CLINICAL STUDY TO DETERMINE THE EFFECTIVENESS OF PHARMAPURE SUGAR BLOCKER REGARDING THE REDUCTION OF GLUCOSE IN THE BLOOD AND THE ACTUAL CRAVINGS FOR SUGAR

INVESTIGATIONAL PRODUCT / TEST MATERIAL:	PharmaPure Sugar Blocker
BIOMETRIX STUDY NUMBER:	0023-2020
DRAFT REPORT DATE:	03/02/2020
SPONSOR:	PURETEK CORP.
SPONSOR REPRESENTATIVE:	Barry Pressman bpressman@puretekcorp.com
INVESTIGATOR:	John Ademola, Ph.D. President / Chief Executive Officer Biometrix Inc.
INVESTIGATIVE SITE:	*Biometrix Research Institution* 2435 Ocean Avenue San Francisco, CA 94127
STARTING DATE:	February 26, 2020
DATE OF COMPLETION:	February 28, 2020
APPROVAL:	
Investigator:	J Ademola John Ademola, Ph.D. Date: 03/05/2020

Quality Assurance Statement

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in CFR 21, part 50 (Protection of Human Subjects Informed Consent).

This study report has been reviewed to assure that it correctly describes the methods of testing and that the reported results accurately reflect the data obtained during the clinical study. Quality Assurance personnel signing below attest that the study was conducted in accordance with Good Clinical Practices / International Conference on Harmonization E6 Guidelines as well as the study protocol and Biometrix Inc. Standard Operating Procedures.

Kelly Lockwood

Kelly Lockwood, M.S Biochemistry
Quality Assurance Manager

03/05/2020

Date

1.1 Introduction / Intended Use

Over the past ten years, testing has become an increasingly important part of health care. Much of the growth can be attributed to people's increased awareness of, and involvement with, the status of their own health. Testing has expanding to include tests for pregnancy, ovulation prediction, glucose, hydrogen, and total cholesterol. The hydrogen breath test is a test that uses the measurement of hydrogen in the breath to diagnose several conditions that cause gastrointestinal symptoms. In humans, only bacteria - specifically, anaerobic bacteria in the colon
- are capable of producing hydrogen. The bacteria produce hydrogen when they are exposed to unabsorbed food, particularly sugars and carbohydrates, but not proteins or fats. Although limited hydrogen is produced from the small amounts of unabsorbed food that normally reach the colon, large amounts of hydrogen may be produced when there is a problem with the digestion or absorption of food in the small intestine, that allows more unabsorbed food to reach the colon. Hydrogen Breath Test allows measurement of carbohydrate absorption and sugar craving following treatment with PharmaPure Sugar Blocker.

1.2 Objective

The primary objective of Clinical Study 2020-10 was to demonstrate the efficacy of PharmaPure Sugar Blocker in sugar craving, specifically, assessing intake hydrogen concentration in end expiratory air at 30 minutes intervals for 3 hours after PharmaPure Sugar Blocker treatment as well as at baseline, prior to treatment.

1.3 Testing Facility

Biometrix Research Institution, 2435 Ocean Avenue, San Francisco, CA 94127

1.4 Investigator

Principal Investigator: John Ademola, Ph D.

2.1 Test Material

PharmaPure Sugar Blocker

2.2 Test Material Handling

Test materials were stored in accordance with Sponsor's instructions. Receipt of test material from the Sponsor was recorded on log sheets and identified in association with Biometrix Study Number 0023-2020.

2.3 Study Design

This was a randomized, double-blind, placebo-controlled, 2-arm parallel study to evaluate the efficacy of PharmaPure Sugar Blocker in sugar craving on parameters of Hydrogen Breath Test as measure of carbohydrate absorption and sugar craving in the presence or absence of PharmaPure Sugar Blocker. Each study group included 15 subjects. Subjects were assigned to one of the two test groups, in accordance with a randomization schedule. One test group ingested glucose alone, and the other test group ingested glucose followed by PharmaPure Sugar Blocker. Subjects were provided with detailed instructions and guidelines [The Guidelines to be followed for prior to Hydrogen/Methane Breath Tests (see **Guidelines to Subjects** below).]

