AROMHA

COVID SMELL TEST

ALZHEIMER'S DISEASE TEST

Breakthrough At-Home App Based Digital and Olfactory Devices
with Instantaneous Return of Results

Executive Summary

- **Enormous Unmet Need for At-Home**, **Non-Invasive Tests** with **Instantaneous Results** for **Front Line Testing** to meet the demand of the more than **200 Million tests needed** with **only 25 Million tests available monthly**[2]
- **Smell Loss** is an **Early Indicator of COVID-19 Infection** and may **Occur in up to ~98%**[1] **of Patients**
- **Founded on 20 Years of Research in Olfactory Diagnostics,** the **COVID Smell Test** provides **Quantitative, Objective Smell Testing** and could **Identify Many Asymptomatic Carriers** with **Instantaneous Return of Results**
- **Aromha Smell Test** demonstrated **100% Sensitivity** and **67% Specificity** in **detecting smell loss related to COVID-19**
- **Aromha Smell Test** represents a **Safe Disposable At-Home Test** used with an **App** for **Cost-Effective Detection of Smell Loss due to COVID-19 in the $2 - $4 Billion Testing Market (deemed 510(k) exempt by FDA)**
- As the **Population Ages**, increasing **Need for At-Home Monitoring of Brain Health** and **Neurodegenerative Disorders**
- **Early detection of Alzheimer's Disease** can help **Identify Appropriate Patients for Clinical Trials, Start Therapeutics Earlier** in the disease process, and provide **Cost-Effective Assessments of Cognitive Function in the $10.6 Billion Market**

1. Mullol, et al, The Loss of Smell and Taste in the COVID-19 Outbreak: a Tale of Many Countries, *Curr Allergy Asthma Rep*.2020; 20(10): 61, August 3, 2020
2. S. Schachter and M. Kingsley, NIH RADx Tech Overview and Market Analysis Webinar October 13, 2020

Leaders in Olfactory Research and At-Home Digital Solutions

Sean Reineke
Chief Executive Officer

Mark Albers, MD, PhD
Founder
Chief Scientific Officer

Dan Tatar
Founder
Chief Technology Officer

Connie Qiu, RAC
Regulatory

Colin Magdamo, BSc
Data Scientist

Larry Berman
Manufacturing

David Tanner
Full Stack Software Engineer

Erin McKenna
Deputy Director

Glenn Miller
Market Sector Leader/EIR

Emily Rusk
Consultant/Project Manager

Boston Biomedical Innovation Center (B-BIC)
Life Sciences Accelerator

Proven, Successful Team

Founders Extensive Experience

Harvard Medical School

BWH

MGH 1811

ADKGROUP

Top-Tier Support

$2.83 M

Blavatnik Sensory Disorders Fund

Mass General Brigham Executive Committee Grant

NIH RADx B-BIC Grant

NIH National Institute of Biomedical Imaging and Bioengineering

NIH National Institute on Aging

Non-Dilutive Funding

20 Years of Leading Olfactory Disorder Research

COVID-19 and the Chemical Senses: Supporting Players Take Center Stage

Neuron CellPress

Cooper et al., *Neuron* (2020), https://doi.org/10.1016/j.*neuron*.2020.06.032

Innate Immune Signaling in the Olfactory Epithelium Reduces Odorant Receptor Levels: Modeling Transient Smell Loss in COVID-19 Patients

medRxiv

medRxiv preprint doi: https://doi.org/10.1101/2020.06.14.20131128.Posted June 16, 2020

Dhilla Albers, et al, Episodic Memory of Odors Stratifies Alzheimer Biomarkers in Normal Elderly

ANNALS of Neurology, 2016;80:846-857.

Annals of NEUROLOGY

At the interface of sensory and motor dysfunctions and Alzheimer's disease

M.W. Albers et al. / *Alzheimer's & Dementia* 11 (2015) 70-98

alzheimer's association | Alzheimer's & Dementia THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION

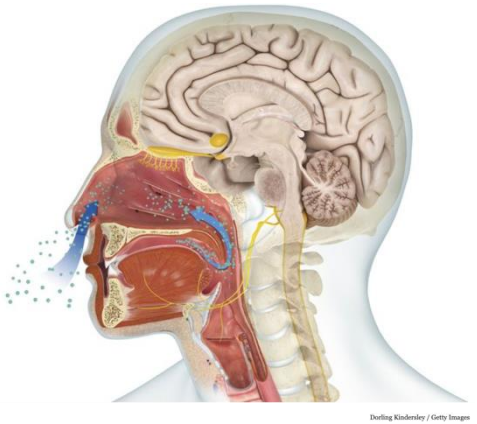
FOCUSED ON EXECUTION

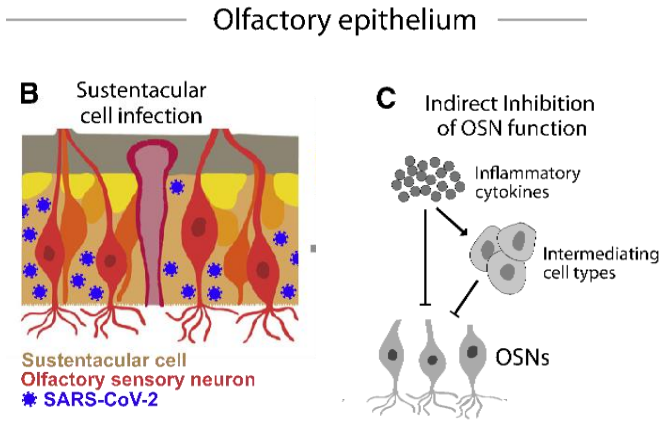
Detecting Smell Deficits Specific to COVID-19 Infection

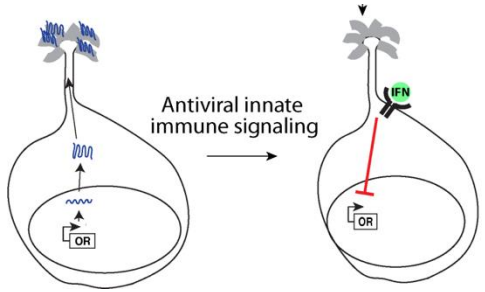
COVID-19 virus accesses smell area in nose through nose or the pharynx

