



# 1 Subject

## 1.1 01-701-1023

### Demography

Sex	M
Race	WHITE
Ethnicity	HISPANIC OR LATINO
Description of Planned Arm	Placebo
Description of Actual Arm	Placebo
Country	USA
Study Site Identifier	701
Date/Time of First Study Treatment	2012-08-05
Date/Time of Last Study Treatment	2012-09-01

### Medical history (Start - End)

Body System or Organ Class	Dictionary-Derived Term	Start Date/Time of Medical History Event
INFECTIONS AND INFESTATIONS	APPENDICITIS	1956
SURGICAL AND MEDICAL PROCEDURES	APPENDICECTOMY	1956
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	UPPER LIMB FRACTURE	1963
INFECTIONS AND INFESTATIONS	SINUSITIS	1978
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	1982
SURGICAL AND MEDICAL PROCEDURES	INGUINAL HERNIA REPAIR	1999
NERVOUS SYSTEM DISORDERS	SCIATICA	2005
VASCULAR DISORDERS	HYPERTENSION	2005-10
NA	NA	2006-03-11
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	PAIN TRAUMA ACTIVATED	2006-04
SURGICAL AND MEDICAL PROCEDURES	PENILE PROSTHESIS INSERTION	2006-04
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	2007
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	2007
INFECTIONS AND INFESTATIONS	CELLULITIS	2009
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	2009
EYE DISORDERS	MYOPIA	NA
GASTROINTESTINAL DISORDERS	DYSPEPSIA	NA
GASTROINTESTINAL DISORDERS	GASTROESOPHAGEAL REFLUX DISEASE	NA
GASTROINTESTINAL DISORDERS	HIATUS HERNIA	NA
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	NA
NERVOUS SYSTEM DISORDERS	HEADACHE	NA
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	NA

### Concomitant medications

ACETYLSALICYLIC ACID - ASPIRIN - 325 - mg - PRN - ORAL		
UNCODED - MYLANTA - 1 - Tbsp - PRN - ORAL		
UNCODED - TUMS - 1 - TABLET - PRN - ORAL		

**Medication Class**

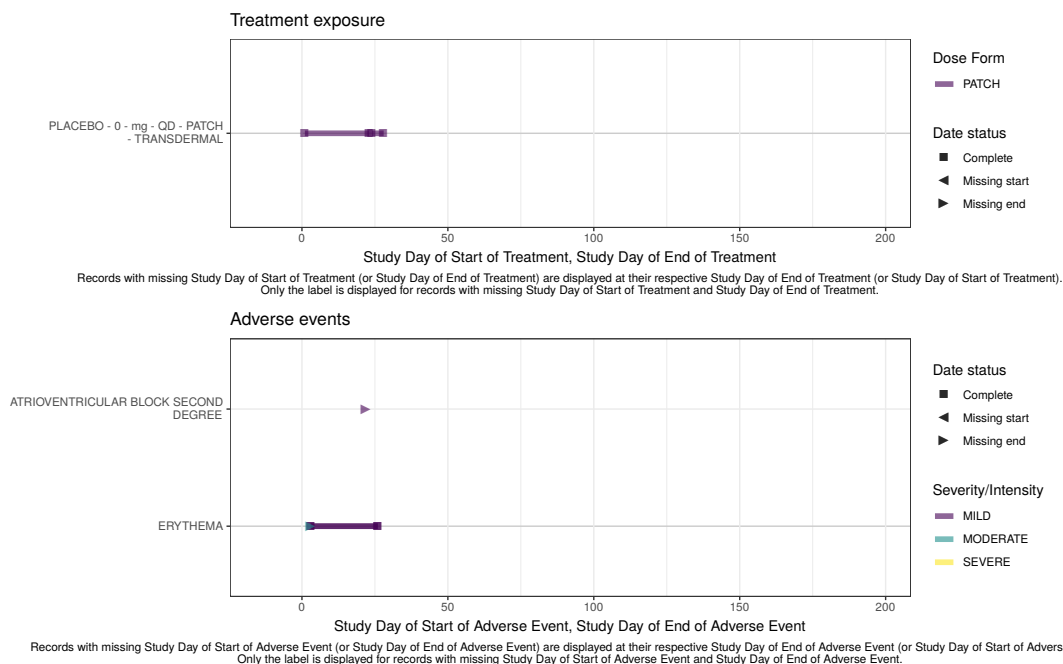
- ALIMENTARY TRACT AND METABOLISM
- ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
- BLOOD AND BLOOD FORMING ORGANS
- CARDIOVASCULAR SYSTEM
- DERMATOLOGICALS
- GENITO URINARY SYSTEM AND SEX HORMONES
- NERVOUS SYSTEM
- RESPIRATORY SYSTEM
- SYSTEMIC HORMONAL PREPARATIONS, EXCL.
- UNCODED

