Salivary Diagnostics

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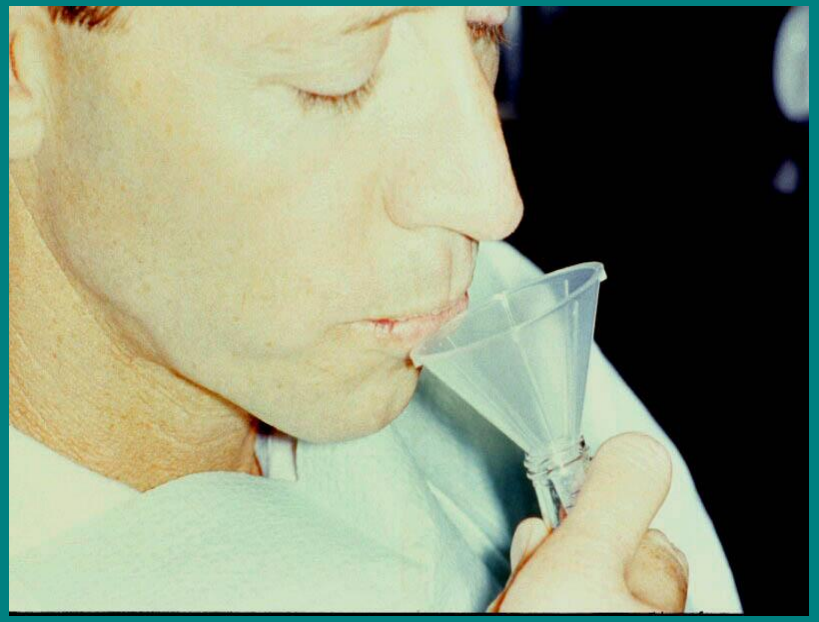
Salivary Diagnostics

- Preliminary Information
  - Not yet ready for Prime Time
- Three Major Concepts
  - Salivary Diagnostics
  - Point of Care Testing
  - Lab on a Chip

Salivary Diagnostics

- Is it comparable to blood?
- Biological fluid that contains many analytes
- Non-invasive collection
  - Easily done at multiple outpatient settings



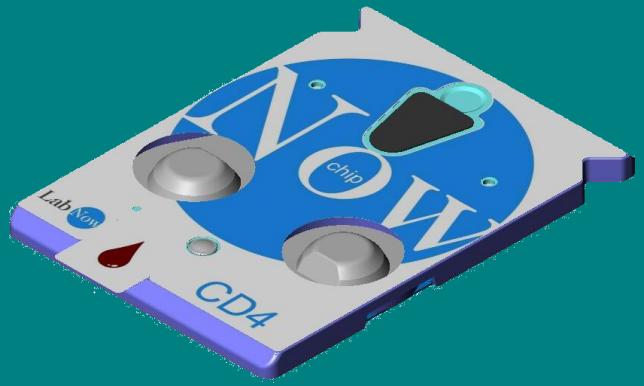
Salivary Diagnostics

- Utilized in other disease processes
  - Cancer
  - Infectious disease
  - Diabetes mellitus
  - Potential for virtually any disease

Point of Care Testing

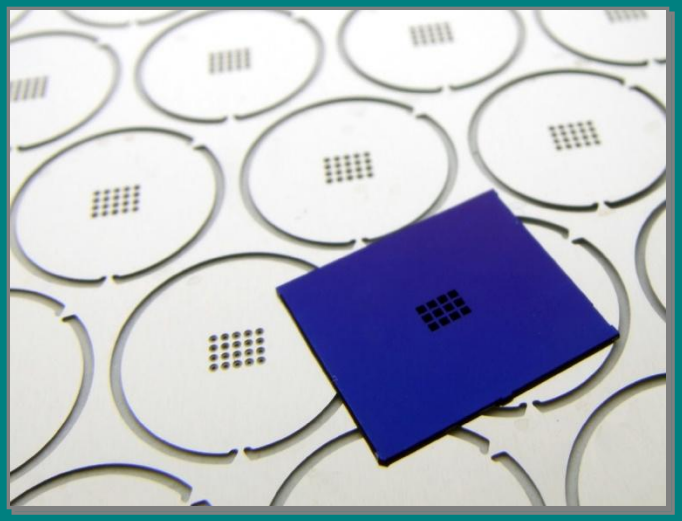
- Gurney/bedside vs. Centralized lab
- Cost of equipment greatly reduced
- Results in 10-15 minutes vs 1-6 hours

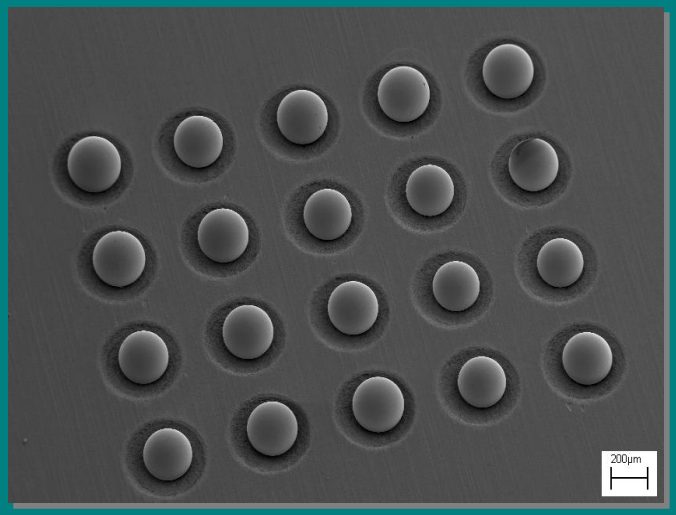
Point of Care Testing



- Samples placed on individual card for the appropriate test
- Card placed in common analyzer where result is reported