COVID-19 virus does not infect smell neurons

Smell neurons lose detectors for odors







Cooper….Albers, Barlow, Datta, Di Pizio, Neuron, 2020

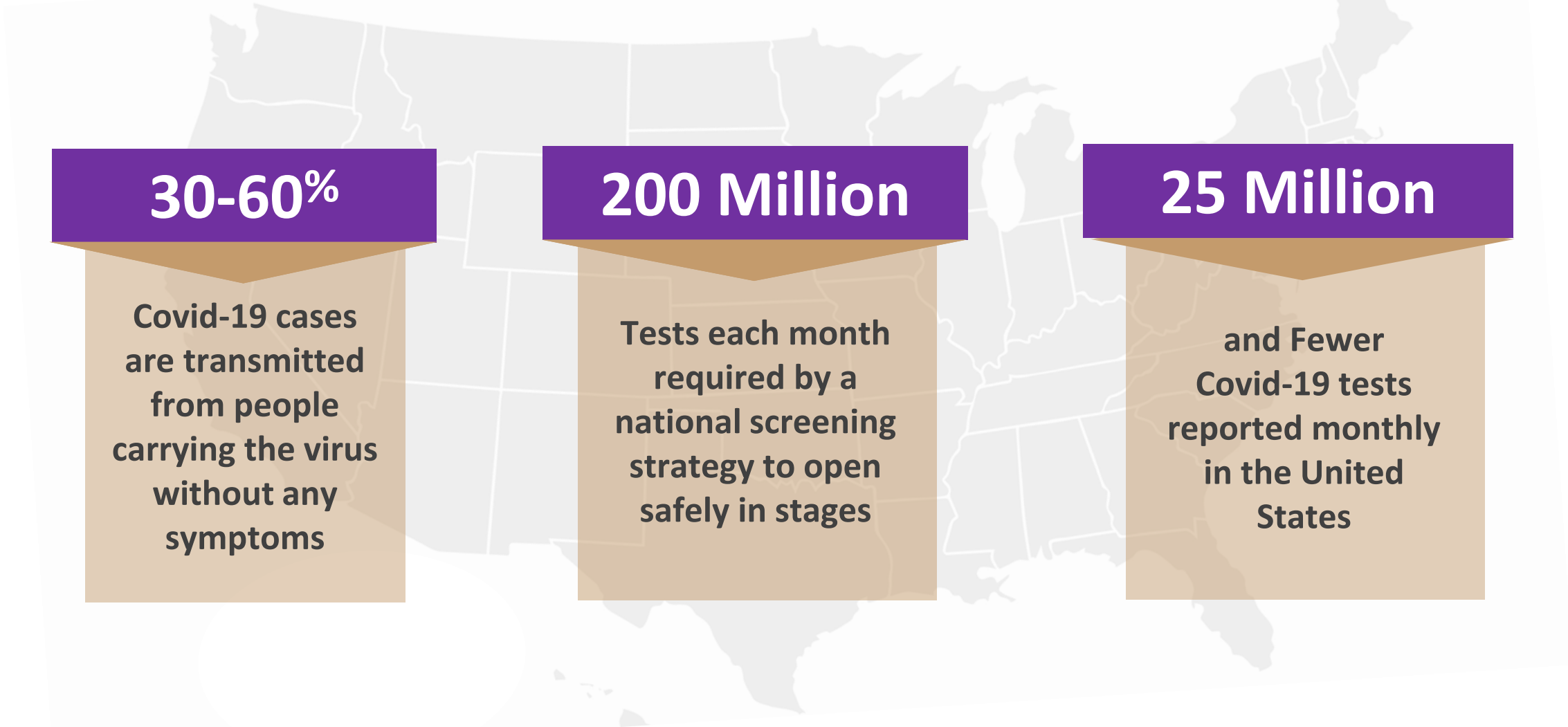
Rodriguez….Tatar….Albers, MedRxiv, 2020

- COVID Smell Test is an objective odor test based on proprietary biological insights into how COVID-19 elicits smell loss with research completed at Harvard Medical School / Massachusetts General Hospital [1,2]
- Proprietary-blended, odors prevent confounding by genetic anosmia
- Personalized algorithm for quantitative measurement of scent which helps prevent false positives from smell loss due to other conditions, particularly in senior population

1. Cooper et al, COVID-19 and the Chemical Senses: Supporting Players Take Center Stage, *Neuron* (2020), https://doi.org/10.1016/j.*neuron*.2020.06.032
2. Rodriguez et al, Innate Immune Signaling in the Olfactory Epithelium Reduces Odorant Receptor Levels: Modeling Transient Smell Loss in COVID-19 Patient medRxiv preprint doi: https://doi.org/10.1101/2020.06.14.20131128. Posted June 16, 2020

COVID-19 Spreading in the US: > 30,000 Positive Tests Daily

Gap of Available Tests and Need for Cost-Effective, At-Home Tests



30-60%

Covid-19 cases are transmitted from people carrying the virus without any symptoms

200 Million

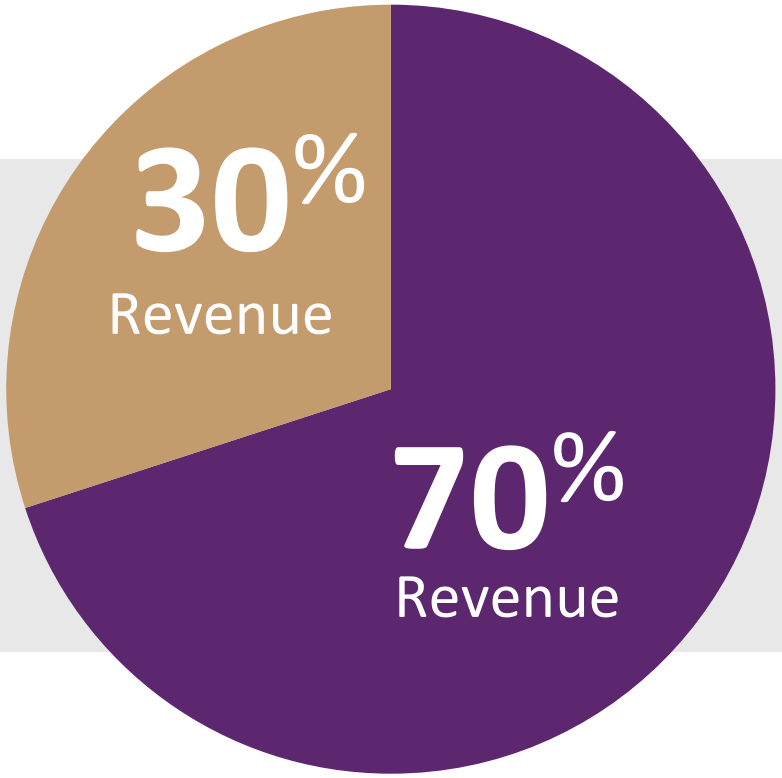
Tests each month required by a national screening strategy to open safely in stages

