

GLP Final Report

Report No.: T50372020

Sponsor

Solaplus Biotech Co., Ltd.
No.75 FengFang Road, Ouhai Economic Development
Zone, Wenzhou

Study Title

Hemostatic Xerogel Sponge Hemostasis Efficacy Animal
Study

Test Article

Hemostatic Xerogel Sponge
Model: XLJ- I -4

Test Facility

Mid-Link Technology Testing Co., Ltd.
B6, RongTong Building,
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Summary

Purpose: The purpose of this study was to evaluate the effectiveness of the control of sever bleeding by comparing the test article (Hemostatic xerogel sponge manufactured by Solaplus Biotech Co., Ltd.) against control article (HemCon® ChitoGauze® PRO).

Methods: Before study, the coagulation ability of each animal was determined. The femoral artery of animal was transacted to simulate the sever bleeding condition, then the test and control articles were applied on the wound (test articles for test group and control articles for control group). Observation was made on 3 minutes, 6 minutes and 10 minutes to determine bleeding condition and hemostasis time. The weights of the article before and after application were documented and calculated to determine the bleeding amount. Then the animals were allowed for survive for 3 hours (or any time IBP is lower than 20mmHg) to determine whether there was second bleeding.

Results: The animals in test group and control group had similar coagulation ability and blood flow condition before the study, because there was no statistical difference ($P \geq 0.05$) between the test group and the control group regarding the coagulation ability, hemostasis time. The hemostasis time of test group (6.43 ± 3.63 min) and control group (7.79 ± 4.00 min) was similar ($P \geq 0.05$). The readings of heart rate and IBP were stable before and after the study for both test and control group. All animals in both group survived for 3 hours. Blood loss during the hemostasis process of test group (23.56 ± 9.15 ml) and control group (18.07 ± 4.80 ml) were similar ($P \geq 0.05$).

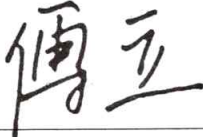
Conclusion:

Under the condition of this study, the test article was as effective and safe as the control article.

Surgeons and Evaluators:

Siqi Wang
Weiyi Chen

Approved by:



Lee Fu, Study Director



Date

Note: Authorization for duplication of this report, except in whole, is reserved pending Mid-Link's written approval.

GLP STATEMENT

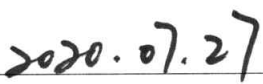
This nonclinical laboratory study was conducted in accordance with the United States Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58.

There was no deviation to the protocol or provisions of GLP Regulation noted during the course of the study.

Approved by:



Lee Fu, Study Director



Date

1. Purpose

The purpose of this study was to evaluate the effectiveness of the control sever bleeding by comparing the test article (Hemostatic xerogel sponge manufactured by Solaplus Biotech Co., Ltd.) against control article (HemCon® ChitoGauze® PRO).

2. Dates

Test Article Received: 07/06/2020
Initiated: 07/06/2020
Completed: 07/19/2020

3. Materials

Test Article Hemostatic xerogel sponge
Model XLJ-I-4
Manufacturer Same as sponsor
Status Irradiation Sterilization
Physical Description Solid
Composition Chitosan; Sodium polyacrylate; Polyethylene glycol
Stability Stability was determined by and on file with the sponsor.
Strength Not applicable, no active ingredient
Purity Not applicable, no active ingredient
Storage Condition Room Temperature
Note Information regarding the test article was provided by sponsor in the Sample Submission Form.

Control Article ChitoGauze
Model 7.5cm×3.7m
Manufacturer Hemcon Medical Technologies , Inc
Status Irradiation Sterilization
Physical Description Solid
Composition Not provide
Stability Marketed device, the stability is characterized by labeling.
Strength Not applicable, no active ingredient
Purity Not applicable, no active ingredient
Storage Condition Room Temperature
Note Information regarding the test article was provided by sponsor in the Sample Submission Form.

4. Materials and Equipments

Anesthetic Propofol Injectable Emulsion
Manufacturer Nhwa Pharma. Corporation
Lot Number 20190316

Anesthetic Xylazine Hydrochloride Injection
Manufacturer Changsha Best Biological Technology Institute CO.,LTD.