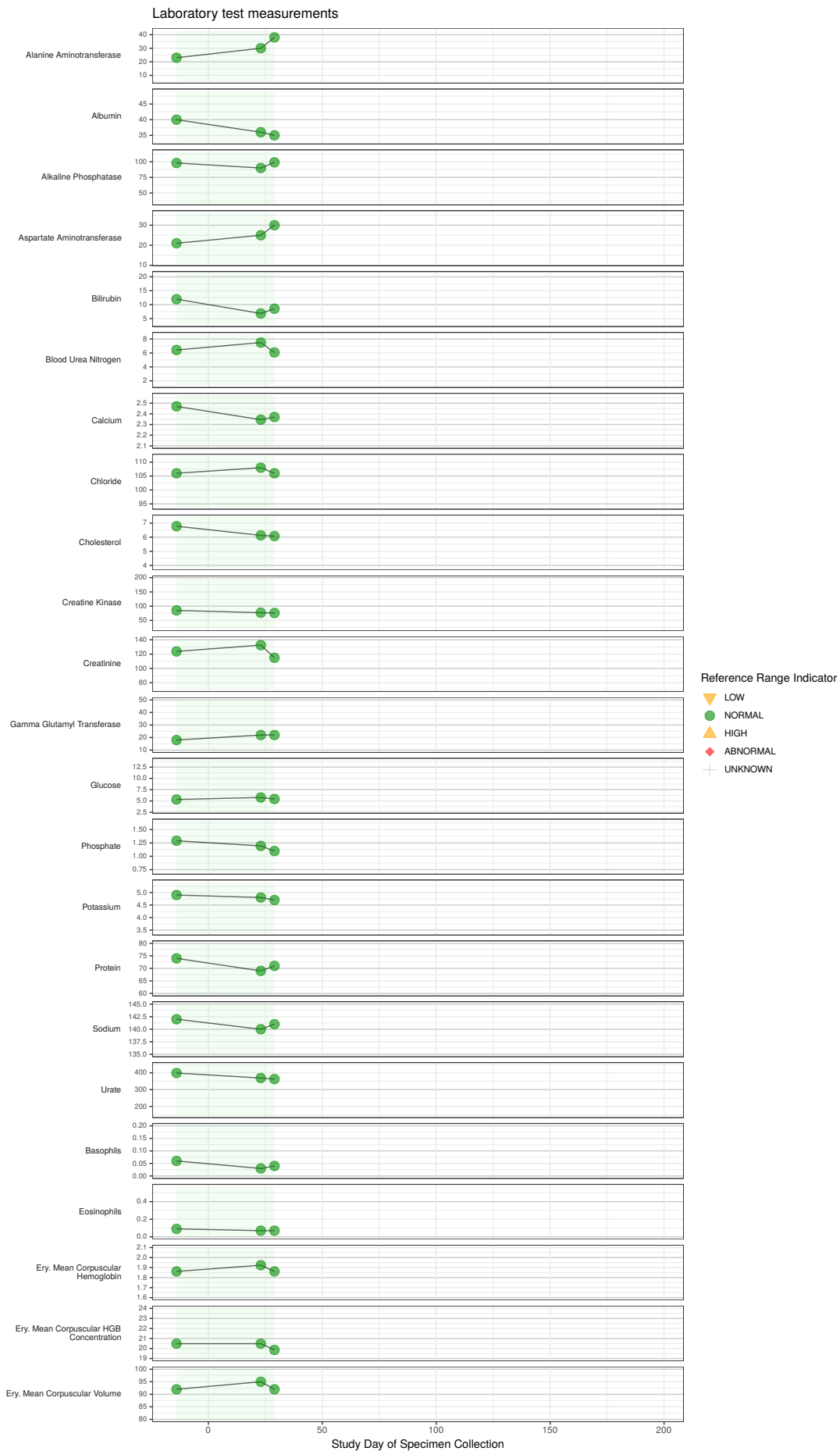
**Date status**

