### High-Sensitivity C-Reactive Protein (hs-CRP) (HSCRP\_I)

Data File: HSCRP\_I.xpt

First Published: May 2019

Last Revised: NA

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## Component Description

Measurement of C-Reactive protein (CRP) aids in evaluation of stress, trauma, infection, inflammation, surgery, and associated diseases. Cardiac CRP assays are indicated for use as an aid in the identification and stratification of individuals at risk for future cardiovascular disease. When used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, CRP may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or acute coronary syndrome.

## Eligible Sample

Examined participants aged 1 and older were eligible.

## Description of Laboratory Methodology

SYNCHRON System(s) High Sensitivity C-Reactive Protein reagent is based on the highly sensitive Near Infrared Particle Immunoassay rate methodology. An anti-CRP antibody-coated particle binds to CRP in the patient sample resulting in the formation of insoluble aggregates causing turbidity.

The SYNCHRON System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 26 parts reagent. The system monitors the change in absorbance at 940 nanometers. This change in absorbance is proportional to the concentration of C-reactive protein in the sample and is used by the System to calculate and express C-reactive protein concentration based upon a single-point adjusted, pre-determined calibration curve.

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

This is a new component in the 2015-2016 survey cycle. However, there was a change in lab equipment. HS-CRP was measured on the Beckman Coulter UniCel DxC 600 Synchron and the Beckman Coulter UniCel DxC 660i Synchron Access chemistry analyzers in the 2015-2016 cycle.

## Laboratory Method Files

[High Sensitivity C-Reactive Protein](#) (May 2019)

## Laboratory Quality Assurance and Monitoring

Serum specimens were processed, stored, and shipped to the Collaborative Laboratory Services, Ottumwa, Iowa for analysis.

Detailed instructions on specimen collection and processing are discussed in the [NHANES Laboratory Procedures Manual \(LPM\)](#). Vials were stored under appropriate frozen ( $-30^{\circ}\text{C}$ ) conditions until they were shipped to Collaborative Laboratory Services for testing.

The NHANES quality control and quality assurance protocols (QA/QC) meet the 1988 Clinical Laboratory Improvement Act 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 quality-control 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 quality control 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

A change in laboratory equipment occurred in mid-2016. A comparison study between the old reference analyzer (Beckman UniCel® DxC 600 Synchron Access Clinical System) and the new replacement analyzer (Beckman UniCel® DxC 660i Synchron Access Clinical System) was conducted. It was determined that no statistical adjustment is required.

Refer to the [2015 - 2016 Laboratory Data Overview](#) for general information on NHANES laboratory data.

Please refer to the NHANES [Analytic Guidelines](#) and the on-line NHANES [Tutorial](#) for further details on the use of sample weights and other analytic issues.

### Demographic and Other Related Variables

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The [NHANES 2015 - 2016 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 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)	0.11

## 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

<b>Variable Name:</b>	SEQN
<b>SAS Label:</b>	Respondent sequence number
<b>English Text:</b>	Respondent sequence number.
<b>Target:</b>	Both males and females 1 YEARS - 150 YEARS

## LBXHSCRCP - HS C-Reactive Protein (mg/L)

**Variable Name:** LBXHSCRCP**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
0.08 to 188.5	Range of Values	7867	7867	
.	Missing	1298	9165	

## 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	6602	6602	
1	Below lower detection limit	1265	7867	
.	Missing	1298	9165	