Lot Number	20191002
仪器	Patient Monitor
Manufacturer	Contec Medical Systems Co., Ltd.
Modle	CMS8000VET
Anesthetic	Stop Watch
Manufacturer	Shanghai Star Diamond stopwatch Co., Ltd
Modle	DM1-001
Anesthetic	Multi-function electronic balance
Manufacturer	Shanghai Puchun Measuring Instrument Co., Ltd
Modle	JX6001
Anesthetic	Semi-automatic coagulation analyzer
Manufacturer	Pram Medical Co., Ltd
Modle	PUN-2048A

5. Test System, Group and Justification

Species	Porcine
Breed:	Bama
Soruce:	Tianjin Bainong Laboratory Animal Breeding Technology Co., Ltd.
Sex:	Male and female, females were nulliparous and non-pregnant
Age:	Adult
Acclimation Period:	Minimum 7 days
Weight (kg)	62.4-67.8Kg
Identification	Ear Tag
Number and Group	28, 14 in test groups and 14 in control groups
Justifications	In history, Pig has been widely used in wound dressing research ^[1] . The sample size is statistically valid as follows: $N = \ln(1-q) / \ln(p)$, where N was the sample size, q was the confidence level which was 95% and p was the reliability which was 80%. The calculated result was 13.42, therefore, 14 animals for each group were used.
Note:	The details of each animal are provided in Appendix 2: Laboratory Animals Details.

6. Animal Management

Husbandry, Housing and Environment	Conditions conform to MID-LINK Standard Operating Procedures that are based on the “Guide of the Care and Use of Laboratory Animals”. Animals were individually housed in stainless steel cages identified by a card indicating the animal number, test identification and sex.
Food, Water and Contaminants	A commercially available porcine feed was provided daily. Potable water was provided ad libitum through species appropriate water containers. No contaminant present in the feed and water was expected to impact the results of this study.
Personnel	Associates involved in this study were appropriately qualified and trained.