Baseline breath sampling and venous blood glucose testing was performed 30 minutes prior to administration of any oral product. The subject then ingested glucose alone or glucose followed by PharmaPure Blocker, as determined by the test group to which the subject was assigned. Glucose was prepared for each subject by dissolving 25g glucose in 100mL of water.

Additional breath samples for hydrogen and blood samples for glucose were collected every 30 minutes for three hours following ingestion of the glucose solution with or without treatment with the test material. All sampling was performed by trained staff. Breath samples were analyzed after each collection using calibrated equipment, with results recorded immediately into each subject record.

2.4 Study Duration

The duration of the study for each subject was approximately 3 to 4 hours including the screening period. The screening period was a maximum of 1 hour for eligibility determination, followed by a baseline measurement followed by a 3-hour experimentation period for breath and blood sampling.

3.1 Panelist Enrollment

The subjects were screened to ensure compliance with the Inclusion Criteria of the study protocol, listed below:

- Adult men and women (minimum 18 years of age).
- Subjects who follow detailed instructions and guidelines **prior to Hydrogen/Methane Breath Tests**.
- Educational levels from high school to post-graduate college education.
- The subjects must be able and willing to give informed consent.
- The subjects must be willing to provide pertinent dietary history if required.
- The subjects must be willing to follow the instructions related to the study.
- The subjects must NOT BE on antibiotic therapy, bismuth products, antimicrobial herbals* (i.e. berberine, oregano oil) or probiotics, bowel purgatives or Laxatives before the test.

Subjects were excluded for failure to meet any of the above criteria and for knowledge of any condition that is considered medically [relevant to the study and/or clinically significant] or would put the staff at risk for infection.

Vital signs were collected from all enrolled subjects. Demographic and vital sign information of enrolled subjects is listed in Appendix 1.

3.2 Informed Consent

An Informed Consent document was obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and limits of liability. Panelists signed and dated the Informed Consent to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number. The consent forms are available for inspection on the premises of BIOMETRIX.

3.3 Guidelines to Subjects

Subjects were provided with the following instructions in printed form.

Instructions and The Guidelines to be followed prior to Hydrogen/Methane Breath Tests

The day before your test, please limit your diet.

A low-residue diet that minimizes nonabsorbable carbohydrates (starches and sugars) is strongly recommended. Here are examples of foods that you CAN eat:

- Baked or broiled chicken, fish or turkey. (salt and pepper only)
- White bread only.
- Plain steamed white rice.
- Eggs
- Clear chicken or beef broth.
- Drink water, non-flavored black coffee, or tea.

AVOID foods like:

- Pasta, whole grain products, bran, high fiber cereals, granola, etc.
- Fruit juices, applesauce, apricots, bananas, cantaloupe, canned fruit cocktail, grapes, honeydew melon, peaches, watermelon. Raw and dried fruits like raisins and berries.
- Vegetable juices, potatoes, alfalfa sprouts, beets, green/yellow beans, carrots, celery, cucumber, eggplant, lettuce, mushrooms, green/red peppers, squash, zucchini, broccoli, cauliflower, brussels sprouts, cabbage, kale, swiss chard, beans, lentils, corn, etc.
- All nuts, seeds and beans, as well as foods that may contain seeds
- Milk, cheese, ice cream, yogurt, butter

- On the day of the study, subjects will report to **study clinic** *30 minutes* before to register.

4.1 Data Management and Analysis

To facilitate the accurate processing of the data, all data was carefully entered onto source document forms and analyzed. All data was then recorded on summary worksheets.

