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Established in 1957

October 11, 2001

Mr. Tom Brigliadoro
Lane Labs – USA, Inc.
110 Commerce Drive
Allendale, NJ 07401

RE: **RTL 215.0401_A** Clinical Evaluation Of The Safety And Efficacy Of A Dietary Formulation In Improvement of Age-Related Skin Changes In Women With Moderate To Severe Wrinkling Of The Periorbital Area – Lane Labs

Dear Mr. Brigliadoro:

Enclosed please find the following document for the above referenced study:

- ▶ copy of IRB Research Report Form – End Study, stamped received by the IRB on October 10, 2001

The IRB acknowledges that this study is now closed out. Should you have any questions, please feel free to contact me directly.

Sincerely,

Irwin M. Weinstock, Ph.D.
Administrator, IRB/RTL

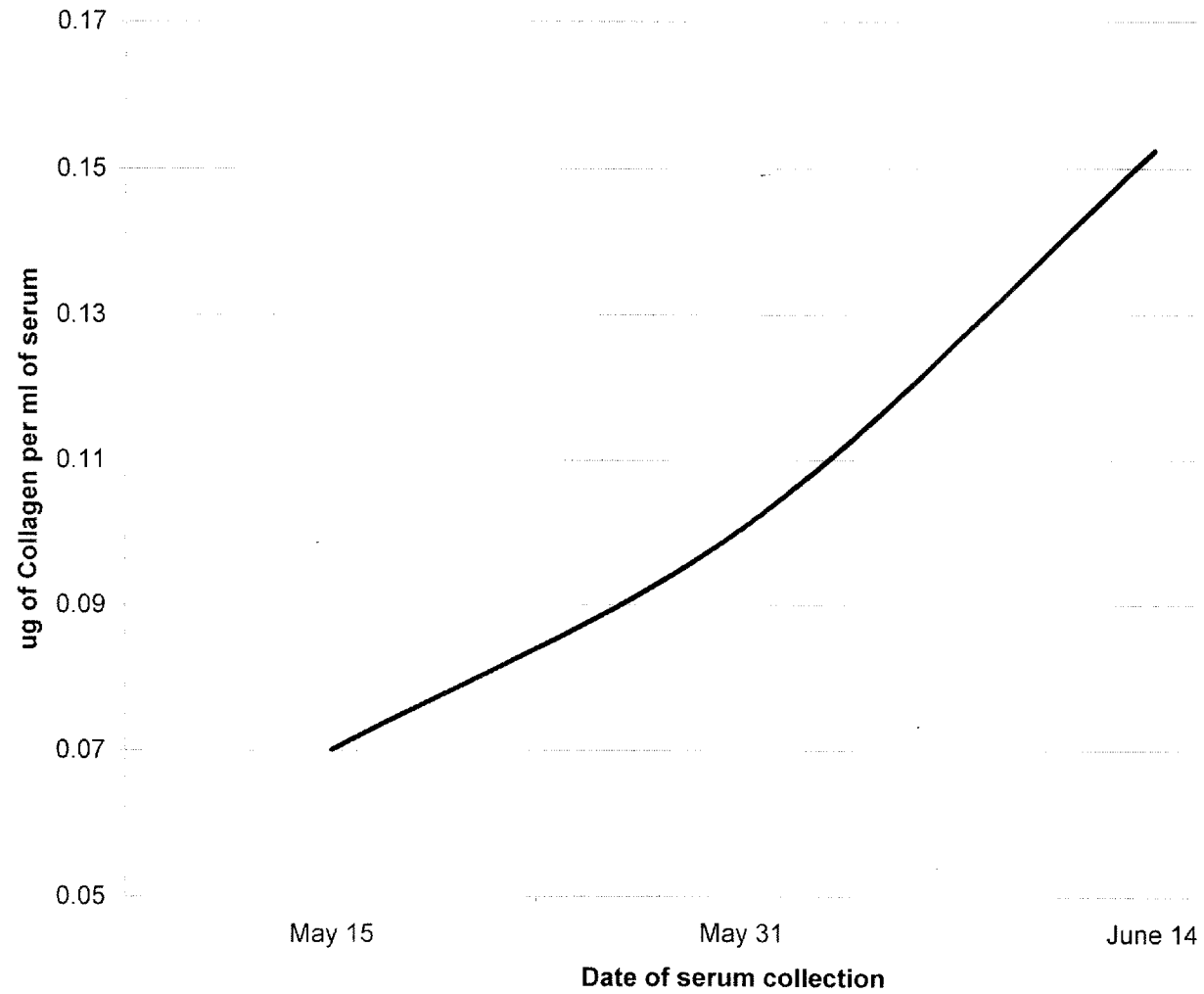
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Enclosure

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Toki Blood Collagen Assay

(summary data n = 33)