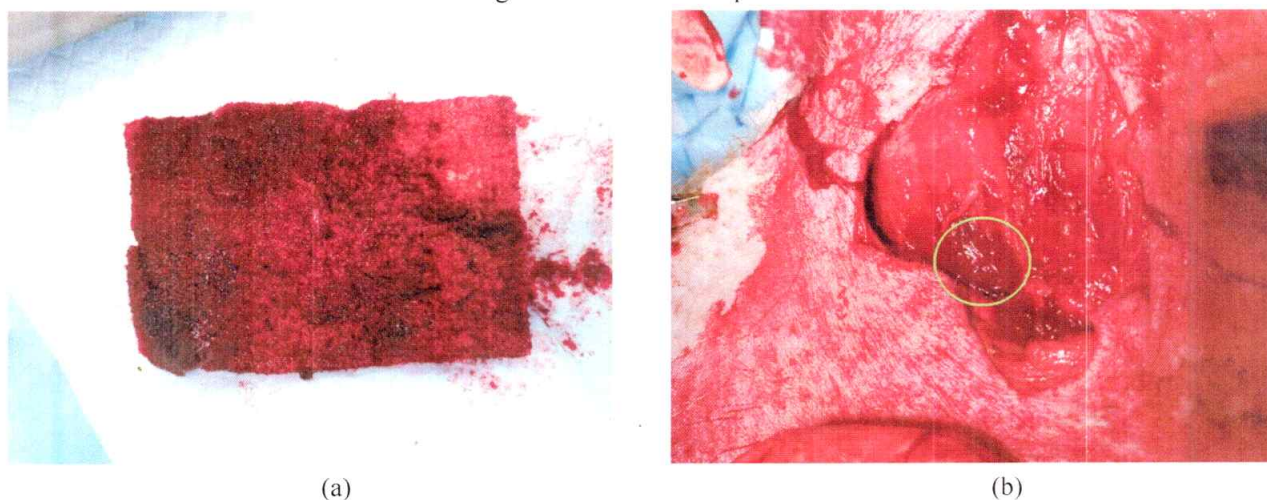
Veterinary Care

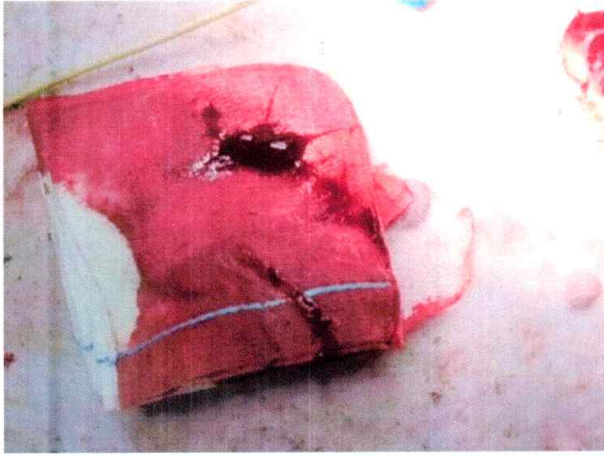
All anaesthetics, analgesics, and other medications are given or altered at the discretion of the attending veterinarian in accordance with standard veterinary practice and the study objectives. This applies to specific medication, dose, and dosing intervals. In the unlikely event that an animal should become injured, ill or moribund, care is conducted in accordance with current veterinary medical practice.

7. Method

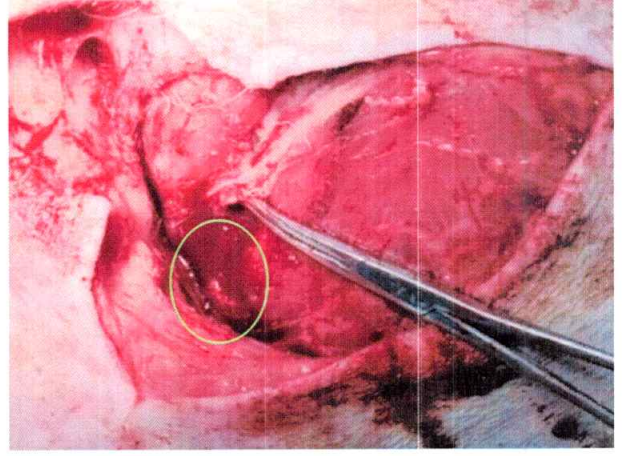
Animal is fast at least 8 hours prior to the operation. Xylazine Hydrochloride is injected intramuscularly for anesthesia induction, then propofol is dosed intravenously to maintain anesthesia. The animal is weighed and intubated. During the operation, the animal is kept in the state of deep anesthesia, vital signs are monitored. All the medical gauze and samples are weighed before application, the weight is recorded as W_0 . The animal is fixed on the operating table, the hair is removed from the suitable site of the operation, disinfect the surgical site using iodine. Blood is collected to evaluate the coagulation status (Sec 8.1). An incision is made to expose the femoral artery. Before creating the wound, sufficient medical gauze is placed under the artery. Formal artery is transacted and free bleeding is allowed for 5 seconds, then the artery is clamped, the medical gauze is removed and used for evaluation of initial rate of blood flow (Sec 8.2), the blood surrounding the wound is cleaned quickly and the clamp is released, then apply the sample to the wound, press with hand, and apply pressure to prevent a large amount of arterial blood from overflowing. Observation is made on 3 minutes, 6 minutes and 10 minutes to determine bleeding condition and hemostasis time (Sec 8.3). then the animals is allowed for survival for three hours, bleeding condition (Sec 8.3) and vital signs (Sec 8.4) is observed every 30 minutes, animal is terminated after 3 hours or any time when IBP is lower than 20mmHg. Before termination, the test sample is removed from the animal (see Fig.1) and weighed again. The weight is recorded as W_1 , then blood loss is calculated (Sec 8.5).

Fig1 Illustration of the operation





(c)



(d)

- (a) Test sample after test
 (b) test group: The wound after the examination
 (c) control sample after test
 (d) control group: The wound after the examination
 Note: '○' represents the hemostasis site

8. Evaluations

8.1 Coagulation Ability

Blood collected from each animal before the surgery is tested for Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (FIB). Results for each animal shall be reported. Means and standard deviations of test and control group shall be reported respectively. Independent T-Test is used to compare the results of test and control group, $P < 0.05$ indicates statistical difference.

8.2 Initial rate of blood flow

Initial rate of blood flow is calculated according to the following formula using the weight of medical gauze:

$$\text{Initial rate of blood flow (ml/sec)} = [(W_1 - W_0) / 1.05] / 5 ;$$

Results for each animal shall be reported. Means and standard deviations of test and control group shall be reported respectively. Independent T-Test is used to compare the results of test and control group, $P < 0.05$ indicates statistical difference.

8.3 Bleeding and Hemostasis Time

For each time point (3, 6 or 10 minutes), bleeding condition is determined. If there is no secondary bleeding, the time is recorded as Hemostasis Time. Results for each animal shall be reported. Means and standard deviations of test and control group shall be reported respectively. Independent T-Test is used to compare the results of test and control group, $P < 0.05$ indicates statistical difference.

