

A5332 Testing Completeness

Target Enrollment: 7,500

Actual Enrollment: 7,560

Lipids

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Cholesterol	Cholesterol HDL Ratio	HDL Cholesterol	LDL Cholesterol	NON-HDL Cholesterol	Triglycerides	Percent Result
Entry	7,222	7,220	7,212	7,211	7,211	7,211	7,211	7,211	7,211	99.85%
Month 12	6,625	6,625	6,587	6,586	6,586	6,586	6,586	6,586	6,586	99.41%
Month 24	6,234	6,228	6,215	6,212	6,212	6,212	6,212	6,212	6,212	99.65%
Month 36	5,787	5,796	5,777	5,774	5,774	5,774	5,772	5,774	5,774	99.78%
Month 48	5,497	5,483	5,464	5,367	5,367	5,367	5,364	5,367	5,367	97.64%
Month 60	4,691	4,644	4,622	4,502	4,502	4,502	4,499	4,502	4,502	95.97%
Month 72	2,248	2,226	2,205	2,100	2,100	2,100	2,100	2,100	2,100	93.42%
Month 84	858	854	843	791	791	791	790	791	791	92.19%
Month 96	20	20	20	17	17	17	17	17	17	85.00%
Premature Study Discontinuation	214	208	211	209	209	209	209	209	209	97.66%
Premature Study Medication Discontinuation	763	751	747	741	741	741	741	741	741	97.12%
Study Termination	5,368	5,256	5,231	4,196	4,196	4,196	4,196	4,196	4,196	78.17%

Criteria: One aliquot of serum is sent at entry, month 12, month 24, month 36, month 48, month 60, month 72, month 84, and month 96

Glucose

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped From BRI	Observed Results	Percent Result
Entry	7,204	7,184	7,185	7,185	99.74%
Month 12	6,541	6,532	6,505	6,499	99.36%
Month 24	6,224	6,208	6,206	6,202	99.65%
Month 36	5,790	5,781	5,777	5,761	99.50%
Month 48	5,377	5,362	5,275	5,258	97.79%
Month 60	4,629	4,599	4,503	4,473	96.63%
Month 72	2,250	2,247	2,221	2,192	97.42%
Month 84	856	863	858	848	99.07%
Month 96	21	20	20	20	95.24%
Premature Study Discontinuation	232	205	205	205	88.36%
Premature Study Medication Discontinuation	820	750	746	734	89.51%
Study Termination	5,413	5,193	5,076	5,076	93.77%

Criteria: One aliquot of plasma is sent at entry, month 12, month 24, month 36, month 48, month 60, month 72, month 84, and month 96.

Albumin (from urine samples)

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	7,447	7,416	2,834	2,832	38.03%
Month 12	3,842	3,834	2,548	2,546	66.27%
Month 24	3,429	3,420	2,464	2,463	71.83%
Month 48	2,808	2,803	2,088	2,077	73.97%

Albumin-Creatinine Ratio (from urine samples)

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	7,447	7,416	2,834	2,832	38.03%
Month 12	3,842	3,834	2,548	2,435	63.38%
Month 24	3,429	3,420	2,464	2,290	66.78%
Month 48	2,808	2,803	2,088	1,923	68.48%

Creatinine (from urine samples)

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	7,447	7,416	2,834	2,831	38.02
Month 12	3,842	3,834	2,548	2,547	66.29
Month 24	3,429	3,420	2,464	2,463	71.83
Month 48	2,808	2,803	2,088	2,088	74.36

Protein (from urine samples)

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	7,447	7,416	2,834	2,734	36.71%
Month 12	3,842	3,834	2,548	2,545	66.24%
Month 24	3,429	3,420	2,464	2,463	71.83%
Month 48	2,808	2,803	2,088	2,076	73.93%

Protein-Creatinine Ratio G (from urine samples)

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	7,447	7,416	2,834	2,734	36.71%
Month 12	3,842	3,834	2,548	2,426	63.14%
Month 24	3,429	3,420	2,464	2,283	66.58%
Month 48	2,808	2,803	2,088	1,963	69.91%

Protein-Creatinine Ratio MG (from urine samples)