Conclusion: On average, patients' blood/collagen levels increased 114%

Lane Collagen Study

Subject	Date During Treatment	HyPro pmol detected	nmol/mL serum	HyPro total pmol	Equivalent ug HyPro	Equivalent mg cream	ug Cream per mL serum
DLM	5/17/2001	1.72	17.2	344	0.0392	0.00153	0.058
	5/31/2001	3.53	35.3	706	0.0805	0.00315	0.119
	6/14/2001	3.28	32.8	656	0.0748	0.00292	0.111
MPB	5/17/2001	3.19	31.9	638	0.0727	0.00284	0.108
	5/31/2001	3.53	35.3	706	0.0805	0.00315	0.119
	6/14/2001	13.87	138.7	2774	0.3162	0.01236	0.469
MAM	5/17/2001	2.33	23.3	466	0.0531	0.00208	0.079
	5/31/2001	2.67	26.7	534	0.0609	0.00238	0.09
	6/14/2001	3.62	36.2	724	0.0825	0.00323	0.122
NAK	5/17/2001	3.27	32.7	654	0.0746	0.00292	0.111
	5/31/2001	3.45	34.5	690	0.0787	0.00308	0.117
	6/14/2001	3.97	39.7	794	0.0905	0.00354	0.134
MML	5/17/2001	3.15	31.5	630	0.0718	0.00281	0.107
	5/31/2001	5.06	50.6	1012	0.1154	0.00451	0.171
	6/14/2001	6.89	68.9	1378	0.1571	0.00614	0.233
CJW	5/17/2001	2.82	28.2	564	0.0643	0.00251	0.095
	5/31/2001	3.53	35.3	706	0.0805	0.00315	0.119
	6/14/2001	5.78	57.8	1156	0.1318	0.00515	0.196
TAT1	5/17/2001	3.97	39.7	794	0.0905	0.00354	0.134
	5/31/2001	2.98	29.8	596	0.0679	0.00266	0.101
	6/14/2001	4.81	48.1	962	0.1097	0.00429	0.163
EEB	5/17/2001	3.49	34.9	698	0.0796	0.00311	0.118
	5/31/2001	7.89	78.9	1578	0.1799	0.00703	0.267
	6/14/2001	7.39	73.9	1478	0.1685	0.00659	0.25
MC	5/17/2001	4.32	43.2	864	0.0985	0.00385	0.146
	5/31/2001	4.14	41.4	828	0.0944	0.00369	0.14
	6/14/2001	6.63	66.3	1326	0.1512	0.00591	0.224
AKK	5/17/2001	2.94	29.4	588	0.067	0.00262	0.099
	5/31/2001	3.95	39.5	790	0.0901	0.00352	0.134
	6/14/2001	5.6	56	1120	0.1277	0.00499	0.189
JEG	5/17/2001	2.44	24.4	488	0.0556	0.00218	0.083
	5/31/2001	3.26	32.6	652	0.0743	0.00291	0.11
	6/14/2001	3.55	35.5	710	0.0809	0.00316	0.12
JGG	5/17/2001	3.61	36.1	722	0.0823	0.00322	0.122
	5/31/2001	6.55	65.5	1310	0.1493	0.00584	0.222
	6/14/2001	5.17	51.7	1034	0.1179	0.00461	0.175
RDS	5/17/2001	4.93	49.3	986	0.1124	0.00439	0.167
	5/31/2001	3.61	36.1	722	0.0823	0.00322	0.122
	6/14/2001	4.39	43.9	878	0.1001	0.00391	0.148
GH	5/17/2001	4.96	49.6	992	0.1131	0.00442	0.168
	5/31/2001	7.05	70.5	1410	0.1607	0.00628	0.238
	6/14/2001	4.91	49.1	982	0.1119	0.00438	0.166
RK	5/17/2001	3.05	30.5	610	0.0695	0.00272	0.103
	5/31/2001	5.74	57.4	1148	0.1309	0.00512	0.194