All triplicate or duplicate readings (analysis of hydrogen breath levels and glucose levels in capillaries and serum) for individual subjects and time points were averaged, and the average values are reported in the data tables in Appendices 2 through 7 by treatment category. Descriptive statistics (change from baseline for each evaluation parameter and subject and mean change of the study population at each post-baseline study interval) are reported to compare between the glucose alone and glucose plus PharmaPure Sugar Blocker treated subjects

4,2 Reporting Criteria

Breath hydrogen was measured at approximately 30-minutes intervals for 3 hours following ingestion of 25g glucose dissolved in 100 ml of water in subjects treated with and without PharmaPure Sugar Blocker. The definition of a positive test varies, but a rise of 10–20 ppm over basal values is usually considered to indicate sugar malabsorption. A positive test indicative of sugar malabsorption usually peaks at 2–4 hours while an early peak (within one hour of ingestion) may reflect rapid small bowel transit.

Breath hydrogen increase over the baseline, and lowest preceding value within the test period may be indicative of a positive result, i.e we expect to see the hydrogen levels increase if the glucose was not digested / absorbed in subjects treated with the test material at later time points after ingestion of the glucose solution.

A negative test over baseline value (before dosing with glucose with or without test material treatment) after treatment with PharmaPure Sugar Blocker will confirm the efficacy of PharmaPure Sugar Blocker in sugar craving.

5.1 Results

Hydrogen Levels from Breath Samples

Hydrogen levels measured from breath samples are listed in Appendix 2 for subjects receiving treatment with glucose plus PharmaPure Sugar Blocker. Appendix 3 lists the hydrogen levels for subjects ingesting glucose only. Changes from baseline are summarized below:

Treatment Group	Mean Change in Hydrogen Levels (ppm) from Baseline					
	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
Glucose + PharmaPure Sugar Blocker (n=18)	-0.6	-3.1	-2.5	2.9	2.9	2.6
Glucose Only (n=11)	-0.8	-4.7	-5.5	-3.1	-4.0	-3.4

Glucose Levels from Lancet Blood Samples

Glucose levels measured from lancet samples (capillary blood) are listed in Appendix 4 for subjects receiving treatment with glucose plus PharmaPure Sugar Blocker. Appendix 5 lists the glucose levels in capillary blood for subjects ingesting glucose only. Changes from baseline are summarized below:

Treatment Group	Mean Change in Capillary Glucose Levels (mg/dL) from Baseline					
	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
Glucose + PharmaPure Sugar Blocker (n=18)	39.7	2.1	-12.9	-15.1	-9.3	-5.2
Glucose Only (n=11)	49.9	34.3	7.4	-2.5	-0.8	-0.5

5.1 Results (Continued)

Post-Treatment:	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
Mean Glucose Reduction in Capillaries Percentage for treated group (%)	+33.5	+1.7	-10.9	-12.7	-7.8	-4.3

Glucose Levels from Venous Blood Samples

Glucose levels measured from venous blood samples are listed in Appendix 6 for subjects receiving treatment with glucose plus PharmaPure Sugar Blocker. Appendix 7 lists the glucose levels in venous blood for subjects ingesting glucose only. Changes from baseline are summarized below:

Treatment Group	Mean Change in Venous Glucose Levels (mg/dL) from Baseline					
	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
Glucose + PharmaPure Sugar Blocker (n=18)	40.8	-2.2	-12.1	-14.4	-7.6	-9.3
Glucose Only (n=11)	47.8	34.5	15.0	1.6	2.5	2.0

5.1 Results (Continued)

Post-Treatment:	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
Mean Glucose Reduction in Venous Blood Percentage for treated group (%)	+34.3	-1.8	-10.2	-12.1	-6.4	-8.1

5.2 Adverse Events

No adverse events were reported or observed during the study.

5.3 Conclusion

Under the conditions of this study, the test material, PharmaPure Sugar blocker demonstrated efficacy to reduce sugar absorption.