25 Million

and Fewer Covid-19 tests reported monthly in the United States

1. McClellan, et al, A National Decision Point: Effective Testing and Screening for Covid-19, Duke University's Margolis Center for Health Policy with support from The Rockefeller Foundation, September 7, 2020

Large Addressable U.S. Market for COVID-19 Diagnostics



$2-4 Billion in the U.S.

With 30% of revenue from non-traditional diagnostic tests

With 70% of revenue from nasal swabs and PCR tests

Source: PitchBook Data Covid-19 Diagnostics Market Size Estimates November 2020

Large Addressable Market

Employers, Healthcare Workers, Universities, Nursing Homes, Sports

Large Patient Population

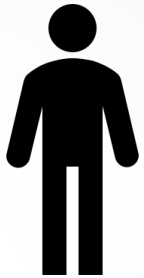
PATIENT POPULATION	US
Employers/Employees	**100 Million**
University Students and Faculty	**21 Million**
Healthcare Workers	**18 Million**
Nursing Home Residents	**1.35 Million**
Professional Sports Teams **Players, Staff, Families** **NFL, NBA, MLB, NHL**	**~50,000**
Total	**140 Million**

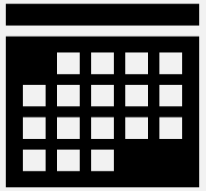
Sources: Anthony Caruso, Statistics of U.S. Businesses Employment and Payroll Summary: 2012, Released February 2015, CDC January 17, 2017, Statista 2018, US Department of Education, National Center for Education Statistics, 2019, USA Facts 2016.