	6/13/2001	7.88	78.8	1576	0.1797	0.00702	0.267
MM	5/17/2001	3.91	39.1	782	0.0891	0.00349	0.132
	5/31/2001	5.02	50.2	1004	0.1145	0.00448	0.17
	6/14/2001	4.91	49.1	982	0.1119	0.00438	0.166
PKS	5/17/2001	3.58	35.8	716	0.0816	0.00319	0.121
	5/31/2001	6.3	63	1260	0.1436	0.00562	0.213
	6/14/2001	3.52	35.2	704	0.0803	0.00314	0.119
IHK	5/17/2001	2.89	28.9	578	0.0659	0.00258	0.098
	5/31/2001	3.85	38.5	770	0.0878	0.00343	0.13
	6/14/2001	3.3	33	660	0.0752	0.00294	0.112
JAM	5/17/2001	3.87	38.7	774	0.0882	0.00345	0.131
	5/31/2001	4.07	40.7	814	0.0928	0.00363	0.138
	6/14/2001	5.39	53.9	1078	0.1229	0.00481	0.182
BKS	5/17/2001	3.99	39.9	798	0.091	0.00356	0.135
	5/31/2001	3.74	37.4	748	0.0853	0.00333	0.127
	6/14/2001	3.85	38.5	770	0.0878	0.00343	0.13
RM	5/17/2001	2.48	24.8	496	0.0565	0.00221	0.084
	5/31/2001	3.41	34.1	682	0.0777	0.00304	0.115
	6/14/2001	4.16	41.6	832	0.0948	0.00371	0.141
EAS	5/17/2001	3.35	33.5	670	0.0764	0.00299	0.113
	5/31/2001	4.86	48.6	972	0.1108	0.00433	0.164
	6/14/2001	3.74	37.4	748	0.0853	0.00333	0.127
BJS	5/17/2001	2.31	23.1	462	0.0527	0.00206	0.076
	5/31/2001	3.42	34.2	684	0.078	0.00305	0.116
	6/14/2001	5.47	54.7	1094	0.1247	0.00488	0.185
CBT	5/17/2001	2.43	24.3	486	0.0554	0.00217	0.082
	5/31/2001	3.21	32.1	642	0.0732	0.00286	0.109
	6/14/2001	5.12	51.2	1024	0.1167	0.00456	0.173
LCW	5/17/2001	0	0	0	0	0	0
	5/31/2001	0	0	0	0	0	0
CGS	5/17/2001	3.54	35.4	708	0.0807	0.00316	0.12
	5/31/2001	4.31	43.1	862	0.0983	0.00384	0.146
	6/14/2001	5.12	51.2	1024	0.1167	0.00456	0.173
CIG	5/17/2001	3.15	31.5	630	0.0718	0.00281	0.107
	5/31/2001	2.81	28.1	562	0.0641	0.00251	0.095
	6/14/2001	5.25	52.5	1050	0.1197	0.00468	0.178
CL	5/17/2001	3.03	30.3	606	0.0691	0.0027	0.102
	5/31/2001	4.34	43.4	868	0.099	0.00387	0.147
	6/14/2001	6.55	65.5	1310	0.1493	0.00584	0.222
JHD	5/17/2001	3.12	31.2	624	0.0711	0.00278	0.106
	5/31/2001	6.09	60.9	1218	0.1389	0.00543	0.206
	6/14/2001	4.59	45.9	918	0.1047	0.00409	0.155
control		2.77					
control		3.68					
BKP	5/17/2001	2.5	25	500	0.057	0.00223	0.085
	5/31/2001	3.08	30.8	616	0.0702	0.00275	0.104
	6/14/2001	3.11	31.1	622	0.0709	0.00277	0.105

MMK	5/17/2001	3.95	39.5	790	0.0901	0.00352	0.134
	5/31/2001	3.78	37.8	756	0.0862	0.00337	0.128
	6/14/2001	3.82	38.2	764	0.0871	0.00341	0.129
JDG	5/17/2001	3.74	37.4	748	0.0853	0.00333	0.127
	5/31/2001	5.76	57.6	1156	0.1318	0.00515	0.196
	6/14/2001	6.68	66.8	1336	0.1523	0.00596	0.226
JM	5/17/2001	3.37	33.7	674	0.0768	0.003	0.114
	5/31/2001	4.28	42.8	856	0.0976	0.00382	0.145
	6/14/2001	4.98	49.8	996	0.1135	0.00444	0.168
LJD	5/17/2001	3.92	39.2	784	0.0894	0.00349	0.133
	5/31/2001	3.76	37.6	756	0.0862	0.00337	0.128
	6/14/2001	4.38	43.8	876	0.0999	0.0039	0.148
Sum	5/15/2001	109.32	684.3	13686	1.56	0.06101	2.315
	5/31/2001	503.79	9101.9	19638.926	2.275	1.46255	3.32
	6/14/2001	148.71	1487.1	29742	3.3905	0.13255	5.03
Ave (/33) (/33)	5/15/2001	3.313	20.736	414.727	0.047	0.002	0.070
	5/31/2001	15.266	275.815	595.119	0.069	0.044	0.101
	6/14/2001	4.506	45.064	901.273	0.103	0.004	0.152

Subject	HyPro pmol detected	nmol/mL serum	HyPro total pmol	Equivalent ug HyPro	Equivalent mg Collagen	ug Collagen per mL serum
May 15	3.31	20.74	414.73	0.05	0.00	0.07
May 31	15.27	275.82	595.12	0.07	0.04	0.10
June 14	4.51	45.06	901.27	0.10	0.00	0.15