Hydrogen levels collected from breath samples of subjects ingesting the test material were consistent with that expected for sugar blockage. Hydrogen increases were detected at 120, 150 and 180 minutes after treatment with glucose and the test material, while hydrogen levels decreased at all time points for the test group receiving only glucose. As described in Section 4.2, sugar malabsorption is indicated by peaks in hydrogen levels between 2 and 4 hours from time of ingestion.

5.3 Conclusion (Continued)

This efficacy in blocking sugar absorption was supported by glucose levels in capillary and venous blood. Spikes in glucose levels in the capillaries were much lower, absent or decreased in the group receiving treatment with PharmaPure Sugar Blocker relative to the untreated control group receiving only glucose. Reductions in capillary glucose values were up to 12.7% relative to baseline, with peak decreases observed at 120 minutes. **Relative to the untreated group, capillary glucose absorption levels were 17.9% less in the treated group at 30 minutes, 33.7% less at 60 minutes, 18.5 % at 90 minutes, 17.7% at 120 minutes,9.2% at 150 minutes, and 4.8% at 180 minutes.**

Venous blood samples of treated subjects exhibited decreased glucose levels from one hour to three hours after glucose consumption, while untreated subjects exhibited higher venous glucose values at all intervals during the three-hour interval after ingesting the glucose solution. Reductions in venous blood glucose values were up to 12.1% relative to baseline, with peak decreases observed at 120 minutes. **Relative to the untreated group, venous glucose absorption levels were 14.9% less in the treated group at 30 minutes, 37.7% less at 60 minutes, 25.6% at 90 minutes, 14.7% at 120 minutes, 10.0% at 150 minutes, and 10.3% at 180 minutes.**

6.0 Document Retention

Documentation, including Informed Consent Forms, and all source documents generated during the conduct of this study will be retained in accordance with Biometrix Standard Operating Procedures and as determined by the Sponsor specification(s).

Appendix 1

Panelist Demographics and Vital Signs

Subject Number	Age	Ethnicity	Visit Date	Height (ft.in)	Weight (lbs)	BP (diastolic)	BP (systolic	Heart Rate	Temp. (°F)	Respiratory Rate
1	50	Asian	26-Feb	5.11	165.2	116	78	75	97.9	18
2	56	Caucasian	26-Feb	5.1	126.2	111	61	60	94.9	12
3	69	Caucasian	26-Feb	6	250	159	95	100	97.7	15
4	34	Asian	26-Feb	5.6	147	110	16	71	98.3	16
5	55	Caucasian	26-Feb	5.5	144.6	106	69	60	98.1	8
6	54	Latino	27-Feb	5.8	226.6	139	80	82	96.9	14
7	57	Caucasian	27-Feb	5.5	169.8	152	112	86	97.9	13
8	61	Caucasian	27-Feb	5.4	165	154	101	75	97.7	21
9	36	Asian	27-Feb	5.3	127	104	61	63	96.9	18
10	23	Caucasian	27-Feb	5.3	110	116	72	75	98.1	15
11	51	Caucasian	27-Feb	5.2	120	108	81	73	97.2	14
12	63	Caucasian	27-Feb	5.1	127	144	101	86	97.2	16
13	62	Caucasian	28-Feb	5.10	176.8	109	64	61	96.8	17
14	53	Asian	28-Feb	4.7	113	106	59	64	96.8	16
15	35	Caucasian	28-Feb	5.25	138	103	73	77	97.4	14
16	54	Caucasian	28-Feb	5.4	160	133	88	77	98.1	11
17	68	Asian	28-Feb	5	122	145	91	93	97.2	13
18	69	Caucasian	28-Feb	5.5	165	106	77	63	98.1	16
19	61	Asian	29-Feb	5.1	123.2	110	70	69	96.9	18
20	69	Caucasian	29-Feb	5.5	130.2	141	72	60	97.4	16
21	46	Chinese Asian	29-Feb	5	139.8	106	72	71	97.4	15
22	41	Caucasian	29-Feb	5.6	172.4	135	70	68	96.9	19
23	53	African American	29-Feb	5.10	193.5	176	117	69	97.1	11
24	25	Pacific Islander	29-Feb	5.4	227.6	122	73	74	97.1	18
25	34	Asian – Philipino	29-Feb	5.6	215	128	90	86	97.7	15
26	45	Caucasian	29-Feb	5.45	147.5	135	97	83	97.7	13
27	59	Asian	29-Feb	5.2	118.4	136	76	61	96.9	12
28	40	Asian Indian	29-Feb	5.4	147	130	80	62	98	16
29	51	Asian	29-Feb	5.9	160	110	80	77	96	16