Choosing A Smell Test Should Be Simple

Central Lab
vs
Point of Care
vs
At-Home Test

Symptomatic
vs
Asymptomatic

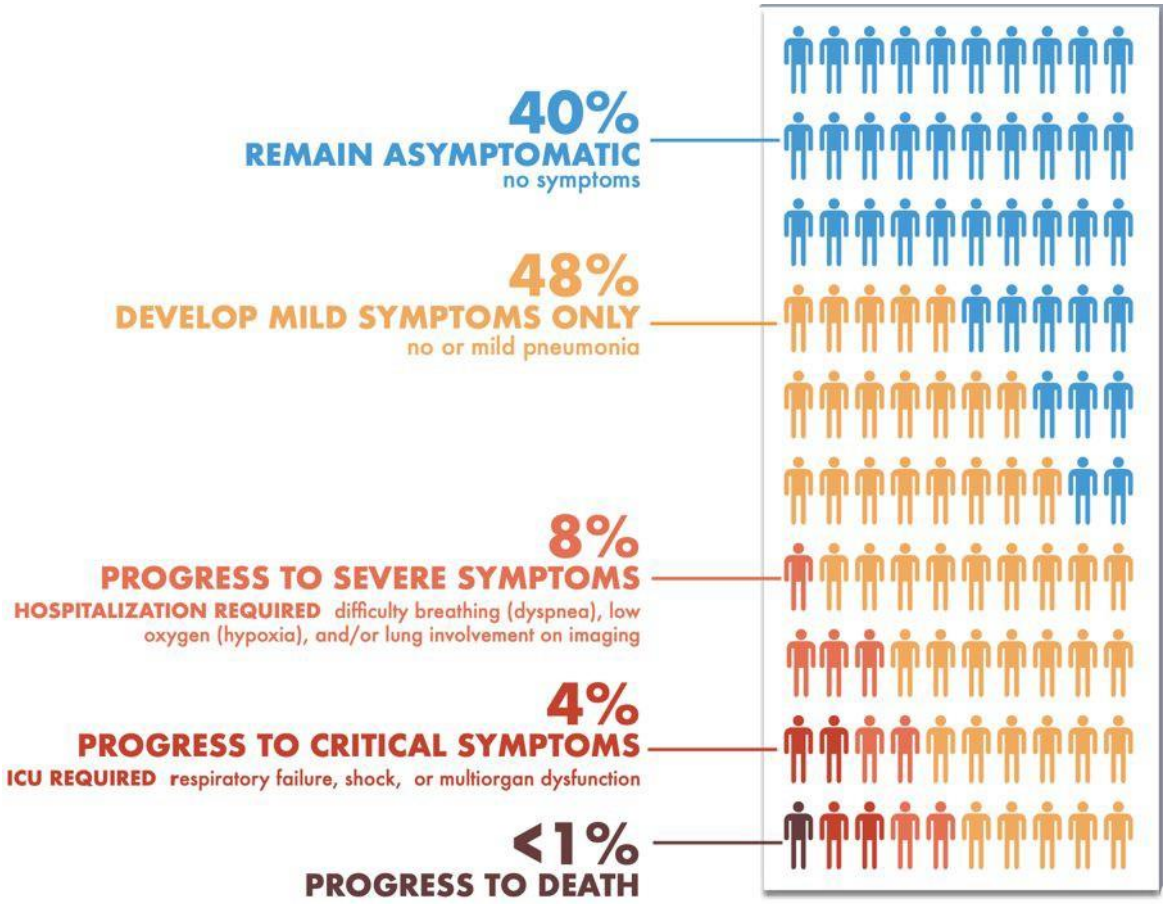


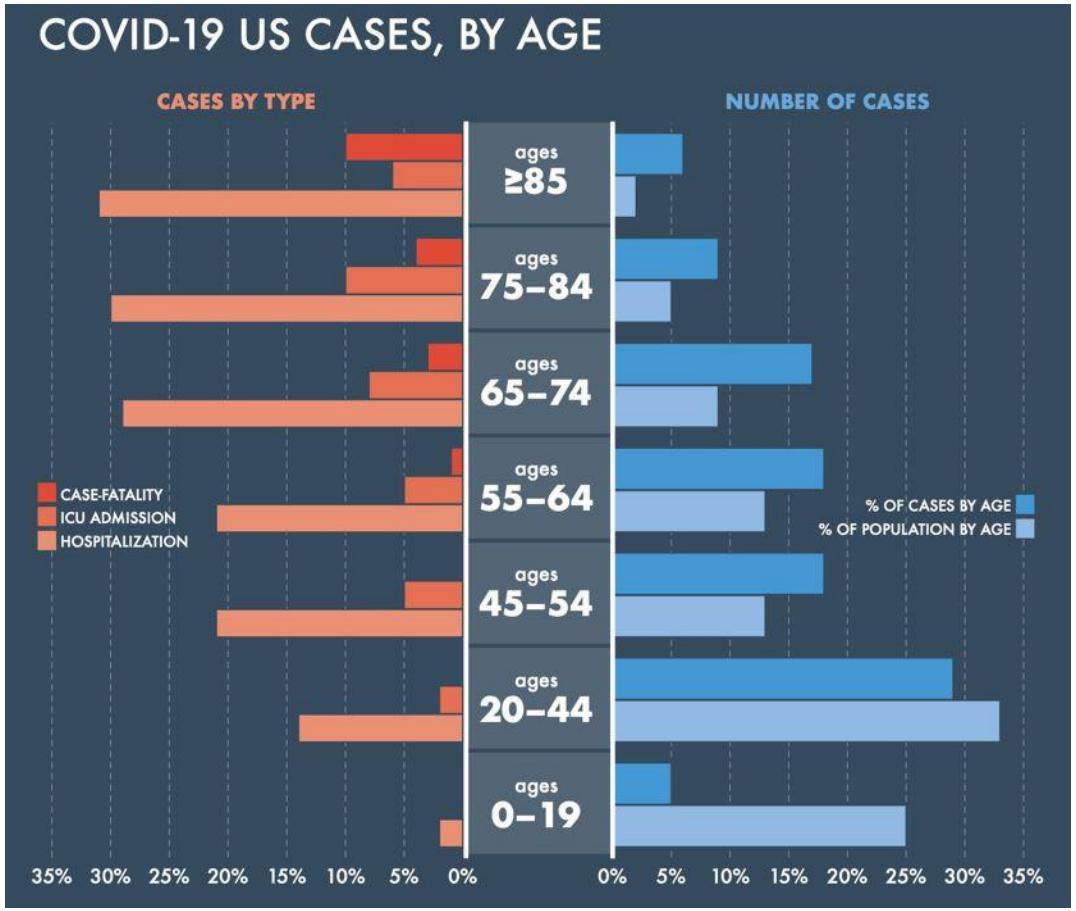


Weekly
vs
Daily

1. S. Schachter and M. Kingsley, NIH RADx Tech Overview and Market Analysis Webinar October 13, 2020

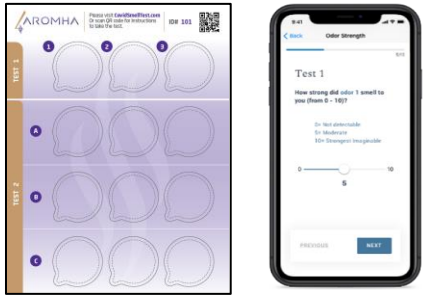
Two Realities Make Testing an Essential Component





1. S. Schachter and M. Kingsley, NIH RADx Tech Overview and Market Analysis Webinar October 13, 2020

Competition

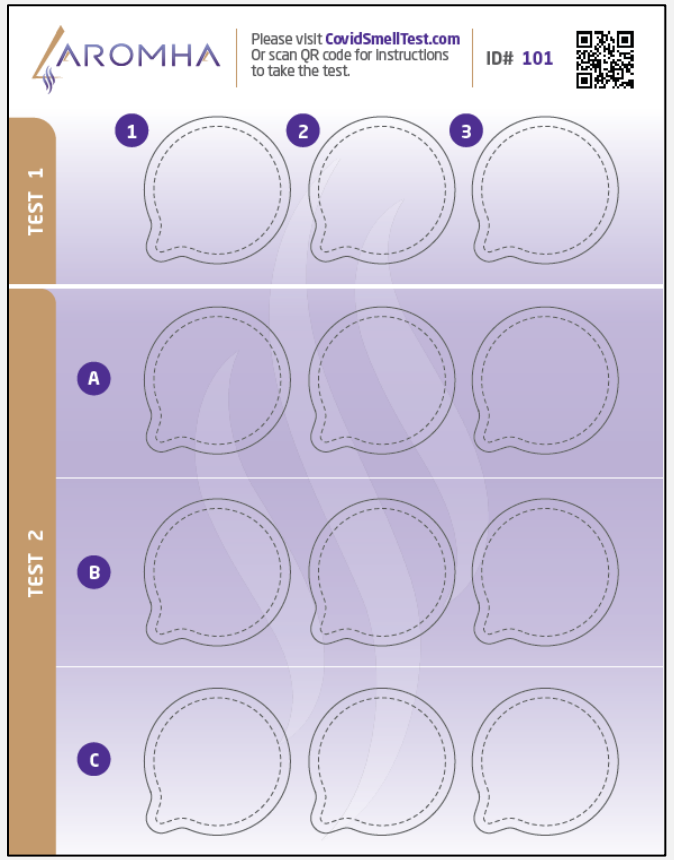
FDA Status	Product Name	Company	Product
FDA EUA Reviewed ***Class II Device 510(k) exempt path cleared***	**COVID Smell Test (3)** **COVID Smell Test (18)** 6 Cards *Forecast and Payor Reimbursement work pending*	AROMHA	
Wellness	**University of Pennsylvania Smell Identification Test (40)** UPSIT $30.45 **Brief Smell Identification Test (12)** B-SIT $20.45	SENSONICS INTERNATIONAL	
Wellness	**Sentidos Smell Kit (12)** $18.95	identiMD, LLC	
Wellness	**Sniffin Sticks (12)** €243.02 **Extended Stick Test (48)** €1,031.37	burghart MESSTECHNIK	

