

EVALUATION OF RAPID, ON-SITE APOE GENETIC TESTING FOR SUBJECT OUTREACH AND RECRUITMENT

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INTRODUCTION

- Although there remains no disease modifying treatment for Alzheimer's disease, knowledge of risk can inspire lifestyle alterations to slow disease progression and may aid in drug development.
- After age, family history/genetics represent the second highest risk factor for Alzheimer's disease and polymorphisms in the APOE gene (E2, E3, E4) have been recognized as the highest genetic risk factor for typical Late Onset Alzheimer's disease.
- Conventional APOE testing involves blood collection and a result often takes several weeks.
- Three independent memory clinics investigated whether rapid APOE genotyping would be feasible at their centers and what impact such testing might have on subject outreach and recruitment.

METHODS

FEASIBILITY AND USER EXPERIENCE

- Representatives from Spartan Bioscience were present to train and support clinic operators on how to use the Spartan Cube rapid APOE assay.
- Training included a presentation highlighting the assay workflow and software interface.
- Clinic operators completed a questionnaire to evaluate the training and use of the testing system.

ASSAY WORKFLOW: SPARTAN CUBE RAPID APOE DNA TEST

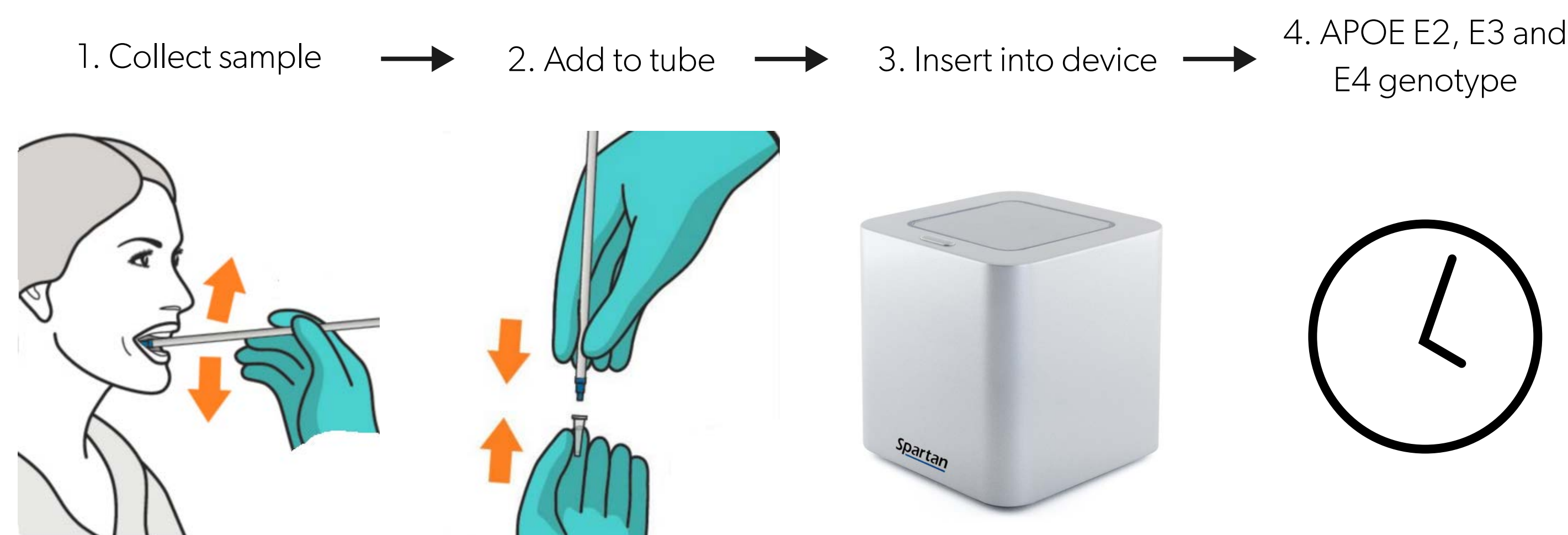


FIGURE 1. Workflow of the Spartan Cube APOE rapid DNA test. The cartoon illustrates the steps involved in obtaining an APOE genotype using the Spartan Cube. (1) Collect Buccal Samples. (2) Place into assay cartridge (contains all reagents necessary). (3) Load into Spartan Cube. (4) Start test: results in 52 minutes.