Appendix 2

Hydrogen Levels in Breath Samples of Subjects Treated with Glucose Plus PharmaPure Sugar Blocker

Subject Number	Baseline (Before Glucose & Treatment)	Hydrogen Levels (ppm) After ingestion of glucose + PharmaPure Sugar Blocker						Change from Baseline					
		30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
2	8	9	0	0	0	0	6	1	-8	-8	-8	-8	-2
3	8	6	6	8	14	8.5	10	-2	-2	0	6	0.5	2
4	7.5	10.5	9	9	13.5	17	18.5	3	1.5	1.5	6	9.5	11
5	7.5	10	8	8	7.5	7.5	7.5	2.5	0.5	0.5	0	0	0
6	14.5	10	9	7.5	14	17.5	10	-4.5	-5.5	-7	-0.5	3	-4.5
7	17.5	19	17	17	17	13.5	13.5	1.5	-0.5	-0.5	-0.5	-4	-4
10	10	12	18.5	25	29	35	30.5	2	8.5	15	19	25	20.5
12	38	33	28	22	31	24	28	-5	-10	-16	-7	-14	-10
13	20	23	18	18	15.5	12.5	16	3	-2	-2	-4.5	-7.5	-4
15	70.5	57	37	23.5	28	26	25.5	-13.5	-33.5	-47	-42.5	-44.5	-45
17	16.5	20	15.5	20	14.5	12.5	15.5	3.5	-1	3.5	-2	-4	-1
19	0	0	0	0	0	0	0	0	0	0	0	0	0
21	7	9	8	13	17	14	8	2	1	6	10	7	1
22	14	21	20	20.6	24	23	28	7	6	6.6	10	9	14
23	6	6	6	10	9	8.5	7.5	0	0	4	3	2.5	1.5
25	17	12	13	19	36	29.5	24	-5	-4	2	19	12.5	7
27	7	0	0	0	13.5	9.5	11	-7	-7	-7	6.5	2.5	4
29	8	9.5	8.5	11	46	71.5	64	1.5	0.5	3	38	63.5	56
Mean	**15.4**	**14.8**	**12.3**	**12.9**	**18.3**	**18.3**	**18.0**	**-0.6**	**-3.1**	**-2.5**	**2.9**	**2.9**	**2.6**

Appendix 3

Hydrogen Levels in Breath Samples of Subjects Treated with Glucose Only

Subject Number	Hydrogen Levels (ppm)							Change from Baseline					
	Baseline (Before Glucose)	After ingestion of glucose											
		30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
1	8	9	0	0	0	0	6	1	-8	-8	-8	-8	-2
8	8	6	6	8	14	8.5	10	-2	-2	0	6	0.5	2
9	7.5	10.5	9	9	13.5	17	18.5	3	1.5	1.5	6	9.5	11
11	7.5	10	8	8	7.5	7.5	7.5	2.5	0.5	0.5	0	0	0
14	14.5	10	9	7.5	14	17.5	10	-4.5	-5.5	-7	-0.5	3	-4.5
16	17.5	19	17	17	17	13.5	13.5	1.5	-0.5	-0.5	-0.5	-4	-4
18	10	12	18.5	25	29	35	30.5	2	8.5	15	19	25	20.5
20	38	33	28	22	31	24	28	-5	-10	-16	-7	-14	-10
24	20	23	18	18	15.5	12.5	16	3	-2	-2	-4.5	-7.5	-4
26	70.5	57	37	23.5	28	26	25.5	-13.5	-33.5	-47	-42.5	-44.5	-45
28	16.5	20	15.5	20	14.5	12.5	15.5	3.5	-1	3.5	-2	-4	-1
Mean	**19.8**	**19.0**	**15.1**	**14.4**	**16.7**	**15.8**	**16.5**	**-0.8**	**-4.7**	**-5.5**	**-3.1**	**-4.0**	**-3.4**