Aromha Smell Test At-Home Diagnostic with Immediate Results

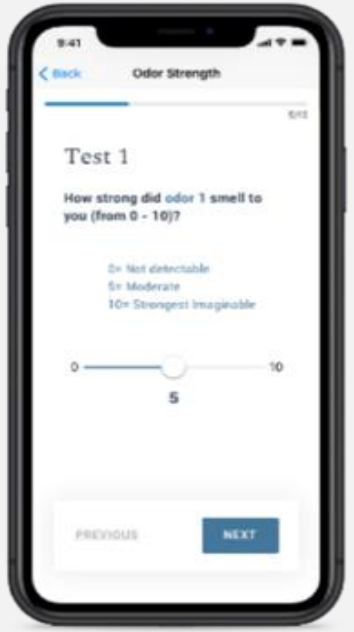
User Experience

- Obtain COVID Smell Test card and access Aromha web/mobile application
- Register and input number or scan custom QR code printed on smell card
- Answer Symptom Tracker questions
- Peel and sniff odor labels and answer corresponding questions on Aromha application
- Receive results instantly upon completion of the test
- Customizable workflow enables users to share results with healthcare professional or employer if desired
- Data handled on HIPPA-compliant AWS server

Aromha Smell Test Card



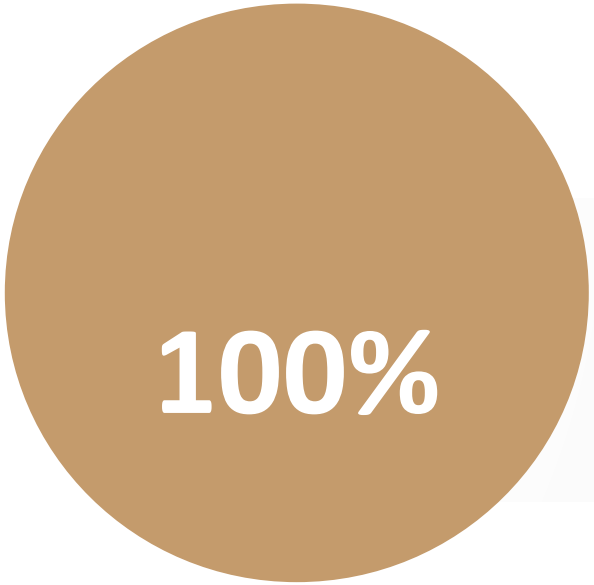
HIPAA-Compliant Application



Aromha Smell Test Sensitivity and Specificity for predicting RT-PCR SARS-CoV-2

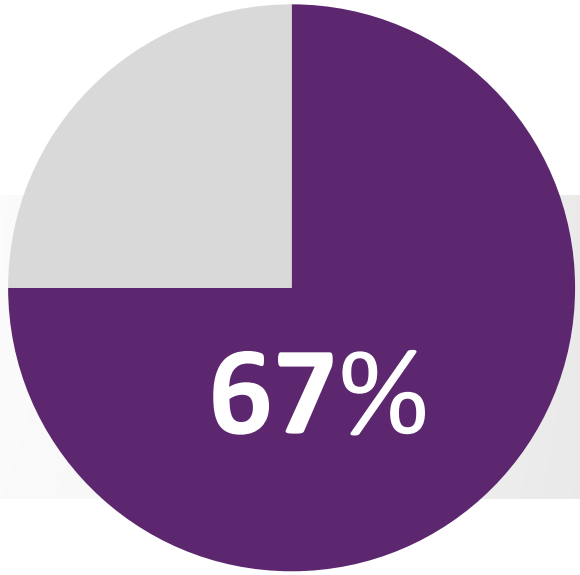
PERFORMANCE

Sensitivity



COVID-19 Positive RT-PCR tests (n = 47)
COVID-19 Negative RT-PCR tests (n = 79)

Specificity



COVID-19 Positive RT-PCR tests (n = 47)
COVID-19 Negative RT-PCR tests (n = 79)

Negative Predictive Value

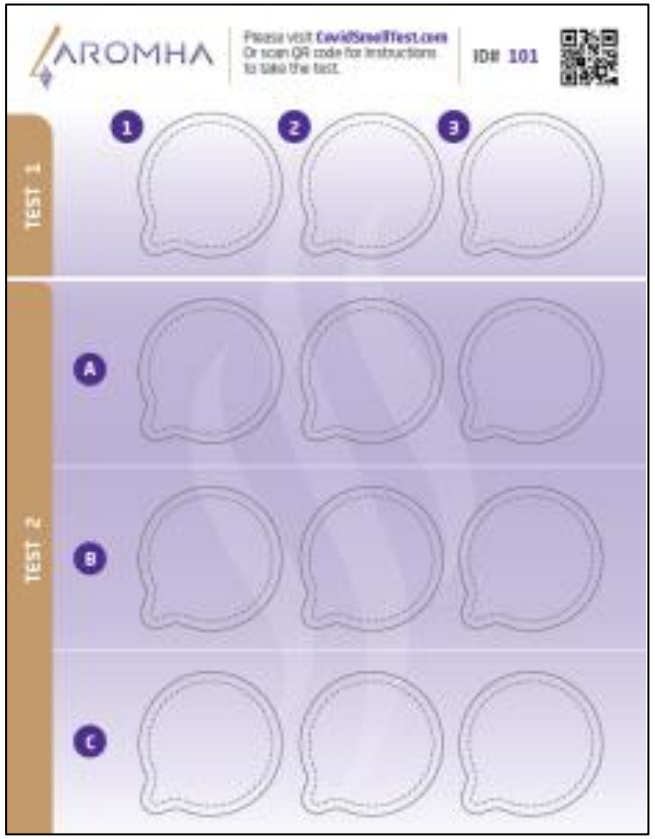
100%

1. Mark Albers, MD, PhD, COVID Smell Test Clinical Trial 2020

Aromha Smell Test – Results

GREEN: **Normal** Your sense of smell appears to be normal. Normal results do not exclude the possibility of potential loss of smell, of respiratory or of neurologic disease. If you may have been exposed to the SARS-CoV-2 virus or are feeling unwell, please consult a healthcare professional.