Lab on a Chip





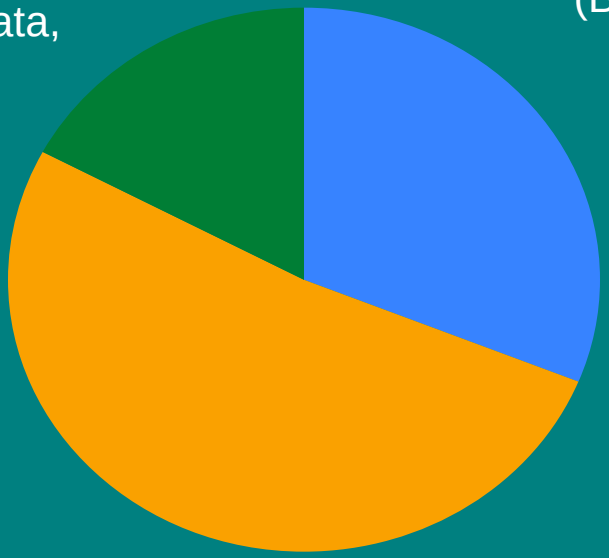
Lab on a Chip

- Sample placed on card
- Card placed in analyzer

Cardiac Diagnostics

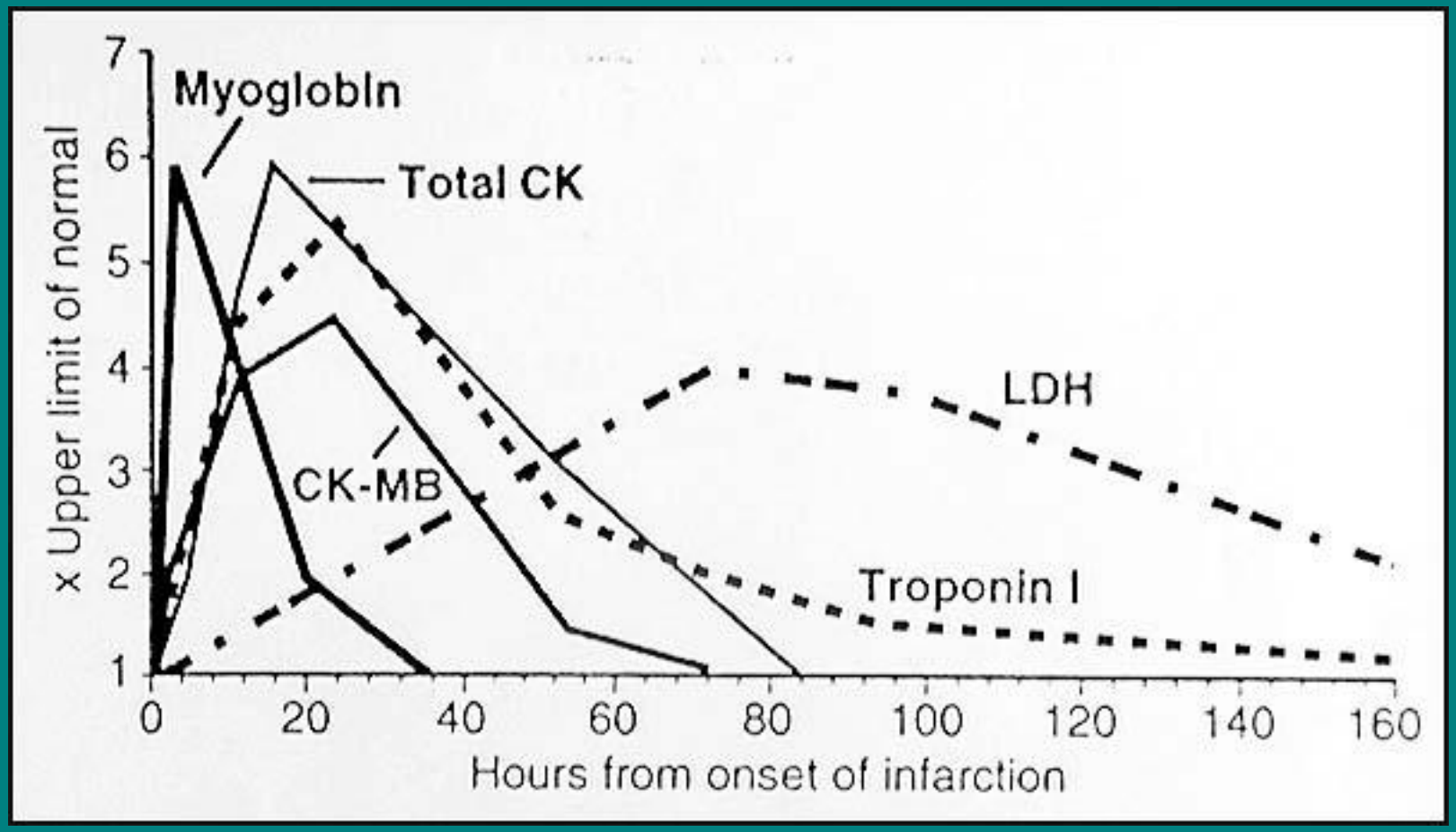
At Risk Testing
(CRP, TNF Alpha, IL1-data, WBC)

Congestive Heart Failure Prognosis
(BNP, Pro BNP, Urotensin)

