



WAYNE STATE
College of Nursing

Saliva, the Golden Biofluid

Emergence as a major specimen type due to COVID-19

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CONFIDENTIAL

Dedication



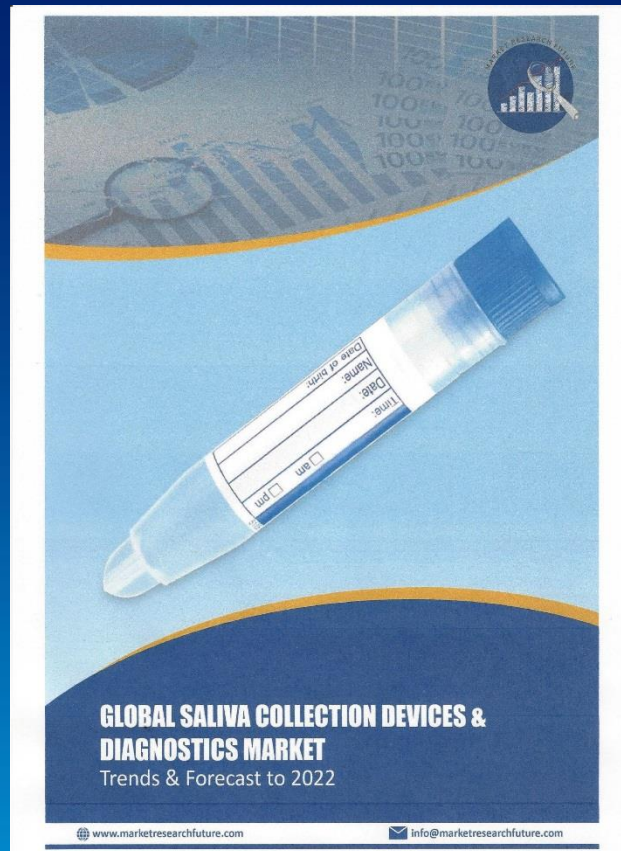
Richard William Slowey May 30th 1990 – September 8th 2014

Why Saliva?

- ✓ Most easily collected specimen?
- ✓ Non-invasive
- ✓ Most analytes present
- ✓ Easy disposal
- ✓ Ease of transportation
- ✓ Better indicator of disease?
- ✓ Religious / cultural considerations
- ✓ Cost effective
- ✓ Patient preference



Market Statistics Indicate a Rapidly Growing Market !!!



- 2017 – First Market Report strictly dealing with market size and revenue forecasts for Saliva Collection Devices and Diagnostics [\$2.56 Billion by 2022]
- 2017-Nutrigenomics Market to be \$17.3 Billion by 2023 [Saliva segment, \$10.6 Billion]
- 2019 – Saliva Collection- Consumer ReportsReview.com – No figures but “large growing market”- 6 Companies [Quest, OraSure, Oasis, etc.]
- 2019 – Exosome Dx / Rx -\$34.7 MM in 2018 to \$186.2 MM in 2023, CAGR 40%

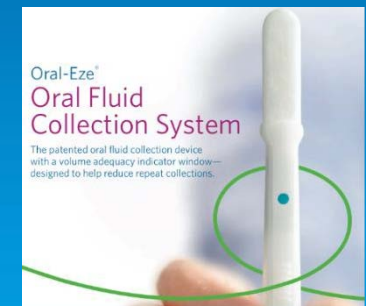
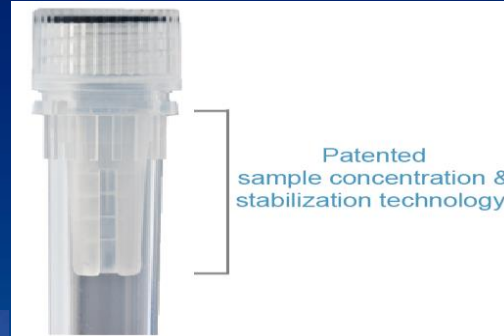
- Ancestry.com- 15 Million Saliva Specimens Processed
- 23andMe- 8 Million Customers

Market Statistics Indicate Rapidly Growing Market !!