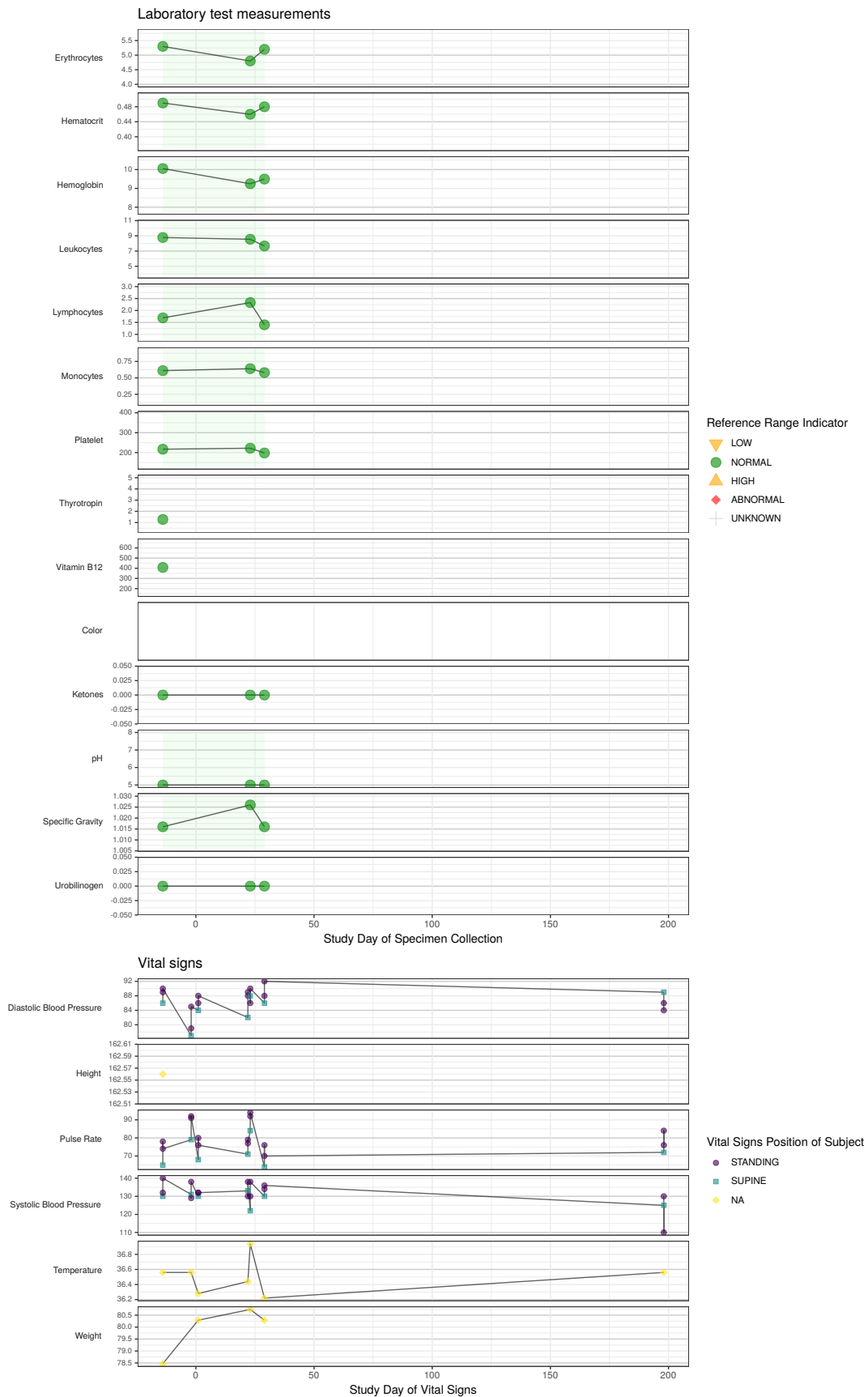
- Complete
- Missing start
- Missing end