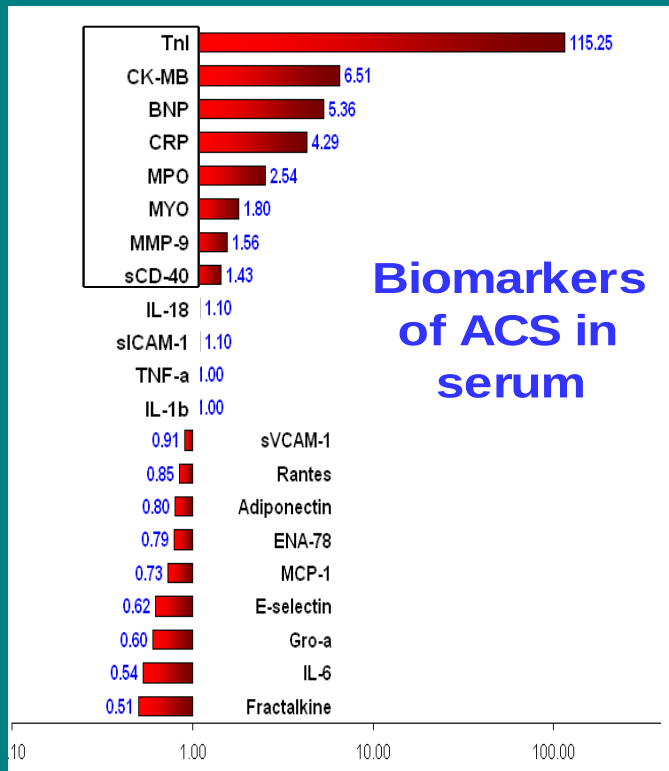


Acute Coronary Syndrome
(IMA,D-dimer, Troponin I, Troponin T, CKMB, Myoglobin and Digoxin)

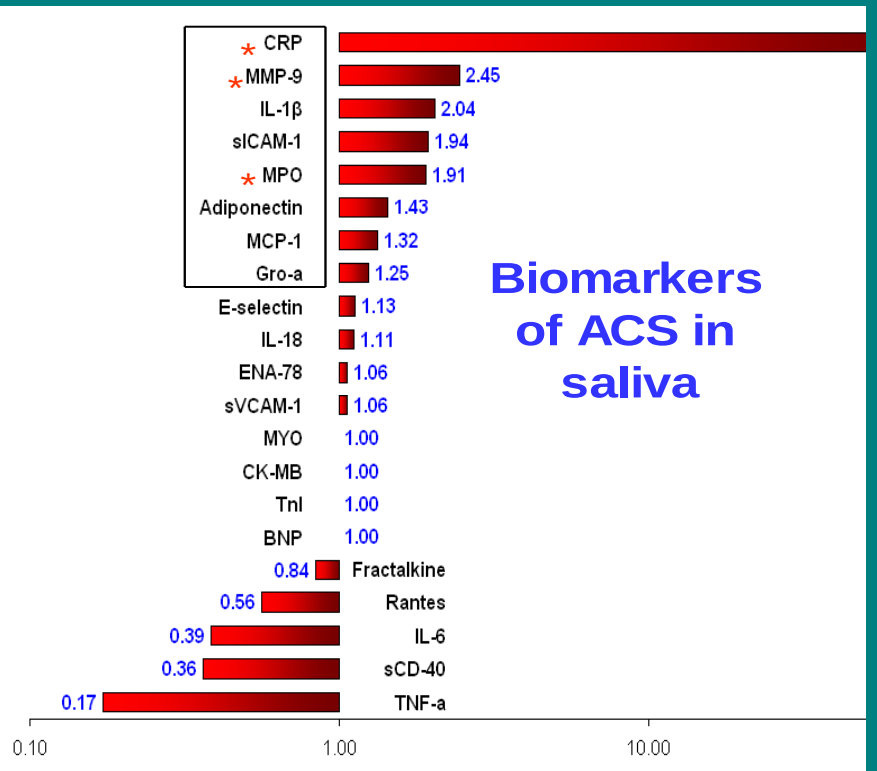
Time Course of Established AMI Biomarkers in Serum



Biomarkers of ACS



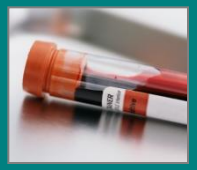
Biomarkers of ACS in serum



Biomarkers of ACS in saliva

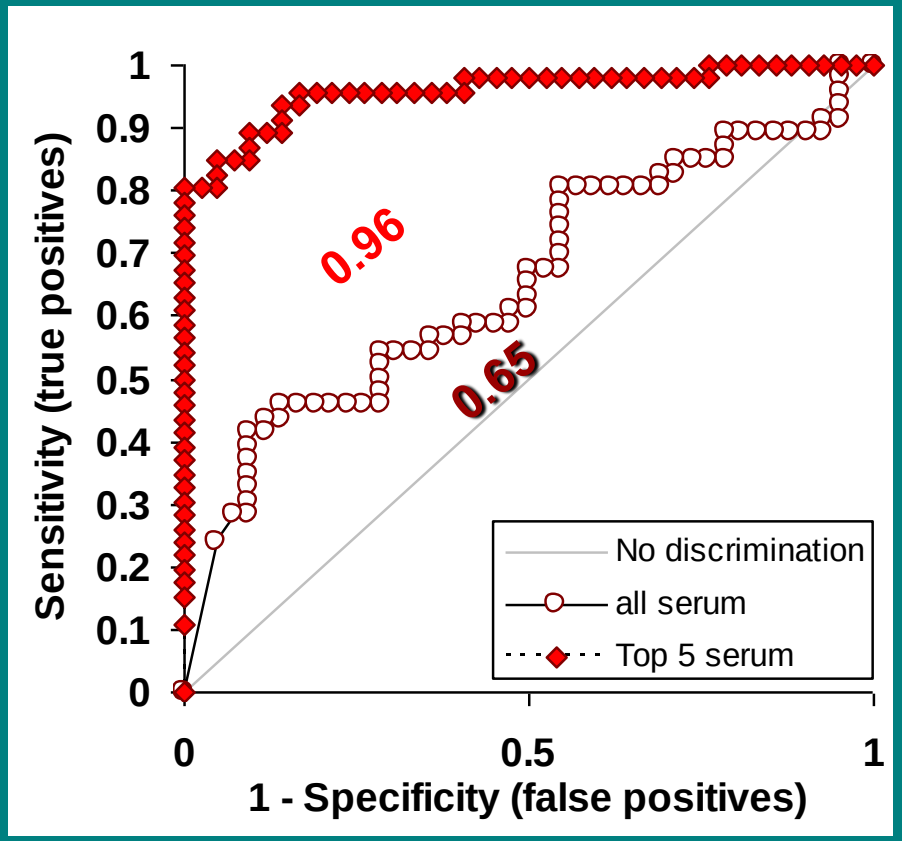
Ratio of <u>median</u> concentration for the ACS (NSTEMI &STEMI) over median concentration for the controls