Appendix 4

Glucose Levels in Lancet Samples (Capillary Blood) of Subjects Treated with Glucose Plus PharmaPure Sugar Blocker

Subject Number	Glucose Levels (mg/dL)							Change from Baseline					
	Baseline (Before Glucose & Treatment)	After ingestion of glucose + PharmaPure Sugar Blocker											
		30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
2	81	93	127	121	82	68	74	12	46	40	1	-13	-7
3	104	110	101	108	120	135	134	6	-3	4	16	31	30
4	89	100	87	89	124	157	117	11	-2	0	35	68	28
5	107	130	108	98	93	90	88	23	1	-9	-14	-17	-19
6	259	311	270	247	205	244	264	52	11	-12	-54	-15	5
7	88	151	121	95	108	112	126	63	33	7	20	24	38
10	101	164	103	106	103	95	97	63	2	5	2	-6	-4
12	69	145	105	102	104	126	Refused	76	36	33	35	57	X
13	96	100	108	88	72	70	66	4	12	-8	-24	-26	-30
15	84	108	112	80	104	103	80	24	28	-4	20	19	-4
17	112	180	116	108	92	100	104	68	4	-4	-20	-12	-8
19	103	197	95	76	80	95	197	94	-8	-27	-23	-8	94
21	128	159	124	96	101	103	97	31	-4	-32	-27	-25	-31
22	115	149	85	69	69	82	77	34	-30	-46	-46	-33	-38
23	118	166	118	103	97	106	164	48	0	-15	-21	-12	46
25	225	270	210	155	118	100	88	45	-15	-70	-107	-125	-137
27	149	193	94	77	83	101	116	44	-55	-72	-66	-48	-33
29	105	122	87	82	107	79	87	17	-18	-23	2	-26	-18
Mean	**118.5**	**158.2**	**120.6**	**105.6**	**103.4**	**109.2**	**116.2**	**39.7**	**2.1**	**-12.9**	**-15.1**	**-9.3**	**-5.2**
Mean Reduction Percentage (%)								**+33.5**	**+1.7**	**-10.9**	**-12.7**	**-7.8**	**-4.3**

X = Cannot be calculated due to subject refusal at 180 minutes

Appendix 5

Glucose Levels in Lancet Samples (Capillary Blood) of Subjects Treated with Glucose Only

Subject Number	Glucose Levels (mg/dL)							Change from Baseline					
	Baseline (Before Glucose)	After ingestion of glucose											
		30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
1	99	105	95	95	82	82	90	6	-4	-4	-17	-17	-9
8	80	157	150	99	109	118	98	77	70	19	29	38	18
9	99	177	159	93	87	88	94	78	60	-6	-12	-11	-5
11	109	191	198	190	130	113	112	82	89	81	21	4	3
14	112	177	101	82	92	95	95	65	-11	-30	-20	-17	-17
16	97	132	114	88	96	91	91	35	17	-9	-1	-6	-6
18	96	144	130	107	88	97	114	48	34	11	-8	1	18
20	99	170	136	102	92	82	73	71	37	3	-7	-17	-26
24	104	113	147	107	96	100	93	9	43	3	-8	-4	-11
26	81	99	96	88	75	97	111	18	15	7	-6	16	30
28	91	151	118	97	92	95	91	60	27	6	1	4	0
Mean	**97.0**	**146.9**	**131.3**	**104.4**	**94.5**	**96.2**	**96.5**	**49.9**	**34.3**	**7.4**	**-2.5**	**-0.8**	**-0.5**
Mean Change Percentage (%)								**+51.4**	**+35.4**	**+7.6**	**-2.6**	**-0.1**	**-.0.1**