8.4 Vital Signs

Vital signs including Heart Rate, SPO_2 and IBP is monitored and they are recorded every 30 minutes.

8.5 Blood loss

Blood loss is calculated according to the following formula using the weight of test sample:

$$\text{Blood loss (ml)} = (W_1 - W_0) / 1.05;$$

Results for each animal shall be reported. Means and standard deviations of test and control group shall be reported respectively. Independent T-Test is used to compare the results of test and control group, $P < 0.05$ indicates statistical difference.

9. Result

9.1 Coagulation Ability

Based on the results listed in Table 1 Coagulation Test Result, there was no statistical difference ($P \geq 0.05$) between the test group and the control group.

Table 1 Coagulation Test Result

item	Test group(n=14)	Control group(n=14)	P value
PTT (S)	12.05 ± 1.18	11.79 ± 0.65	0.492($P \geq 0.05$)
APTT (S)	14.92 ± 2.31	14.61 ± 1.74	0.690($P \geq 0.05$)
FIB (mg/dL)	245.82 ± 31.96	253.6 ± 42.84	0.591($P \geq 0.05$)

9.2 Initial rate of blood flow

Based on the results listed in Table 2 Initial Blood Flow Rate, there was no statistical difference ($P \geq 0.05$) between the test group and the control group.

Table 2 Initial Blood Flow Rate

item	Test group(n=14)	Control group(n=14)	P value
Initial rate of blood flow (ml/s)	8.22 ± 3.29	8.21 ± 2.79	0.994($P \geq 0.05$)

9.3 Bleeding and Hemostasis Time

Based on the results listed in Table 3 Hemostasis Time, there was no statistical difference ($P \geq 0.05$) between the test group and the control group.

Table 3 Hemostasis Time

item	Test group(n=14)	Control group(n=14)	P value
Bleeding and Hemostasis Time (min)	6.43 ± 3.63	7.79 ± 4.00	0.356($P \geq 0.05$)

9.4 Vital Signs

Based on the result listed in Table 4 Vital Signs Monitoring Results, the readings of heart rate and IBP were stable before and after the study for both test and control group. All animals in both group survived for 3 hours.

Table 4 Vital Signs Monitoring Results

item	Test group(n=14)		Control group(n=14)	
	Means	standard deviation	average value	standard deviation
Heart Rate (bpm)				
Before test	97.43	25.48	97.29	22.42
0min	99.57	26.51	96.43	18.60
30min	98.50	24.80	95.14	18.25
60min	94.79	22.92	92.00	17.20
90min	92.93	23.61	90.79	17.08
120min	94.14	23.02	90.21	18.67
150min	91.71	21.21	88.21	17.96
180min	91.71	21.58	88.07	16.79

IBP (mmhg)				
Before test	110.00	15.82	109.86	21.17
0min	96.36	15.04	95.36	11.08
30min	101.36	13.97	97.14	11.35
60min	101.43	14.56	98.50	13.40
90min	103.79	15.61	98.36	11.92
120min	102.50	12.78	96.57	12.76
150min	101.86	11.82	99.00	12.54
180min	102.36	10.59	99.57	12.22

SPO ₂ (%)				
Before test	96.57	2.17	97.71	0.83
0min	96.50	2.24	96.64	1.34
30min	96.43	1.74	96.86	1.56
60min	96.79	2.08	96.71	1.38
90min	95.50	2.07	96.64	1.08
120min	96.21	2.26	95.93	1.59
150min	95.14	2.38	96.43	1.45
180min	95.79	2.64	96.21	1.48

9.5 Blood loss

Based on the results listed in Table 5 Blood Loss Results, there was no statistical difference between the test group and the control group.

Table 5 Blood Loss Results

item	Test group(n=14)	Control group(n=14)	P value
Blood loss (ml/s)	23.56±9.15	18.07±4.80	0.061(P≥0.05)

10. Conclusion

Under the condition of this study, the test article was as effective and safe as the control article.

Quality Assurance Statement

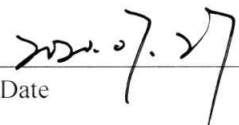
Phase Inspected	Date Inspected
Test	07/10/2020
Study Data Review	07/21/2020
Final Report Review	07/27/2020

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, part 58).