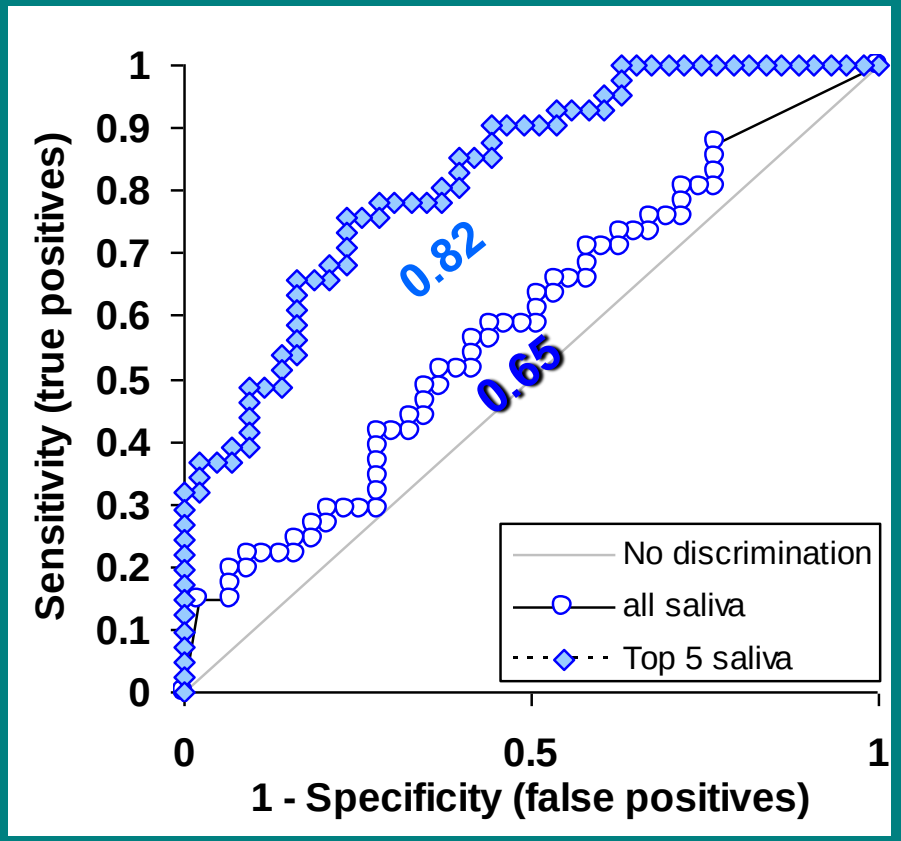
ROC Curves for 21 and Top-5 Biomarkers for AMI Diagnosis



SERUM (UK & UL)

SALIVA (UK & UL)