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	7,447	7,416	2,834	2,734	36.71%
Month 12	3,842	3,834	2,548	2,422	63.04%
Month 24	3,429	3,420	2,464	2,282	66.55%
Month 48	2,808	2,803	2,088	1,962	69.87%

EU5332 Testing Completeness

Target Enrollment: 250
 Actual Enrollment: 213

Lipids EU

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Cholesterol	Cholesterol HDL Ratio	HDL Cholesterol	LDL Cholesterol	NON-HDL Cholesterol	Triglycerides	Percent Result
Entry	212	212	212	212	212	212	212	212	212	100.00%
Month 12	202	202	196	196	196	196	196	196	196	97.03%
Month 24	189	188	185	187	187	187	187	187	187	98.94%
Month 36	179	179	172	177	177	177	177	177	177	98.88%
Month 48	64	64	0	64	64	64	64	64	64	100.00%
Premature Study Discontinuation	19	18	14	18	18	18	18	18	18	94.74%
Premature Study Medication Discontinuation	24	23	16	20	20	20	20	20	20	83.33%
Study Termination	170	170	0	170	170	170	170	170	170	100.00%

Criteria: One aliquot of serum is sent at entry, month 12, month 24, month 36, month 48, month 60, month 72, month 84, and month 96

Glucose

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped From BRI	Observed Results	Percent Result
Entry	206	206	206	206	100.00%
Month 12	199	199	199	191	95.98%
Month 24	187	187	187	179	95.72%
Month 36	179	179	178	169	94.41%
Month 48	64	64	63	21	32.81%
Premature Study Discontinuation	19	18	18	14	73.68%
Premature Study Medication Discontinuation	20	20	19	18	90.00%
Study Termination	170	170	170	48	28.24%

Criteria: One aliquot of plasma is sent at entry, month 12, month 24, month 36, month 48, month 60, month 72, month 84, and month 96.

AMH

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	1,953	1,953	1,889	1,888	96.67%

Criteria: One aliquot of serum from the entry visit is sent for female REPRIEVE participants enrolled after REPRIEVE Version 3.0. 4 aliquots must be available at the time of request.

Estradiol

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	1,953	1,953	1,889	1,888	96.67%

Criteria: One aliquot of serum from the entry visit is sent for female REPRIEVE participants enrolled after REPRIEVE Version 3.0. 4 aliquots must be available at the time of request.

Soluble CD14

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	4,659	4,648	4,584	4,583	98.37%
Month 12	4,192	4,189	4,002	4,002	95.47%

Criteria: One aliquot of EDTA PLASMA from the entry and month 12 visit is sent for participants enrolled after REPRIEVE Version 3.0. Samples won't be pulled for participants enrolled in the Sub-study at entry. 4 aliquots for ACTG sites and 2 aliquots for NON-ACTG sites must be available at time of request. Samples are only sent for month 12 if a sample was shipped for entry.

Oxidized LDL Cholesterol

Visit	Observed Collection	Observed Shipped From Site	Observed Shipped From BRI	Observed Result	Percent Result
Entry	4,659	4,648	4,584	4,583	98.37%
Month 12	4,192	4,189	4,002	4,002	95.47%

Criteria: One aliquot of EDTA PLASMA from the entry and month 12 visit is sent for participants enrolled after REPRIEVE Version 3.0. Samples won't be pulled for participants enrolled in the Sub-study at entry. 4 aliquots for ACTG sites and 2 aliquots for NON-ACTG sites must be available at time of request. Samples are only sent for month 12 if a sample was shipped for entry.

Target Enrollment: 800

Actual Enrollment: 805

Interleukin 6

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	792	99.00%
Month 4	726	723	715	715	98.48%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry, month 4, and month 24.

Note: Once thawed specimens

Oxidized LDL Cholesterol

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	792	99.00%
Month 4	726	723	715	715	98.48%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry, month 4 and month 24.

Note: Once thawed specimens

Lipoprotein Associated Phospholipase

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	792	99.00%
Month 4	726	723	715	715	98.48%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry, month 4 and month 24.