QA Representative



Jing Li, Senior QA Specialist



Date

Appendix 1: Test samples & Control samples

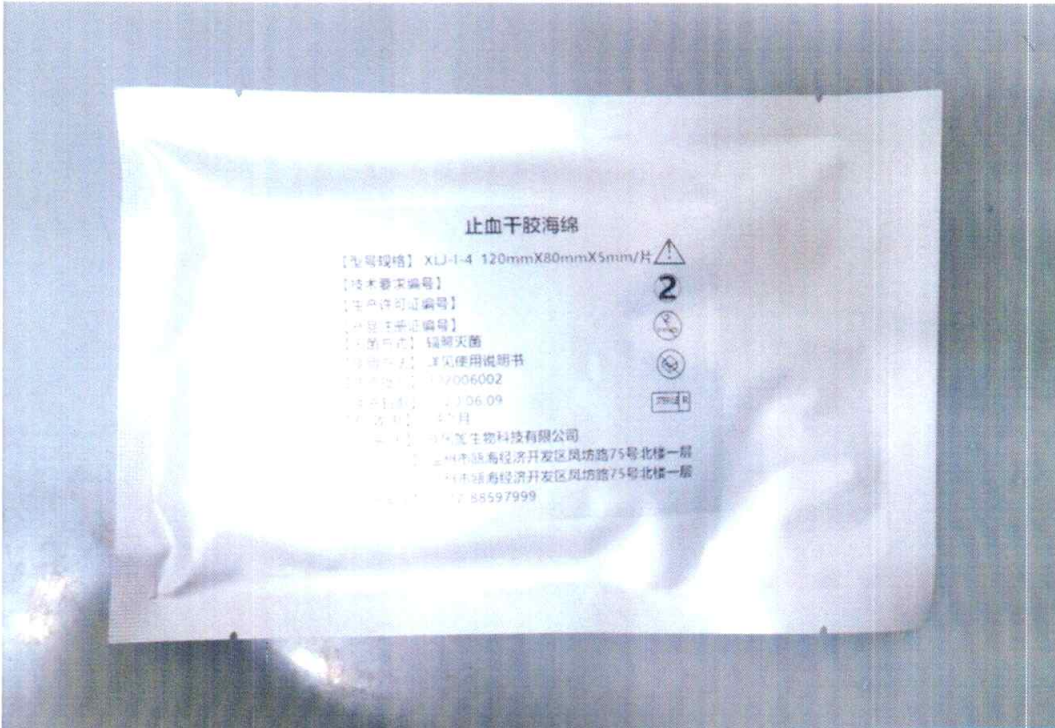


Fig A1-1 Hemostatic xerogel sponge



Fig A1-2 ChitoGauze

Appendix 2: Laboratory Animals Details

Table A2-1 Animal Weight

Ear Tag	group	sex	Preoperative weight(kg)
971	Test	M	65.4
977	Test	F	64.5
961	Test	F	66.2
969	Test	F	64.8
960	Test	M	63.5
975	Test	M	66.9
962	Test	M	65.8
979	Test	M	63.8
403	Test	F	62.4
404	Test	F	64.4
416	Test	F	64.8
414	Test	M	67.1
417	Test	M	65.2
420	Test	F	65.8
973	Control	F	62.7
974	Control	F	63.2
976	Control	F	64.9
978	Control	F	67.8
968	Control	M	65.6
972	Control	M	64.2
401	Control	M	63.7
402	Control	M	66.0
405	Control	F	62.5
406	Control	F	65.9
415	Control	F	63.2
407	Control	M	63.8
419	Control	M	66.7
418	Control	M	64.3