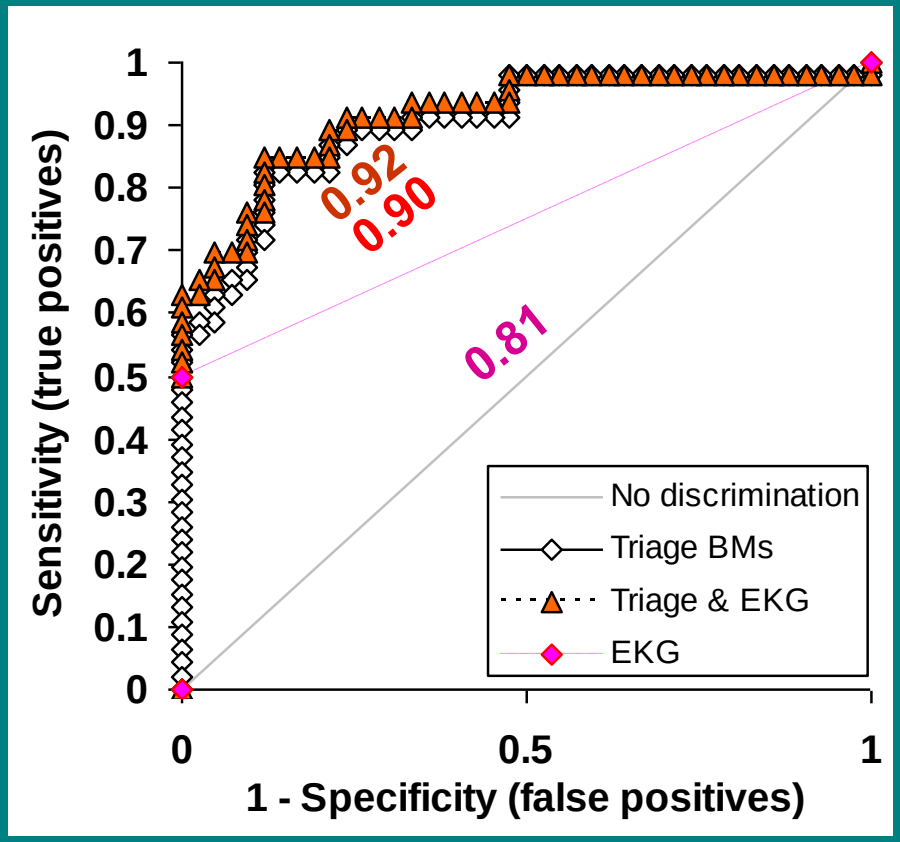


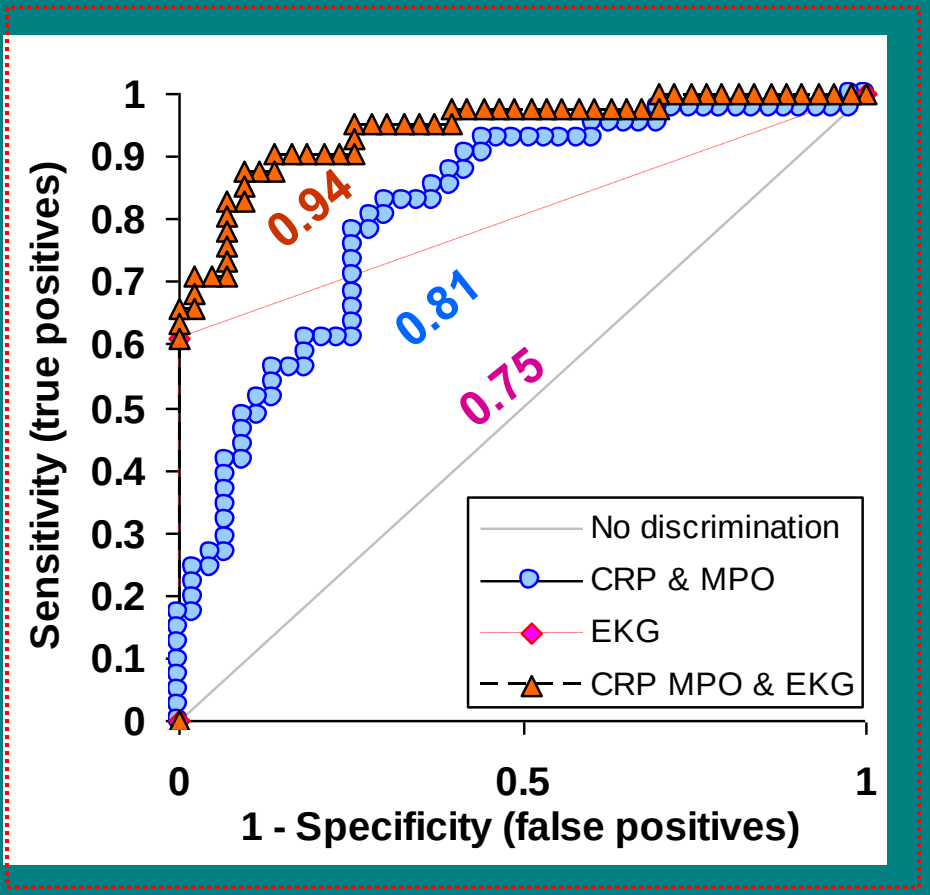
43 Controls, 23 NSTEMI, 25 STEMI

ROC Curves for Combination EKG and Saliva Biomarker Panel

SERUM (UK & UL)

SALIVA (UK & UL)





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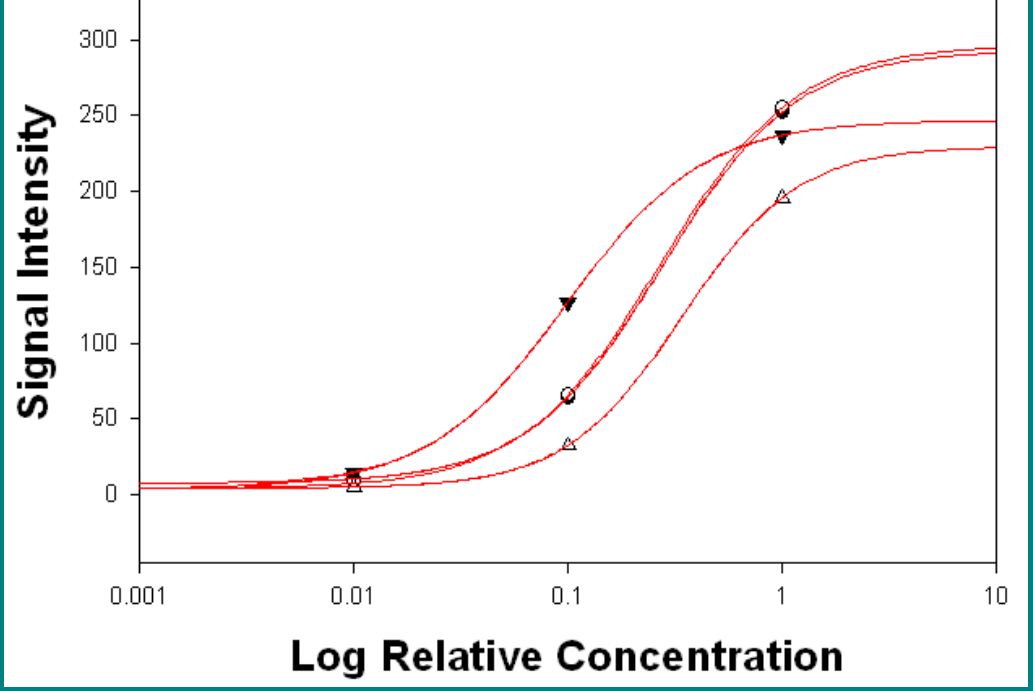