Appendix 6

Glucose Levels in Venous Blood Samples of Subjects Treated with Glucose Plus PharmaPure Sugar Blocker

Subject Number	Glucose Levels (mg/dL)							Change from Baseline					
	Baseline (Before Glucose & Treatment)	After ingestion of glucose + PharmaPure Sugar Blocker											
		30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
2	90	93	104	105	83	93	86	3	14	15	-7	3	-4
3	107	117	105	116	111	126	Refused	10	-2	9	4	19	X
4	94	100	95	88	118	142	119	6	1	-6	24	48	25
5	105	150	97	83	92	94	88	45	-8	-22	-13	-11	-17
6	260	254	268	251	230	231	237	-6	8	-9	-30	-29	-23
7	98	192	111	92	112	111	100	94	13	-6	14	13	2
10	92	176	77	97	96	98	103	84	-15	5	4	6	11
12	94	134	98	100	Refused	102	Refused	40	4	6	X	8	X
13	106	116	88	72	65	66	80	10	-18	-34	-41	-40	-26
15	93	108	95	80	86	78	80	15	2	-13	-7	-15	-13
17	113	172	125	116	102	102	101	59	12	3	-11	-11	-12
19	98	193	105	86	90	110	180	95	7	-12	-8	12	82
21	114	171	123	108	110	112	104	57	9	-6	-4	-2	-10
22	104	136	82	75	85	93	95	32	-22	-29	-19	-11	-9
23	119	148	117	100	103	120	115	29	-2	-19	-16	1	-4
25	232	278	212	153	139	124	101	46	-20	-79	-93	-108	-131
27	Subject Refused Venous Blood Sampling												
29	105	180	85	97	78	93	94	75	-20	-8	-27	-12	-11
Mean	**119.1**	**159.9**	**116.9**	**107.0**	**106.3**	**111.5**	**112.2**	**40.8**	**-2.2**	**-12.1**	**-14.4**	**-7.6**	**-9.3**
Mean Reduction Percentage (%)								**+34.3**	**-1.8**	**-10.2**	**-12.1**	**-6.4**	**-8.1**

X = Cannot be calculated due to subject refusal at 120 and/or 180 minutes

Appendix 7

Glucose Levels in Venous Blood Samples of Subjects Treated with Glucose Only

Subject Number	Glucose Levels (mg/dL)							Change from Baseline					
	Baseline (Before Glucose)	After ingestion of glucose											
		30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.	30 Min.	60 Min.	90 Min.	120 Min.	150 Min.	180 Min.
1	99	72	71	89	75	86	96	-27	-28	-10	-24	-13	-3
8	95	179	144	99	111	118	105	84	49	4	16	23	10
9	94	154	138	90	98	100	94	60	44	-4	4	6	0
11	120	201	182	189	135	112	119	81	62	69	15	-8	-1
14	100	167	100	93	97	99	88	67	0	-7	-3	-1	-12
16	81	125	112	95	94	89	92	44	31	14	13	8	11
18	88	154	146	91	88	99	111	66	58	3	0	11	23
20	96	160	145	116	98	100	97	64	49	20	2	4	1
24	106	111	137	112	103	98	100	5	31	6	-3	-8	-6
26	90	92	101	100	79	85	89	2	11	10	-11	-5	-1
28	100	180	172	160	109	110	100	80	72	60	9	10	0
Mean	**97.2**	**145.0**	**131.6**	**112.2**	**98.8**	**99.6**	**99.2**	**47.8**	**34.5**	**15.0**	**1.6**	**2.5**	**2.0**
Mean Reduction Percentage (%)								**+49.2**	**+35,5**	**+15.4**	**+1.6**	**+2.6**	**+2.1**