Table A2-2 Blood flow, Blood loss and Hemostasis Time

Ear Tag	W0 (g)	W1 (g)	blood flow (ml/s)	W0 (g)	W1 (g)	Blood loss (ml)	Time (min)
971	18.4	41.9	4.48	34.1	69.4	33.62	6
977	19.4	56.7	7.10	32.8	52.3	18.57	3
961	19.3	99.4	15.26	48.8	73.2	23.24	10
969	29.4	59.6	5.75	37.4	66.9	28.10	6
960	19.8	91.2	13.60	50.4	89.2	36.95	6
975	19.7	47.8	5.35	34.2	66.4	30.67	3
962	20.1	53.6	6.38	16.9	36.8	18.95	6
979	19.8	75.2	10.55	32.4	69.2	35.05	10
403	18.7	48.9	5.75	36.8	50.6	13.14	3
404	19.4	55.8	6.93	39.4	58.4	18.10	10
416	19.9	81.2	11.68	40.2	75.3	33.43	15
414	18.2	57.9	7.56	38.2	50.1	11.33	6
417	18.2	62.3	8.40	29.6	43.2	12.95	3
420	19.4	52.2	6.25	16.8	33.3	15.71	3
973	19.7	81.9	11.85	9.8	22.8	12.38	6
974	18.7	65.3	8.88	8.2	23.4	14.48	6
976	19.2	51.8	6.21	9.4	31.6	21.14	6
978	18.4	49.6	5.94	9.8	21.4	11.05	3
968	19.7	82.2	11.90	9.2	31.2	20.95	10
972	20	75.4	10.55	8.2	30.6	21.33	15
401	19.8	89.2	13.22	9.6	37.1	26.19	10
402	20.2	51.3	5.92	8.2	28.8	19.62	3
405	18.9	55	6.88	8.4	22.9	13.81	3
406	18.8	43.2	4.65	8.2	23.2	14.29	10
415	19.4	44.6	4.80	9.4	27.4	17.14	15
407	20.1	57.1	7.05	9.2	25.1	15.14	10
419	19.4	68.8	9.41	9.8	37.2	26.10	6
418	19.6	59.9	7.68	9.8	30.1	19.33	6

Table A2-3 Vital Signs

Ear Tag:971			
	Heart Rate(bpm)	SPO2	IBP(mmHg)
Before test	157	97	96
0 min	147	99	82
30 min	143	98	82
60 min	132	99	78
90 min	129	95	78
120 min	129	95	86
150 min	121	97	84
180 min	125	97	90
Ear Tag:977			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	114	91	112
0 min	139	95	91
30 min	128	98	91
60 min	121	99	96
90 min	123	99	98
120 min	119	98	102
150 min	106	95	96
180 min	110	98	98
Ear Tag:961			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	69	96	98
0 min	71	96	76
30 min	68	98	86
60 min	69	96	86
90 min	67	92	90
120 min	67	95	92
150 min	66	92	93
180 min	67	96	94
Ear Tag:969			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	74	99	117
0 min	79	92	113
30 min	81	96	116
60 min	74	96	112
90 min	76	96	116
120 min	75	99	116
150 min	77	96	112
180 min	75	98	109
Ear Tag:960			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)

Before test	119	98	109
0 min	124	98	101
30 min	121	96	103
60 min	112	99	106
90 min	108	91	106
120 min	116	91	98
150 min	118	90	101
180 min	115	89	96
Ear Tag:975			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	93	98	117
0 min	99	92	103
30 min	101	94	105
60 min	97	94	105
90 min	92	96	109
120 min	95	97	110
150 min	87	96	102
180 min	91	96	105
Ear Tag:962			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	120	98	112
0 min	114	97	107
30 min	112	97	109
60 min	116	97	108
90 min	111	97	114
120 min	112	98	106
150 min	109	98	106
180 min	112	98	109
Ear Tag:979			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	75	94	130
0 min	79	96	106
30 min	76	96	112
60 min	72	92	126
90 min	68	96	121
120 min	72	93	114
150 min	70	93	116
180 min	75	92	109
Ear Tag:403			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	69	95	89
0 min	69	96	82
30 min	74	98	83

60 min	72	98	83
90 min	68	96	85
120 min	70	98	83
150 min	72	98	85
180 min	68	96	85
Ear Tag:404			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	112	98	121
0 min	107	98	108
30 min	114	97	106
60 min	110	96	98
90 min	109	96	96
120 min	111	98	98
150 min	113	95	101
180 min	108	98	105
Ear Tag:416			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	107	97	144
0 min	121	98	124
30 min	118	92	127
60 min	112	96	123
90 min	116	97	122
120 min	116	96	119
150 min	110	96	114
180 min	108	96	114
Ear Tag:414			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	74	95	91
0 min	66	99	75
30 min	62	98	114
60 min	59	99	111
90 min	56	97	130
120 min	59	95	124
150 min	57	94	124
180 min	55	95	123
Ear Tag:417			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	89	98	92
0 min	83	97	83
30 min	87	96	86
60 min	87	96	86
90 min	82	95	88
120 min	85	98	89