- **2018** – Market for Direct-to Consumer Genetics from \$99 MM US today to \$310 MM [2022]
- **2017** – Liquid Biopsy Diagnostics Market increasing from \$580 Million in 2016 to \$2.05 Billion in 2022, CAGR of 23%
- **June 2018 Poll**- Almost 33% of Americans have considered genetic testing [100% saliva]

Select Saliva Collection Technologies

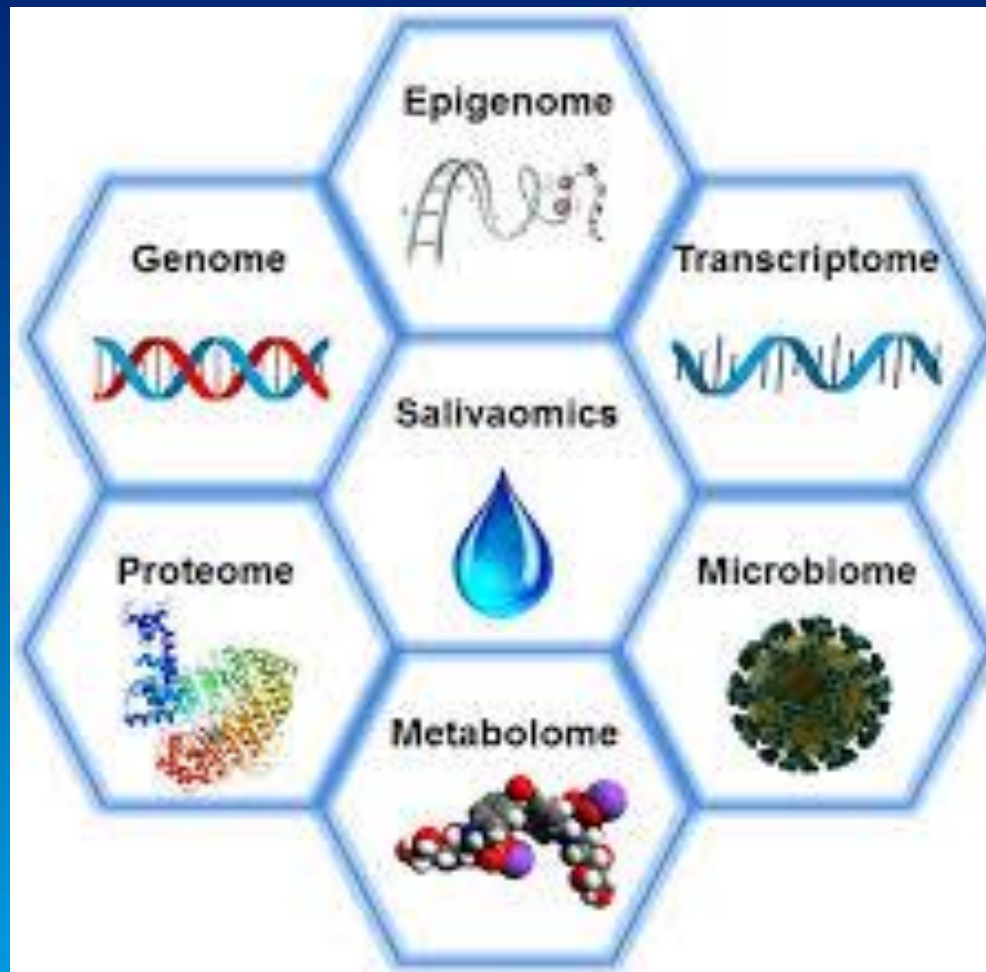


Molecular

Molecular

Non-molecular

Q: What Omics Can Be Performed With Saliva?



A: Most Omics

Image courtesy of Dr
David T Wong Associate
Dean, UCLA Dentistry

Exponential Growth Caused by COVID-19

1. MicroGenDX Laboratories obtains FDA EUA approval for 24-hour saliva test [RT-PCR] 4/4/2020
2. Rutgers University / Infinite Biologics – gets first FDA EUA Approval for saliva high throughput method connected to Thermo Fisher RT-PCR 04/13/2020
3. Curative receives FDA EUA for oral fluid test 04/19/2020
4. FDA announces changes in registration requirements 05/19/2020
5. MLB adopts saliva COVID-19 Testing 05/20/2020
6. Chronomics [UK] Saliva COVID-19 Test Launched 05/20/2020
7. Phosphorus gets FDA EUA for home saliva test [collection] 06/09/2020
8. Sysmex Japan gets approval in Japan with BGI RT-PCR Kit 06/10/2020
9. Yale / Saliva Direct working with the NBA 06/24/2020
10. CRL / OraSure get EUA with RT-PCR 07/31/2020
11. Approval for Yale / Saliva Direct 08/17/2020



Exponential Growth Caused by COVID-19

1. U of Illinois-Urbana- Champaign FDA EUA approval granted 08/20/2020
2. OraSure / MiraDx get EUA for RT-PCR Kit 09/04/2020
3. Spectrum DNA gets FDA EUA for saliva collection kit 10/19/2020

NIH RADx Rapid Acceleration of Diagnostics Program is providing Funding for a multitude of COVID-19 Test Kits, some of which will use saliva specimens

Estimates of Tests to be performed using saliva specimens to be as high as 4MM Per Day



Selection of Saliva Players