RED: **Abnormal** Your sense of smell appears to be abnormal. Please consult a healthcare professional. Loss of smell has been identified as one sign associated with respiratory and neurologic diseases.



Highly Scalable Manufacturing and Distribution

Scents: Top Tier Scent Partners

- ISO 9001 Certification – IFF, Givaudan, Firmenich
- Naturalistic odor blends provided for manufacturing

Manufacturing: Arcade Beauty

- ISO 9001 Certification and FDA Registration
- Robust, rapid, consistent supply chain to manufacture COVID Smell Test

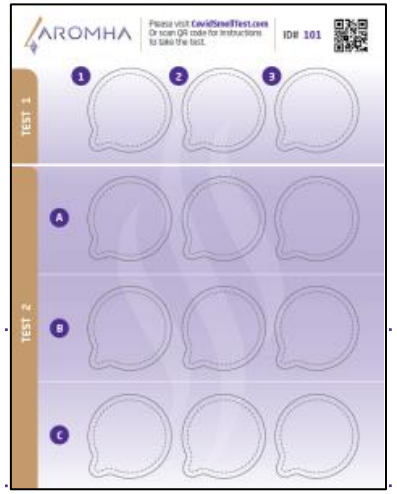
Identifying Distribution Partners

- FDA Registration as a medical device distributor
- Consumer, military, travel, and other markets

Initial and Expansion Opportunities

- Longitudinal monitoring of smell for COVID long haulers
- Alzheimer's Disease, Parkinson's Disease, Traumatic Brain Injury

Initial Launch	COVID Smell Test
Expansion Opportunity	Alzheimer's Disease Detection
Expansion Opportunity	Parkinson's Disease Detection
Expansion Opportunity	Post-trauma Neurological Evaluation



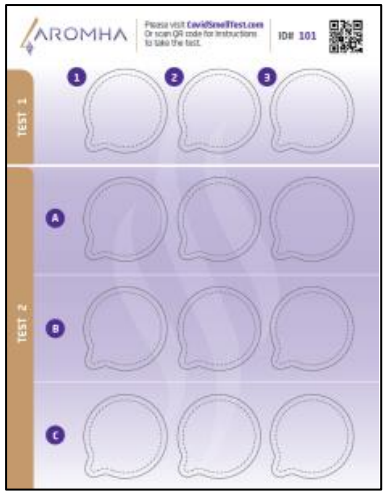
PCT US2015/050957

Awarded Jan 2020 in US, UK, Germany, and France, pending Japan

Spaulding-Harvard
Traumatic Brain Injury Model System

THE FOOTBALL PLAYERS HEALTH STUDY AT HARVARD UNIVERSITY

Early Cognitive Screening For Neurodegenerative Diseases



How do we detect the ***earliest*** potential signs of Alzheimer's in cognitively healthy individuals ***before*** symptoms develop?

Novel domain

- **Odor Identification**
- **Odor Memory**
- **Odor Discrimination**
- **Cognitive Function**

Personalized algorithm to score cognitive and olfactory memory deficit

Inform risk of developing Alzheimer's

Device adjusts for 40-fold *natural variance* in individual's baseline olfactory function

Alzheimer's Disease

DISEASE FORMS (up to 20 years) → **SYMPTOMS SHOW**

When We Diagnose Alzheimer's Disease

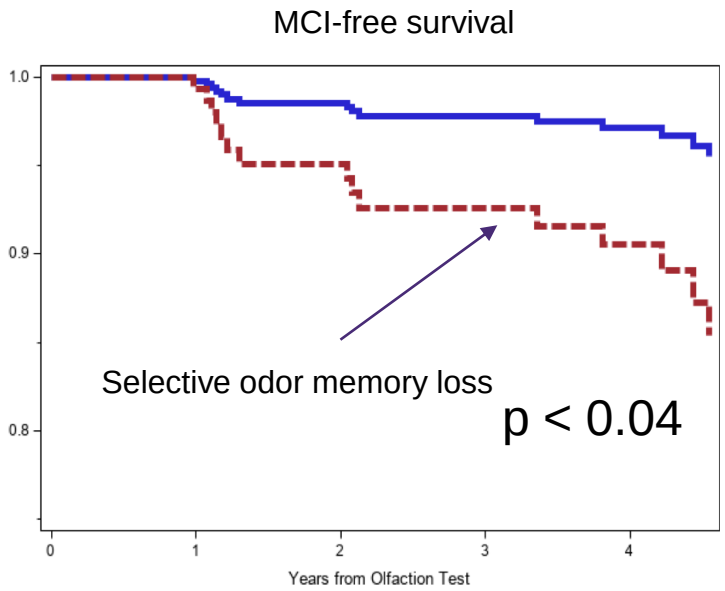
5.8 Million Patients | >$270 Billion Annually in US

Selective Odor Memory Loss Predicts Progression to Alzheimer's Disease and Mild Cognitive Impairment 3 - 4 Years Before Onset of Clinical Symptoms