150 min	85	94	90
180 min	85	94	90
Ear Tag:420			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	92	98	112
0 min	96	98	98
30 min	94	96	99
60 min	94	98	102
90 min	96	94	100
120 min	92	96	98
150 min	93	98	102
180 min	90	98	106
Ear Tag:973			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	94	98	105
0 min	98	96	98
30 min	92	99	96
60 min	92	98	98
90 min	92	98	101
120 min	96	96	108
150 min	94	95	100
180 min	90	96	98
Ear Tag:974			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	110	97	106
0 min	102	98	98
30 min	102	98	100
60 min	94	98	102
90 min	96	96	99
120 min	92	96	98
150 min	92	98	102
180 min	89	96	101
Ear Tag:976			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	103	98	85
0 min	107	96	82
30 min	110	96	85
60 min	105	97	83
90 min	102	98	85
120 min	106	98	83
150 min	100	94	89
180 min	104	94	86
Ear Tag:978			

	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	78	98	92
0 min	76	96	81
30 min	76	97	84
60 min	72	96	88
90 min	74	97	92
120 min	75	98	83
150 min	72	97	80
180 min	72	96	87
Ear Tag:968			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	65	97	106
0 min	72	98	98
30 min	69	99	100
60 min	69	99	102
90 min	64	98	99
120 min	60	95	98
150 min	62	97	102
180 min	66	99	108
Ear Tag:972			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	102	97	165
0 min	96	94	106
30 min	92	94	112
60 min	94	96	118
90 min	90	95	121
120 min	89	95	118
150 min	92	94	118
180 min	88	96	120
Ear Tag:401			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	141	99	116
0 min	136	98	108
30 min	128	96	106
60 min	122	98	109
90 min	126	96	111
120 min	124	98	108
150 min	120	98	116
180 min	118	98	110
Ear Tag:402			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	132	99	102
0 min	121	96	98

30 min	122	98	96
60 min	118	98	92
90 min	112	98	90
120 min	121	95	83
150 min	116	97	92
180 min	112	97	92
Ear Tag:405			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	69	97	92
0 min	78	98	82
30 min	76	96	85
60 min	72	97	85
90 min	74	97	87
120 min	68	96	86
150 min	62	97	88
180 min	65	97	88
Ear Tag:406			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	92	99	89
0 min	102	95	80
30 min	102	97	82
60 min	98	96	82
90 min	97	96	82
120 min	92	96	85
150 min	92	98	90
180 min	92	98	86
Ear Tag:415			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	112	97	138
0 min	104	98	114
30 min	106	98	114
60 min	102	96	120
90 min	98	96	113
120 min	96	97	108
150 min	96	98	106
180 min	98	95	112
Ear Tag:407			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	75	97	111
0 min	70	96	100
30 min	72	98	95
60 min	68	96	106
90 min	68	96	103

120 min	70	95	100
150 min	68	96	105
180 min	69	94	102
Ear Tag:419			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	84	97	122
0 min	90	98	103
30 min	85	95	115
60 min	86	95	112
90 min	84	97	108
120 min	82	96	112
150 min	79	95	116
180 min	76	95	117
Ear Tag:418			
	Heart Rate(bpm)	SPO2(%)	IBP(mmHg)
Before test	105	98	109
0 min	98	96	87
30 min	100	95	90
60 min	96	94	82
90 min	94	95	86
120 min	92	92	82
150 min	90	96	82
180 min	94	96	87

Table A2- 4 Coagulation Ability

ear tag	PT (s)	APTT (s)	FIB(mg/dL)
971	15.74	13.77	254.10
977	12.00	17.76	259.80
961	12.22	18.33	265.80
969	12.00	19.47	259.80
960	12.22	16.43	272.00
975	11.56	16.05	259.80
962	11.56	14.53	272.00
979	11.56	14.91	265.80
403	11.78	12.82	285.20
404	10.89	13.01	210.70
416	12.22	13.01	219.20
414	10.67	12.82	238.10
417	11.78	12.44	206.70
420	12.44	13.58	172.50
973	12.00	13.96	259.80
974	12.66	18.14	278.40
976	10.89	13.77	223.70
978	11.78	16.62	272.00
968	10.67	16.81	272.00
972	11.56	13.96	285.20
401	12.00	14.34	214.90
402	11.56	13.39	299.50
405	12.00	12.25	285.20
406	11.56	12.63	214.90
415	11.78	13.01	332.00
407	11.56	15.67	202.80
419	11.78	14.15	181.70
418	13.32	15.86	228.30