RECRUITMENT

- 3 memory clinics recruited subjects for a cognitive assessment which included a free rapid APOE DNA test (Spartan Cube APOE; Spartan Bioscience Inc.):
 - Clinic 1:** Advertised in a local newspaper for 2 consecutive weeks the offer of APOE genotyping and compared the response rate to the preceding 6 months of advertisements that did not include APOE testing.
 - Clinic 2:** Held an information booth at a local "Walk for Memories" community event and recruited subjects to attend a memory screening session which included APOE genotyping, and compared participant response to past community events offering memory screening alone.
 - Clinic 3:** APOE testing was offered to individuals that were present at the clinic and the response rate was assessed.
- Subjects completed a questionnaire to evaluate their experience with the rapid APOE testing procedure.

RESULTS

FEASIBILITY AND OPERATOR EXPERIENCE

- A total of 12 operators were trained and used the Spartan Cube rapid APOE assay.
- Overall, the operators found the test easy to perform and the amount of training provided to be sufficient (Table 1).
- Operators assessed each step as "EASY" and did not assess any of the steps as "DIFFICULT"

TABLE 1. OPERATOR ASSESSMENT OF "EASE-OF-USE" AND WORKFLOW

ASSESSING ASSAY WORKFLOW (1 = EASY, 5 = DIFFICULT)	1	2	3	4	5
Sample collection	11	1	0	0	0
Sample Processing	11	1	0	0	0
Entering Test Information	12	0	0	0	0
Barcode Scanning	12	0	0	0	0
Understanding Results	12	0	0	0	0
Recording/Storing Results	8	4	0	0	0

RESPONSE TO OFFER OF RAPID APOE DNA TESTING

TABLE 2. SUMMARY OF CLINIC 1 AD RESPONSE AND APOE TESTS PERFORMED

ADVERTISEMENT TYPE	W/ APOE TESTING		W/O APOE TESTING
	WEEK 1	WEEK 2	
Duration of ad (weeks)	2 weeks		21 weeks
Total responses	24	17	93
Average response/week	21		4.5
Cancellations	0	12 ^a	21
Attendance rate	100%	29%	78%
APOE tests performed	25 ^b	0 ^c	N/A
Inconclusive tests	0	N/A	N/A
Individuals declining APOE test	0	N/A	N/A

a Individuals canceled appointments after being informed APOE tests were no longer available
b Number of individuals tested in Week 1 included AD responders and one individual who requested an APOE test
c There were no remaining test kits for Week 2 as all kits were used in Week 1

TABLE 3. SUMMARY OF CLINIC 2 RECRUITMENT AND APOE TESTS PERFORMED

EVENT	W/ APOE TESTING	W/O APOE TESTING
Individuals recruited	80	10
APOE tests performed	60	N/A
Individuals tested	57	N/A
Inconclusive tests	3	N/A
Individuals declining APOE test	0	N/A

TABLE 4. SUMMARY OF CLINIC 3 APOE TESTS OFFERED AND PERFORMED

EVENT	RESULT
APOE tests offered	29
Individuals tested	27
Individuals declining APOE test	2
Inconclusive tests	0