Personalized Algorithm for Risk of Alzheimer's Disease/ MCI

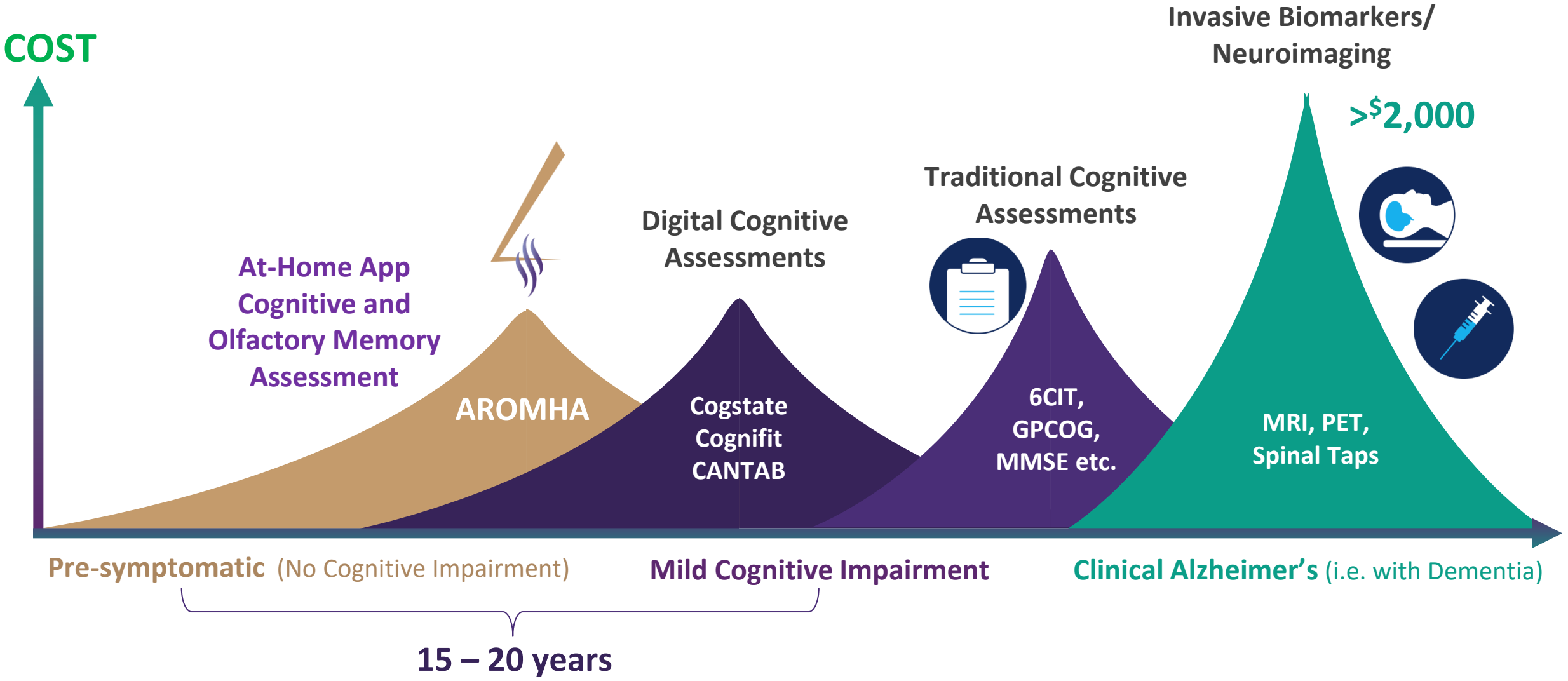
Demographic	Overall (n=127)	Diagnosis Progression		*p*-value
		aMCI/AD (n=15)	Stable (n=112)	
Average age at first olfaction (SD)	75.3 (8.2)	80.9 (7.9)	74.6 (8.0)	0.005⁺
Female (%)	66%	80%	64%	0.263**
Education	16.7 (2.3)	15.1 (2.3)	16.9 (2.2)	0.004⁺

Risk Factor	p-value	Hazard Ratio (95% CI)
Years Education	0.0008	0.653 (0.501-0.833)
Age	0.0015	1.132 (1.054-1.230)
Selective Odor Memory Loss	**0.0278**	**3.445 (1.131-10.716)**



1. Albers, D., et al., Episodic memory of odors stratifies Alzheimer biomarkers in normal elderly, in preparation

Early Screening Alzheimer's Disease



Direct-to-Consumer Opportunities

Unprecedented Growth

$10.6B

Global Cognitive Assessment & Training Market by 2022

32% CAGR

Fragmented Market

Partnership opportunities

with existing niche players

Expand Scale and Reach

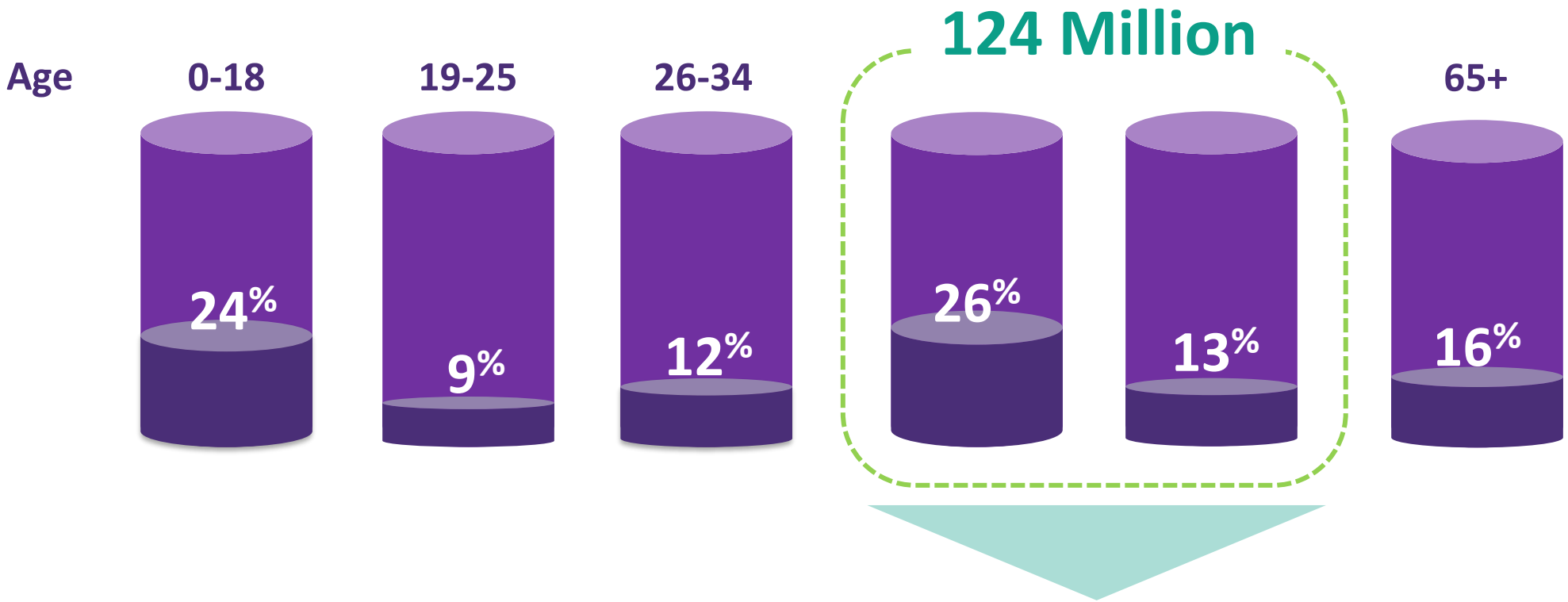
Quickly increase

user install base and enhance algorithm

Strong Market Tailwinds

- Aging demographic
- Mobile enablement
- Payor reimbursement
- Rising focus on Brain Health
- Growing DTC Health funding

