

# Home Sweat Specimen Collection as Part of Gravimetric Sweat Production Assessment for Axillary Hyperhidrosis Studies

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The emergence of COVID-19 has required people to minimize travel and other daily activities. These limitations have far-reaching consequences on the ability to conduct clinical research studies, which are necessary to advance the development of new medical therapies. To address these constraints, study sponsors have begun to explore modification of protocol-mandated research site visits to allow for telehealth or home visits.

A widely accepted efficacy endpoint for hyperhidrosis studies is the assessment of gravimetric sweat production (GSP).<sup>1,2,3,4</sup> The measurements necessary to evaluate GSP are typically performed at a research site on sensitive, non-mobile balances. In anticipation of a possible COVID-related need to perform home-based sweat collection for assessment of primary axillary hyperhidrosis severity, we explored whether transporting specimens affected their weight. For our evaluation, we com-

TABLE 1.

Tares, Pre-, and Post-Transport Total Weights and Sweat Weights, and Sweat Weight Change

Volunteer Number	Left vs Right / #1 VS #2	Travel Type / Temperature Type	Tares (mg)	Total Weight – Pre-Travel (mg)	Sweat Weight Pre-Travel (mg)	Total Weight – Post-Travel (mg)	Sweat Weight Post-Travel (mg)	Difference Pre & Post-Travel Sweat Weight (mg)
1	Right #1	Ambient FedEx	15217.8	15224.6	6.8	15225.2	7.4	0.6
1	Left #1	Ambient Car	14782.8	14799.3	16.5	14798.8	16	-0.5
1	Right #2	Refrigerated FedEx	14796.6	14849.1	52.5	14849.6	53	0.5
1	Left #2	Refrigerated Car	15324.7	15364.4	39.7	15366.4	41.7	2
2	Right #1	Refrigerated Car	14772.3	14819.4	47.1	14820.6	48.3	1.2
2	Left #1	Ambient FedEx	14787	14847.1	60.1	14846.3	59.3	-0.8
2	Right #2	Ambient Car	15167.3	15219.9	52.6	15220.1	52.8	0.2
2	Left #2	Refrigerated FedEx	14820.1	14863	42.9	14870	49.9	7
3	Right #1	Refrigerated FedEx	15033	15145.5	112.5	15148.3	115.3	2.8
3	Left #1	Refrigerated Car	15130.5	15163.9	33.4	15166	35.5	2.1
3	Right #2	Ambient FedEx	14768.5	14830	61.5	14829.3	60.8	-0.7
3	Left #2	Ambient Car	15044.7	15077.5	32.8	15076.8	32.1	-0.7
4	Right #1	Ambient Car	15224.8	15771.2	546.4	15770.2	545.4	-1
4	Left #1	Refrigerated FedEx	15133.7	15324.7	191	15328.1	194.4	3.4
4	Right #2	Refrigerated Car	14780.2	15206.9	426.7	15207.7	427.5	0.8
4	Left #2	Ambient FedEx	14779.5	14997.8	218.3	14997.1	217.6	-0.7
5	Right #1	Ambient FedEx	15204	15300.6	96.6	15300.5	96.5	-0.1
5	Left #1	Ambient Car	14787.8	14855.6	67.8	14855.3	67.5	-0.3
5	Right #2	Refrigerated FedEx	15309	15414.9	105.9	15418.1	109.1	3.2
5	Left #2	Refrigerated Car	15126.7	15235.6	108.9	15237.2	110.5	1.6
6	Right #1	Refrigerated Car	15040.6	15247.5	206.9	15253.4	212.8	5.9
6	Left #1	Ambient FedEx	15018.2	15140.8	122.6	15141	122.8	0.2
6	Right #2	Ambient Car	14783.1	14974	190.9	14973.8	190.7	-0.2
6	Left #2	Refrigerated FedEx	15065.9	15119.9	54	15124.3	58.4	4.4

pared (1) research site specimen collection and weighing, without transport, with (2) research site specimen collection and weighing, with transport by private vehicle or overnight courier.

Volunteers with primary axillary hyperhidrosis were invited to participate. Standard practices for collecting sweat by filter paper were followed.<sup>1</sup> Sweat production was measured for each axilla twice to yield four specimens per volunteer. Specimens were packaged in foam-lined cardboard shipping containers. Specimen assignment was random to one of the four different possible packaging and transport methods. Two specimens from each volunteer were packaged at ambient temperature and two were packaged with endothermic refrigeration packs, in order to maintain temperatures between 2-8°C (Nanocool™ Albuquerque, NM). For each volunteer, one ambient and one refrigerated package was transported away and back to the research site by either private vehicle or overnight courier.

The specimens transported by private vehicle were driven around for 60 minutes. Interior vehicle temperature was maintained at approximately 72°F. Upon return to the clinic, the specimens were unpacked and weighed. Time elapsed between collection and weighing of specimens transported by vehicle averaged four hours. The specimens transported by courier were shipped overnight from the research site. The daily high ambient temperature in the local area for those days ranged from 79 to 93°F. Time elapsed between collection and weighing of specimens transported by courier averaged 24 hours.

Six volunteers participated yielding 24 sweat specimens. The average weight of sweat was 129.6 mg per specimen with a range from 6.8 mg to 546.4 mg. Table 1 illustrates values for tares, pre and post-transport total weights and sweat weights, and sweat weight change. Table 2 shows the percentage change in weight of sweat for each specimen, as well as grouped by method of transportation and packaging. The average absolute change in weight by percent varied from 1.05% to 5.45%. All but one of the refrigerated specimens gained weight during transport. This was thought due to condensation.

All methods demonstrated relatively low variability. However, ambient packaging and vehicle transport of specimens demonstrated the greatest consistency and least variance compared to standard office procedures. Although the collection and measurement of sweat during a research site visit remains the gold standard, remote specimen collection and transport under ambient temperature back to a research site for weighing appears to provide a reliable alternative when in-person visits are not possible.

**DISCLOSURES**

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**TABLE 2.**

Change in Weight of Sweat by Method		
Volunteer	Method	Weight of Sweat, Percent Change
1	Refrigerated car	5.04%
2	Refrigerated car	2.55%
3	Refrigerated car	6.29%
4	Refrigerated car	0.19%
5	Refrigerated car	1.47%
6	Refrigerated car	2.85%
Average		3.06%
1	Refrigerated Fed-Ex	0.95%
2	Refrigerated Fed-Ex	-16.32%
3	Refrigerated Fed-Ex	2.49%
4	Refrigerated Fed-Ex	1.78%
5	Refrigerated Fed-Ex	3.02%
6	Refrigerated Fed-Ex	8.15%
Average		5.45%
1	Ambient car	-3.03%
2	Ambient car	0.38%
3	Ambient car	-2.13%
4	Ambient car	-0.18%
5	Ambient car	-0.44%
6	Ambient car	-0.10%
Average		1.05%
1	Ambient Fed-Ex	8.82%
2	Ambient Fed-Ex	-1.33%
3	Ambient Fed-Ex	-1.14%
4	Ambient Fed-Ex	-0.32%
5	Ambient Fed-Ex	-0.10%
6	Ambient Fed-Ex	0.16
Average		1.98%

ment from Brickell Biotech, Inc. Nancy Seretta, BS and Deepak Chadha, MS, MBA, RAC are employees of Brickell Biotech, Inc. Brandon Kirsch, MD is a former employee of Brickell Biotech, Inc. Dr. Kirsch is also a consultant to Brickell Biotech, Inc.

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