

**Appendix D3**  
**Medical Device Eluates Tested in Aqueous Solutions in the LLNA**  
**Comparative Data**

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## Medical Device Eluates Tested in Aqueous Solutions in the LLNA - Comparative Data

Project #	NS Negative Control (dpm) <sup>1</sup>	NS Extract <sup>2</sup> (dpm) <sup>1</sup>	SI	LLNA Result <sup>4</sup>	NS Extract (spiked) <sup>3</sup> (dpm) <sup>1</sup>	SI	LLNA Result <sup>4</sup>	NS Positive Control <sup>4</sup> (dpm) <sup>1</sup>	SI	LLNA Result <sup>4</sup>
1	133.3	221.6	1.7	-	1,704.1	12.8	+	20,206.3	151.6	+
2	165.2	236.3	1.4	-	2,209.5	13.4	+	5,703.7	34.5	+
3	331.7	376.7	1.1	-	895.1	2.7	+	4,101.7	12.4	+
4	197.8	186.9	0.9	-	1,056.8	5.3	+	2,664.1	13.5	+
5	244.3	195.1	0.8	-	1,311.0	5.4	+	1,851.8	7.6	+
6	381.3	375.0	1.0	-	1,125.5	3.0	+	3,920.6	10.3	+
7	233.7	234.6	1.0	-	456.7	2.0	+	2,396.6	10.3	+
8	314.5	329.4	1.0	-	1,515.1	4.8	+	3,397.2	10.8	+
9	420.6	191.9	0.5	-	1,261.8	3.0	+	2,479.5	5.9	+
10	215.3	194.3	0.9	-	1,822.0	8.5	+	3,736.4	17.4	+
11	175.6	170.9	1.0	-	1,259.9	7.2	+	2,124.1	12.1	+
12	726.6	424.6	0.6	-	1,940.8	2.7	+	8,907.2	12.3	+
13	285.6	377.3	1.3	-	1,586.3	5.6	+	2,819.0	9.9	+
14	390.9	329.7	0.8	-	3,296.0	8.4	+	8,521.3	21.8	+
15	789.2	304.5	0.4	-	1,577.9	2.0	+	4,331.8	5.5	+
16	379.3	849.0	2.2	-	3,824.0	10.1	+	10,466.7	27.6	+
17	461.9	603.9	1.3	-	1,075.3	2.3	+	4,774.0	10.3	+
18	871.9	945.0	1.1	-	8,875.3	10.2	+	10,247.9	11.8	+
19	332.8	316.4	1.0	-	2,719.8	8.2	+	4,534.5	13.6	+
20	198.5	224.4	1.1	-	790.1	4.0	+	3,101.7	15.6	+
21	759.2	902.9	1.2	-	2,323.1	3.1	+	5,725.8	7.5	+
22	261.7	276.9	1.1	-	3,604.0	13.8	+	4,531.7	17.3	+
23	1,513.3	992.2	0.7	-	3,788.0	2.5	+	11,505.5	7.6	+
24	1,453.9	865.9	0.6	-	7,543.1	5.2	+	9,564.9	6.6	+
25	825.3	438.1	0.5	-	5,262.8	6.4	+	9,808.9	11.9	+
26	777.5	893.8	1.1	-	5,173.9	6.7	+	11,150.1	14.3	+
27	595.5	503.9	0.8	-	5,840.9	9.8	+	7,727.1	13.0	+
28	370.4	601.3	1.6	-	7,842.8	21.2	+	13,347.0	36.0	+
29	1,318.8	1,475.9	1.1	-	5,706.1	4.3	+	12,477.5	9.5	+
30	1,177.9	2,268.3	1.9	-	7,555.7	6.4	+	9,089.1	7.7	+
31	558.6	784.5	1.4	-	4,850.6	8.7	+	6,124.0	11.0	+
32	944.5	1,018.5	1.1	-	6,922.7	7.3	+	10,209.2	10.8	+
33	1,243.8	691.6	0.6	-	3,475.9	2.8	+	8,882.2	7.1	+
34	872.1	867.8	1.0	-	11,532.6	13.2	+	10,109.2	11.6	+
35	1,009.6	525.4	0.5	-	4,753.8	4.7	+	7,112.1	7.0	+
36	684.3	1,224.8	1.8	-	6,559.5	9.6	+	9,624.1	14.1	+
37	1,282.0	1,258.5	1.0	-	16,400.3	12.8	+	19,533.0	15.2	+
38	529.0	1,003.9	1.9	-	3,588.5	6.8	+	8,043.5	15.2	+
39	207.7	443.4	2.1	-	2,016.1	9.7	+	4,094.1	19.7	+
40	518.5	904.9	1.7	-	2,755.1	5.3	+	4,874.7	9.4	+
41	862.9	877.3	1.0	-	4,171.6	4.8	+	7,437.7	8.6	+
42	599.8	808.0	1.3	-	3,174.3	5.3	+	7,399.7	12.3	+
43	1,134.8	852.4	0.8	-	8,424.8	7.4	+	10,621.8	9.4	+
44	769.5	636.2	0.8	-	4,422.1	5.7	+	10,450.4	13.6	+
45	389.2	600.8	1.5	-	3,677.9	9.4	+	9,347.1	24.0	+
46	674.1	662.3	1.0	-	2,292.3	3.4	+	3,332.9	4.9	+
47	269.1	584.0	2.2	-	1,557.4	5.8	+	5,865.7	21.8	+
48	602.8	930.0	1.5	-	4,184.8	6.9	+	10,186.1	16.9	+

Abbreviations: dpm = disintegrations per minute; NS = normal saline; SI = stimulation index

<sup>1</sup>Values are an average of dpm from 5 individual animals.

<sup>2</sup>Eluate mixed 5:1 with Pluronic L 92

<sup>3</sup>Eluate spiked with 20% dinitrobenzenesulfonic acid (DNBS) (1:1)

<sup>4</sup>(+) = sensitizer; (-) = non-sensitizer

<sup>5</sup>Positive control is 20% DNBS

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