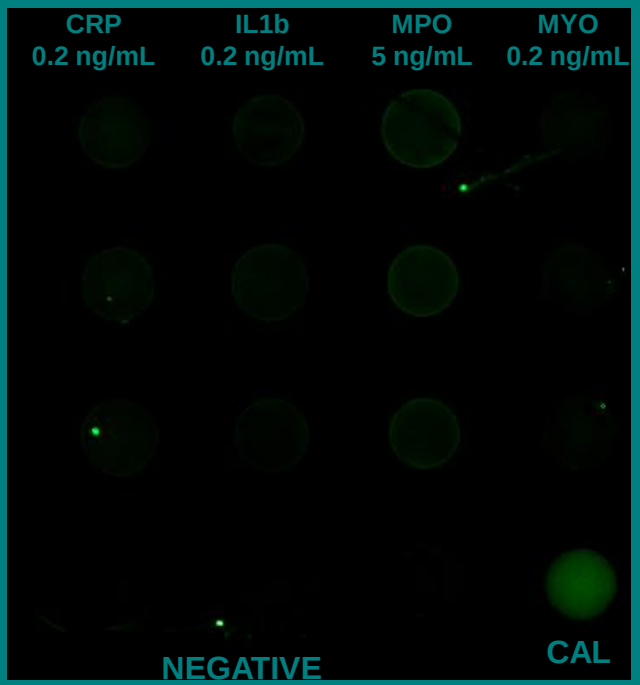

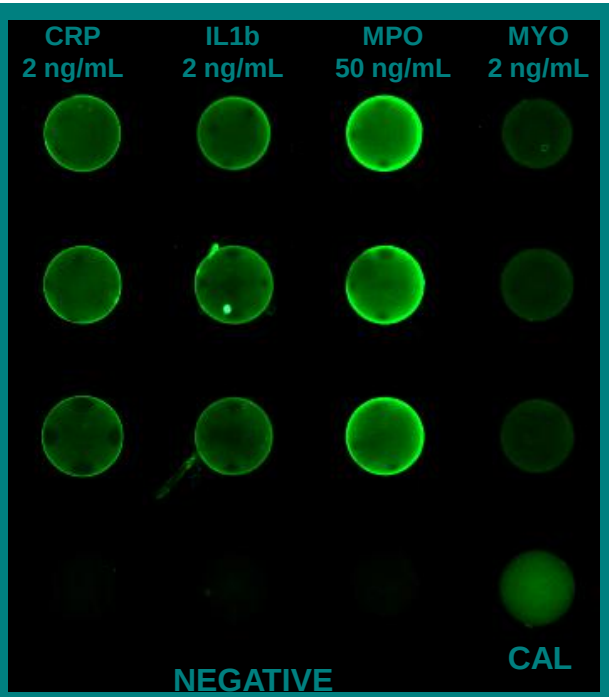

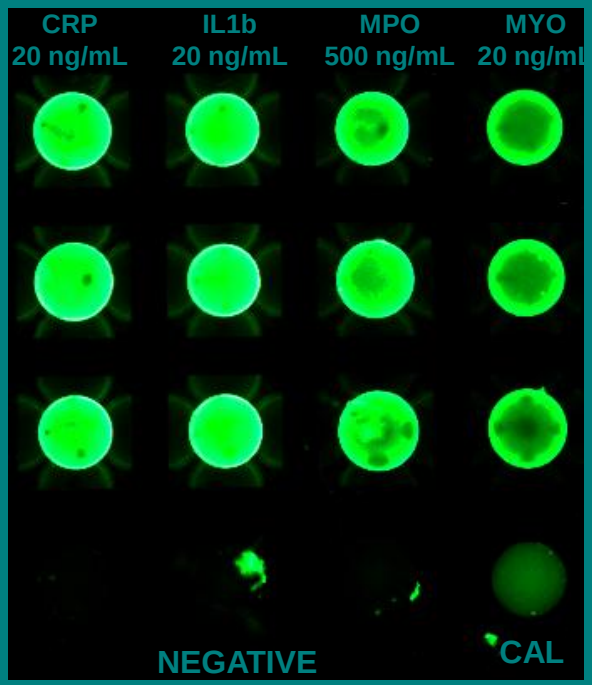

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