RESULTS

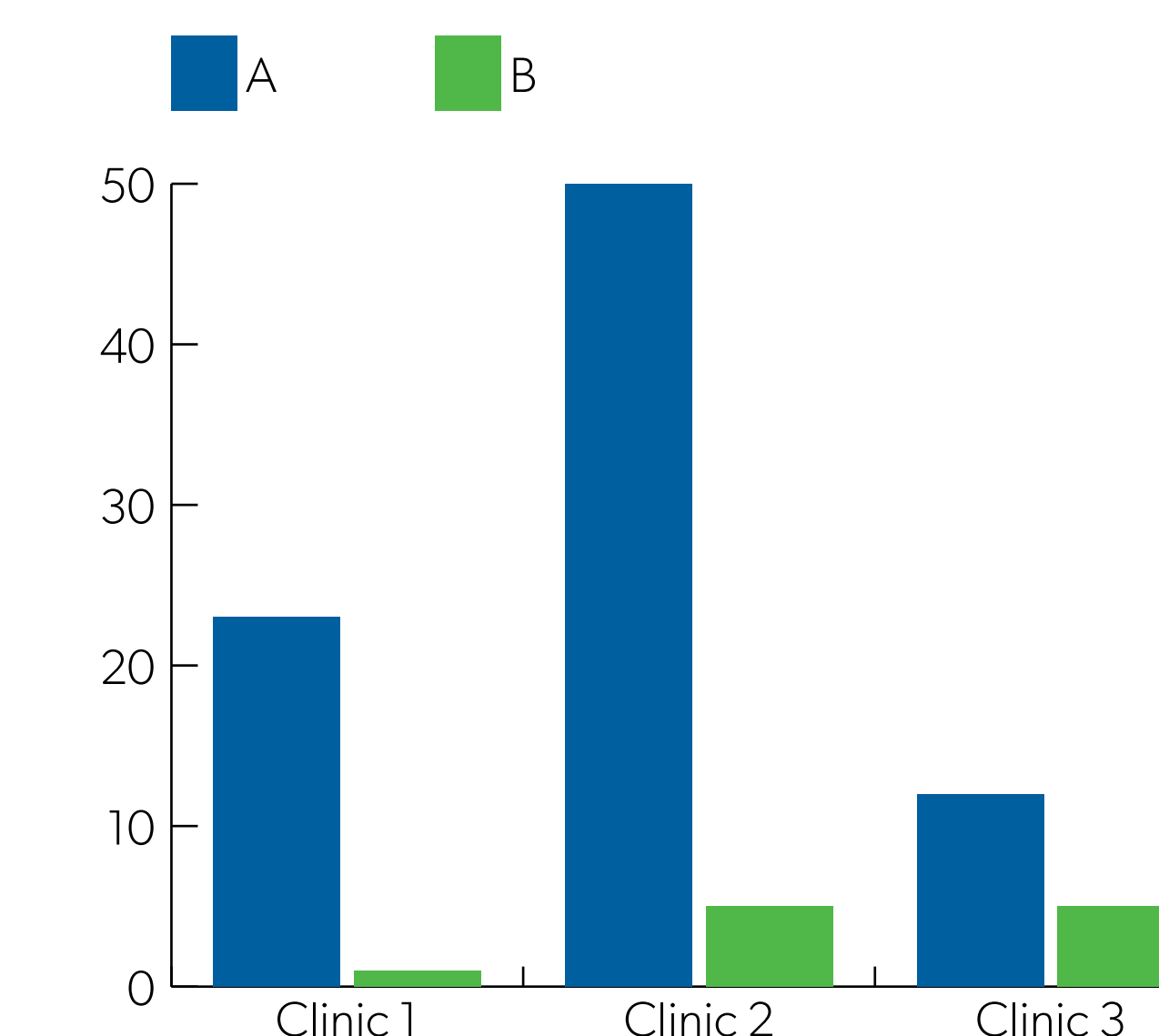
SUBJECT EXPERIENCE AND FEEDBACK

TABLE 5. SUBJECT QUESTIONNAIRE: EXPERIENCE WITH RAPID APOE TESTING

	CLINIC 1		CLINIC 2		CLINIC 3	
	NO	YES	NO	YES	NO	YES
1. Did you have any concerns about having a genetic test performed?	23	1	57	0	18	0
2. Have you had a genetic test performed in the past	17	7	51	6	17	1
3. Did you feel any physical discomfort from the cheek swab collection?	24	0	57	0	18	0
4. Did you feel any anxiety related to the cheek swab collection?	23	1	55	2	18	0

Q1. Would you prefer to:

- (A) wait 1 hour for your test results or
(B) give a blood sample and return for your results in several weeks?



Q2. How much would you be willing to pay out-of-pocket for this test?