Note: Once thawed specimens

Monocyte Chemotactic Protein 1

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	792	99.00%
Month 4	726	723	715	715	98.48%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry, month 4, and month 24.

Note: Once thawed specimens

Soluble CD163

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	792	99.00%
Month 4	726	723	715	715	98.48%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry, month 4, and month 24.

Note: Once thawed specimens



Soluble CD14

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	792	99.00%
Month 4	726	723	715	715	98.48%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry, month 4, and month 24.
 Note: Once thawed specimens

Cholesterol

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Month 4	726	725	718	718	98.90%

Criteria: One aliquot of serum will be sent for each participant on the substudy at month 4.

Cholesterol/HDL-Cholesterol

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Month 4	726	725	718	718	98.90%

Criteria: One aliquot of serum will be sent for each participant on the substudy at month 4.



HDL-Cholesterol

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Month 4	726	725	718	718	98.90%

Criteria: One aliquot of serum will be sent for each participant on the substudy at month 4.

LDL-Cholesterol, Calculated

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Month 4	726	725	718	718	98.90%

Criteria: One aliquot of serum will be sent for each participant on the substudy at month 4.

NON-HDL Cholesterol

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Month 4	726	725	718	718	98.90%

Criteria: One aliquot of serum will be sent for each participant on the substudy at month 4.



Triglycerides

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Month 4	726	725	718	718	98.90%

Criteria: One aliquot of serum will be sent for each participant on the substudy at month 4.

LDL-Direct, Cholesterol

Visit	Observed Collection	Observed Shipped	Observed Shipped from BRI	Triglyceride > 400 mg/dl	Observed Result	Percent Result
Month 4	726	725	718	11	11	100.00%

Criteria: One aliquot of serum will be sent for each participant on the substudy at month 4. Only tested when triglycerides greater than 400mg/dL.

Flow Cytometry

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	797	795	788	98.50%
Month 24	694	691	691	675	97.26%

Criteria: One aliquot of PBMCs will be sent for each participant on the substudy at entry and month 24



CysC

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	721	90.13%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.

CMV IgG

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	721	90.13%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.

IL-10

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	720	90.00%
Month 24	694	691	681	681	98.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.



sTNFR

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	721	90.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry.

D-dimer

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	798	795	795	99.38%
Month 24	687	685	685	683	99.42%

Criteria: One aliquot of SCI plasma will be sent for each participant on the substudy at entry.

HSCRCP

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	797	795	792	792	99.37%
Month 4	726	725	718	712	98.07%
Month 24	693	690	690	690	99.57%

One aliquot of serum will be sent for each participant on the substudy at entry.

INSULIN

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	797	795	792	792	99.37%
Month 24	693	690	690	690	99.57%

One aliquot of serum will be sent for each participant on the substudy at entry.

Fibroblast Growth Factor 21

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	721	90.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry.

Note: Once thawed specimens

Fibroblast Growth Factor 23

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	721	90.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry.

Note: Once thawed specimens

Growth Differentiation Factor 15

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	721	90.13%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry.

Note: Once thawed specimens



Caspase-1

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	800	795	792	754	94.25%
Month 24	694	691	681	679	97.84%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.
 Note: Once thawed specimens

IL-18

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	797	795	792	754	94.60%
Month 24	693	690	690	679	97.98%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.
 Note: Once thawed specimens

IL-1 Beta

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	797	795	792	754	94.60%
Month 24	693	690	690	679	97.98%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.
 Note: Once thawed specimens

DiHydroEpiAndrosterone

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	797	795	792	795	99.75%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.
 Note: Once thawed specimens



Sex Hormone Binding Globulin

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	797	795	792	792	99.37%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.
 Note: Once thawed specimens

Testosterone

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	797	795	792	792	99.37%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.
 Note: Once thawed specimens

Troponin T

Visit	Observed Collection	Observed Shipped from Site	Observed Shipped from BRI	Observed Result	Percent Result
Entry	797	795	792	752	94.35%
Month 24	693	690	690	677	97.69%

Criteria: One aliquot of EDTA plasma will be sent for each participant on the substudy at entry and month 24.
 Note: Once thawed specimens