Study Day of Start of Medication, Study Day of End of Medication

Records with missing Study Day of Start of Medication (or Study Day of End of Medication) are displayed at their respective Study Day of End of Medication (or Study Day of Start of Medication). Only the label is displayed for records with missing Study Day of Start of Medication and Study Day of End of Medication.







## 2 Appendix

### 2.1 Session information

This report was generated the: 2021-11-12 at 14:58:35.

- R version 3.6.1 (2019-07-05), x86\_64-pc-linux-gnu
- Locale: LC\_CTYPE=en\_US.UTF-8, LC\_NUMERIC=C, LC\_TIME=en\_US.UTF-8, LC\_COLLATE=en\_US.UTF-8, LC\_MONETARY=en\_US.UTF-8, LC\_MESSAGES=C, LC\_PAPER=en\_US.UTF-8, LC\_NAME=C, LC\_ADDRESS=C, LC\_TELEPHONE=C, LC\_MEASUREMENT=en\_US.UTF-8, LC\_IDENTIFICATION=C
- Running under: Ubuntu 18.04.4 LTS
- Matrix products: default
- BLAS/LAPACK: /usr/lib/x86\_64-linux-gnu/libopenblas-r0.2.20.so
- Base packages: base, datasets, graphics, grDevices, methods, stats, utils
- Other packages: clinDataReview 1.2.1, **clinUtils 0.1.0**, ggplot2 3.3.3, knitr 1.31, **patientProfilesVis 2.0.2**
- Loaded via a namespace (and not attached): bookdown 0.21, bslib 0.2.4, colorspace 2.0-0, compiler 3.6.1, cowplot 1.1.1, crayon 1.4.1, crosstalk 1.1.1, curl 4.3, data.table 1.14.0, digest 0.6.27, dplyr 1.0.5, DT 0.17, ellipsis 0.3.2, evaluate 0.14, fansi 0.4.2, farver 2.1.0, forcats 0.5.1, generics 0.1.0, glue 1.4.2, grid 3.6.1, gridExtra 2.3, gtable 0.3.0, haven 2.3.1, hms 1.1.1, htmltools 0.5.1.1, htmlwidgets 1.5.3, httr 1.4.2, jquerylib 0.1.3, jsonlite 1.7.2, jsonvalidate 1.1.0, labeling 0.4.2, lazyeval 0.2.2, lifecycle 1.0.0, magrittr 2.0.1, munsell 0.5.0, parallel 3.6.1, pillar 1.5.0, pkgconfig 2.0.3, plotly 4.9.3, plyr 1.8.6, purrr 0.3.4, R6 2.5.0, Rcpp 1.0.6, readr 2.0.2, reshape2 1.4.4, rlang 0.4.10, rmarkdown 2.7, sass 0.3.1, scales 1.1.1, stringi 1.5.3, stringr 1.4.0, tibble 3.1.0, tidyr 1.1.3, tidyselect 1.1.0, tools 3.6.1, tzdb 0.1.2, utf8 1.1.4, V8 3.4.0, vctrs 0.3.8, viridisLite 0.3.0, withr 2.4.1, xfun 0.21, yaml 2.2.1