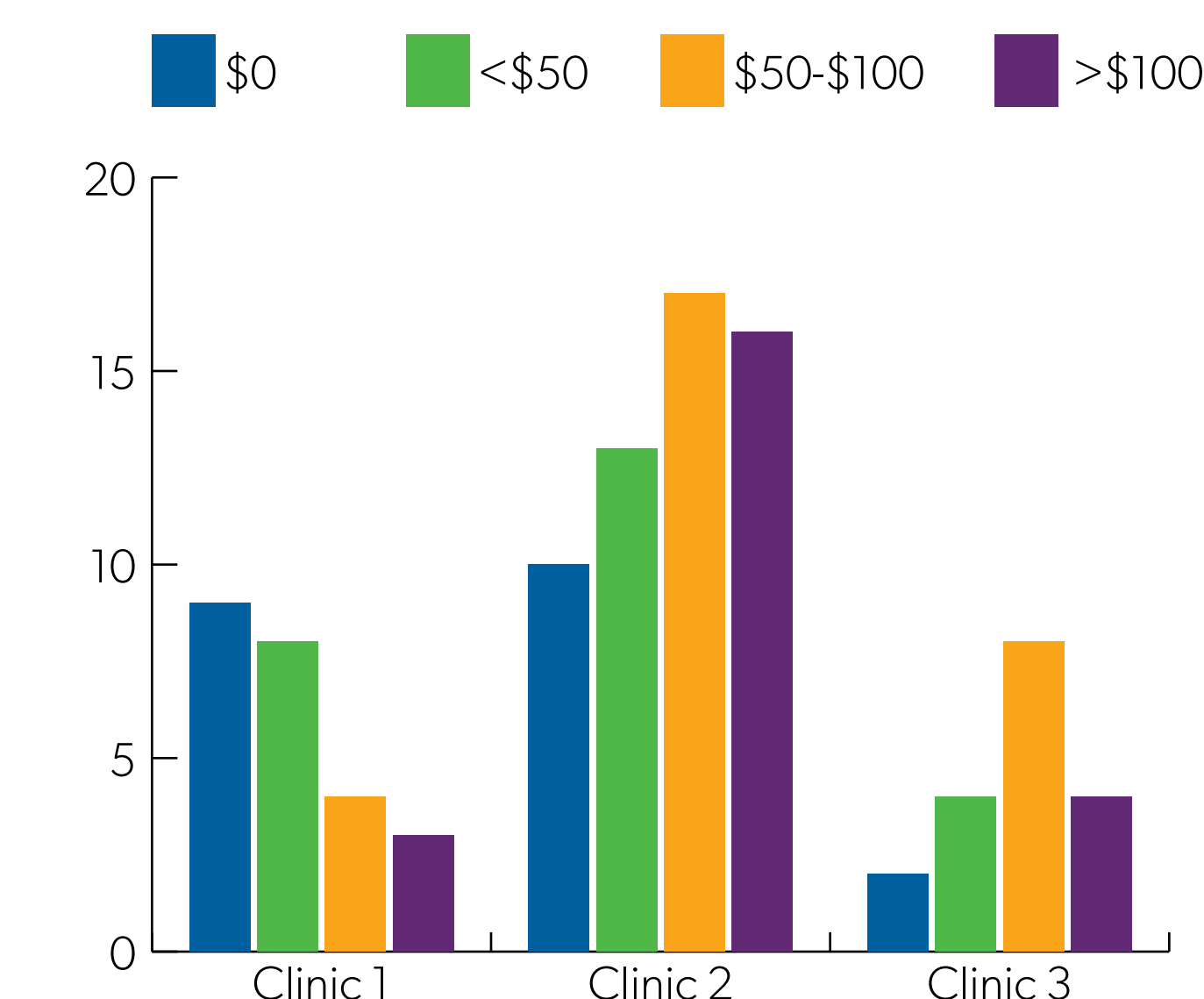


FIGURE 2. Subject evaluation of rapid APOE testing. Tested subjects were asked: (Q1) How long they would prefer to wait for their test results and (Q2) How much they would be willing to pay for a rapid APOE test?

CONCLUSIONS

- The Spartan Cube rapid APOE assay was found to be a quick, non-invasive and easy-to-use test.
- Including this genetic test increased participant interest in all 3 memory clinics.
- Less than 3% of tests were inconclusive (3/114)
- Over 98% of individuals requested, or accepted the offer of APOE testing (112/114)
- These findings suggest that on-site APOE testing may be an effective adjunct to recruitment strategies for AD-related clinical trials.

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 - Compass Research Bioclinica
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