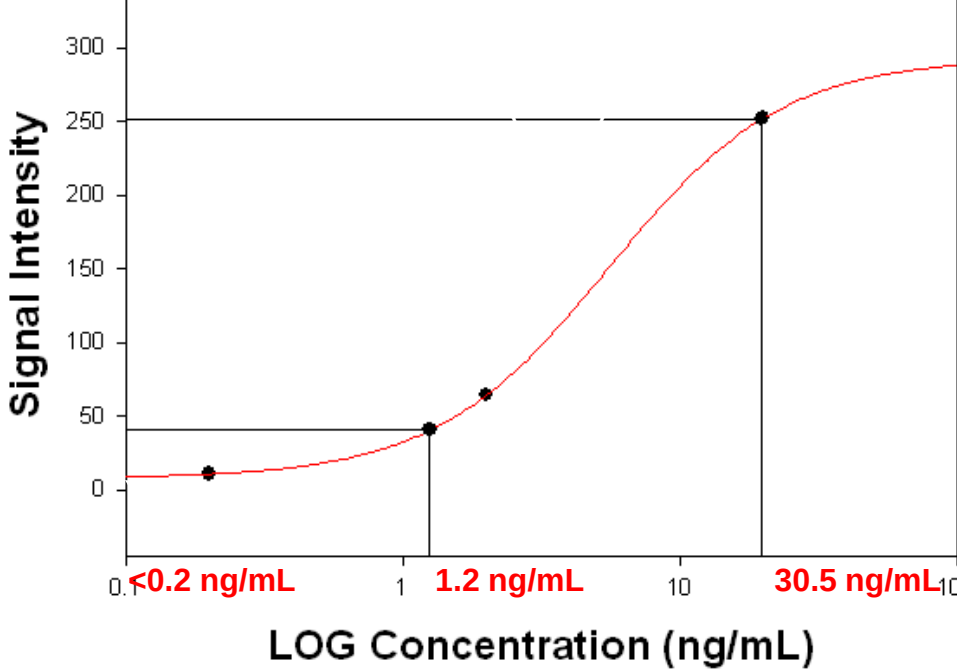
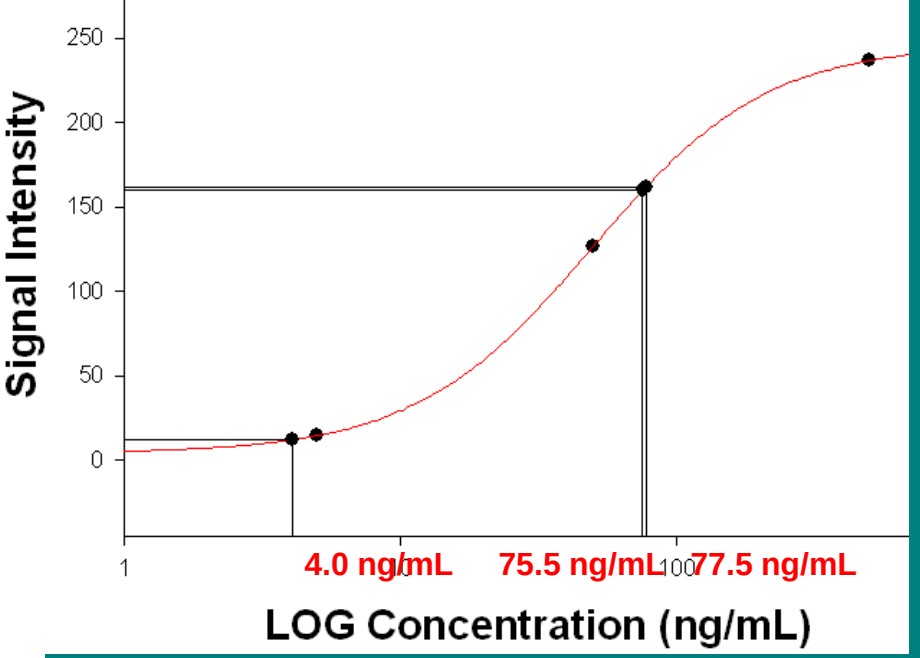
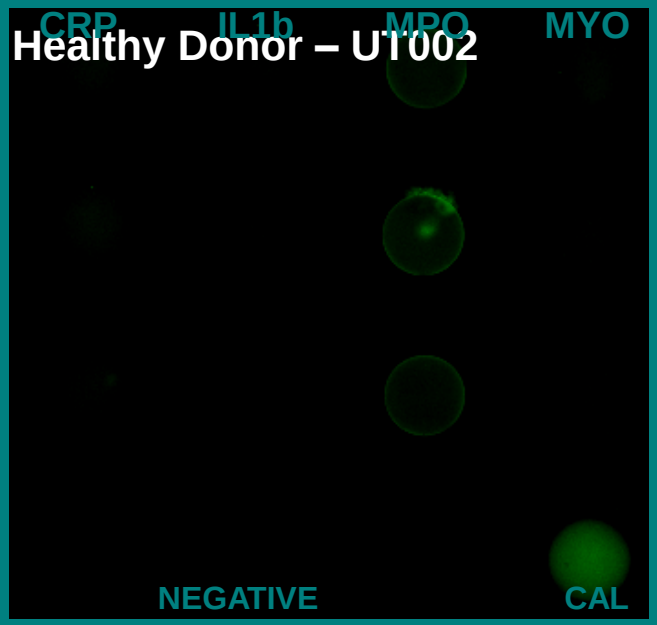
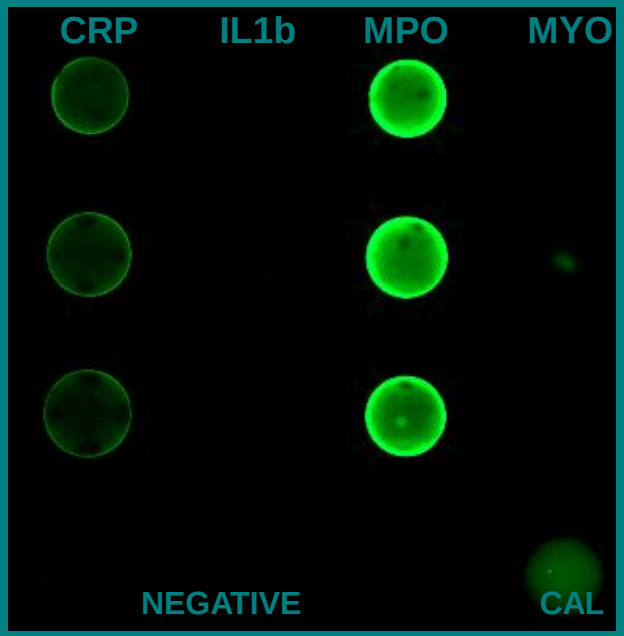