Large Addressable U.S. Market



- Comfortable with technology
- High disposable income ($71K - $83K)
- Concerned about cognitive health
- Likely pre-symptomatic

Direct-to-Consumer Value Proposition

WHO? **Anyone invested in their cognitive health (especially affluent individuals aged 50+)**

WHAT? **Proactively understand and track their cognitive health before symptoms arise**

WHY? **Power of early detection of cognitive decline, inform access to the appropriate professional healthcare pathways / clinical trials / future therapies**

Speedy & Early

Pre-symptomatic, immediate screening

Non-invasive & Accessible

Compared to invasive and expensive diagnostics such as spinal taps, MRI and PET scans

Convenient

Delivered to your door and self-administered in your own home

Unique Domain

Cognitive, Odor memory and discrimination

Intellectual Property

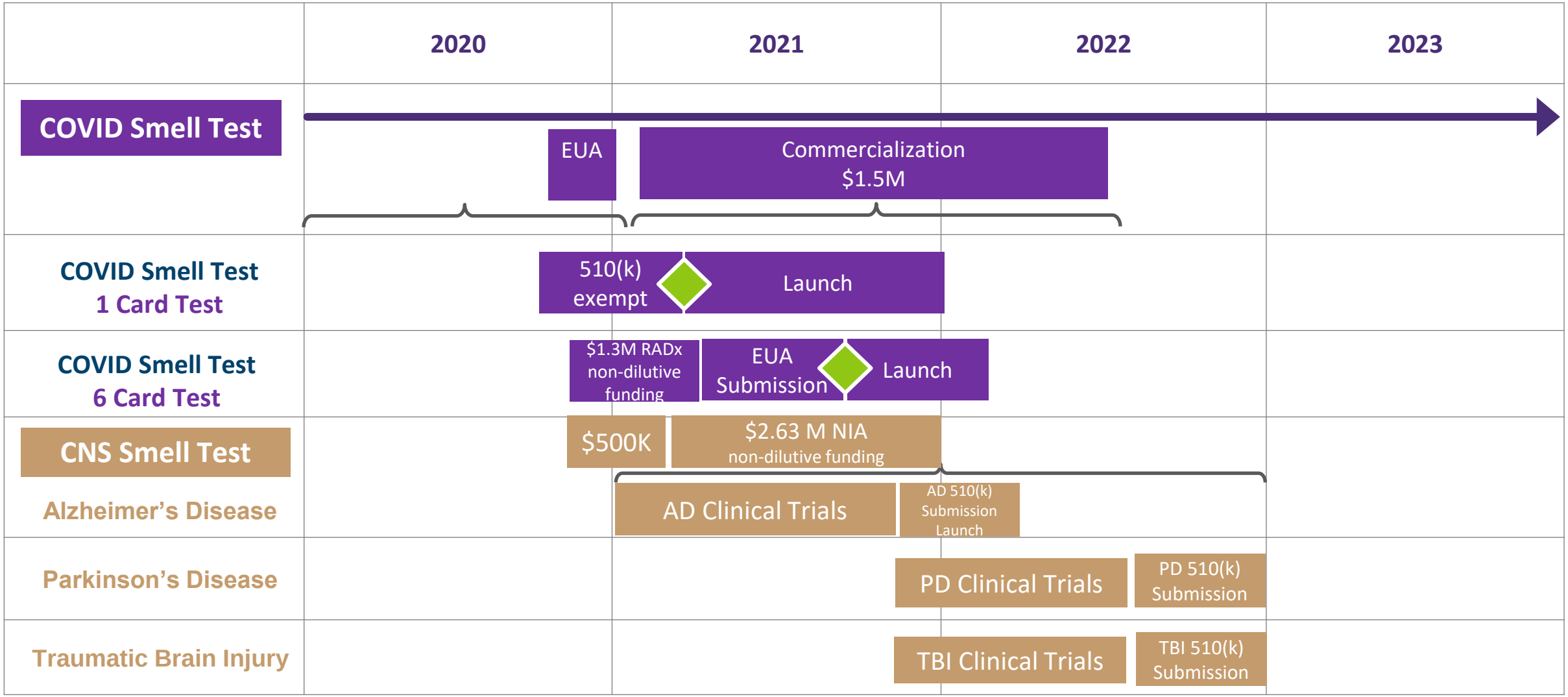
Aromha Smell Test

- Provisional Patent US Application 63/040,915
- Systems and Methods for Administering a Smell Test for SARs Coronaviruses and COVID-19
- Filed June 18, 2020, potential conversion to PCT application on June 18, 2021

Neurodegenerative Disease Screening

- Patent PCT US 2015/050957
- Awarded January 2020 in United States, UK, Germany, France, and pending in Japan
- Neurodegenerative Disease Screening Using an Olfactometer with an algorithm to analyze three olfactory test results to identify a novel risk outcome for Alzheimer's Disease

Timeline


2020
2021
2022
2023
COVID Smell Test
EUA
Commercialization
$1.5M
COVID Smell Test
1 Card Test
510(k)
exempt
Launch
COVID Smell Test
6 Card Test
$1.3M RADx
non-dilutive
funding
EUA
Submission
Launch
CNS Smell Test
$500K
$2.63 M NIA
non-dilutive funding
Alzheimer's Disease
AD Clinical Trials
AD 510(k)
Submission
Launch
Parkinson's Disease
PD Clinical Trials
PD 510(k)
Submission
Traumatic Brain Injury
TBI Clinical Trials
TBI 510(k)
Submission

AROMHA

COVID SMELL TEST

THANK YOU