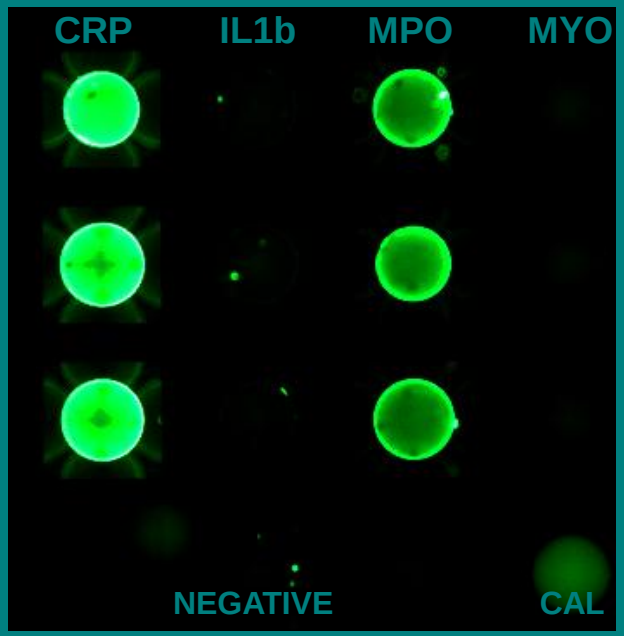
Healthy Donor – UT002



Ambulance Patient - EMS2



Ambulance Patient- EMS3



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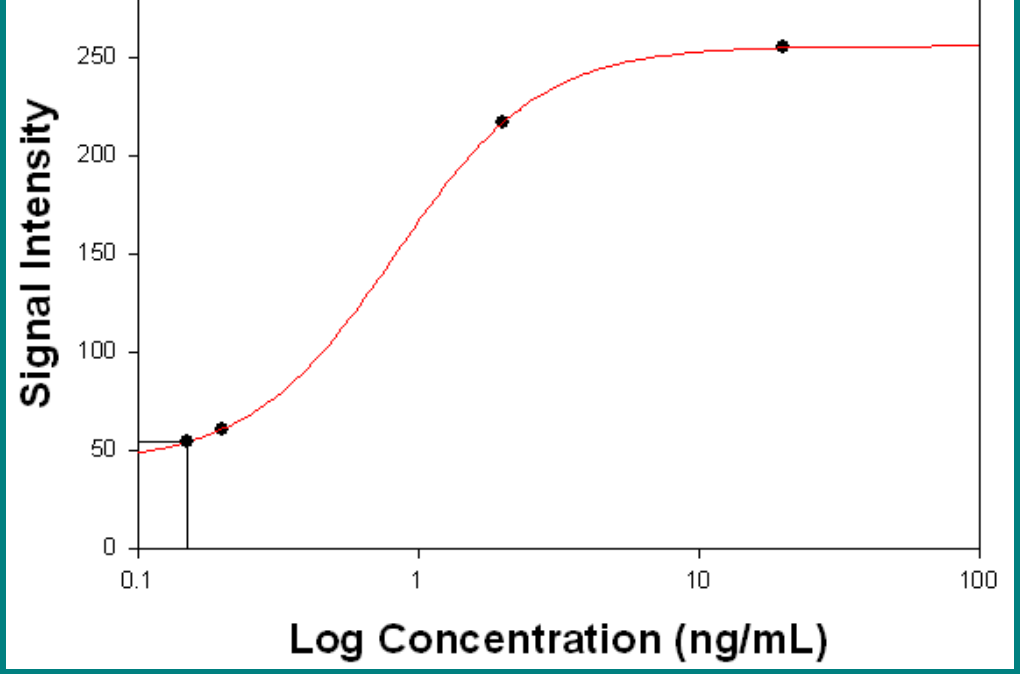
g15/off0/0.75”



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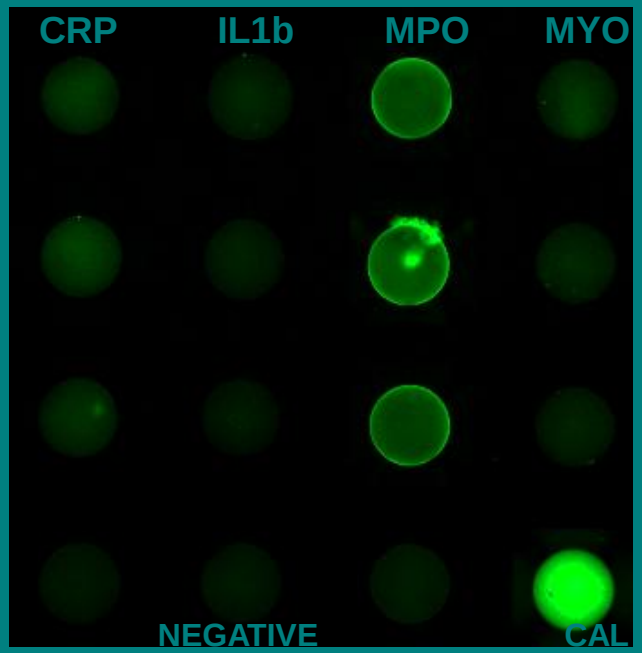

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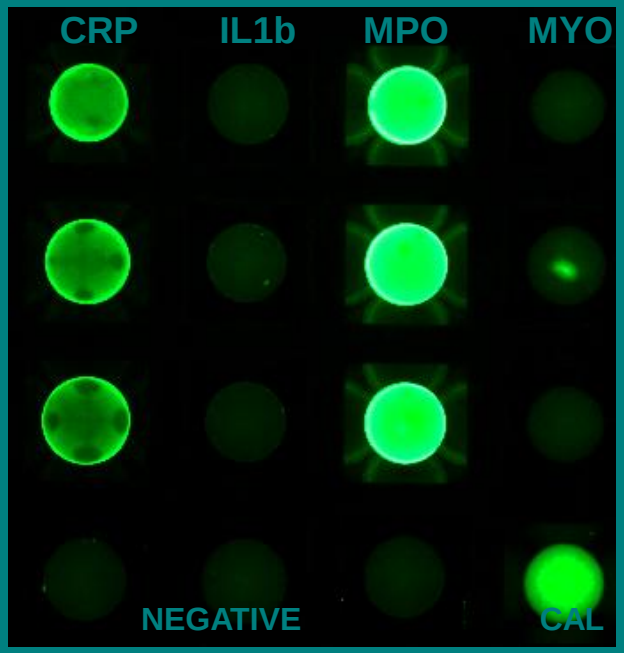
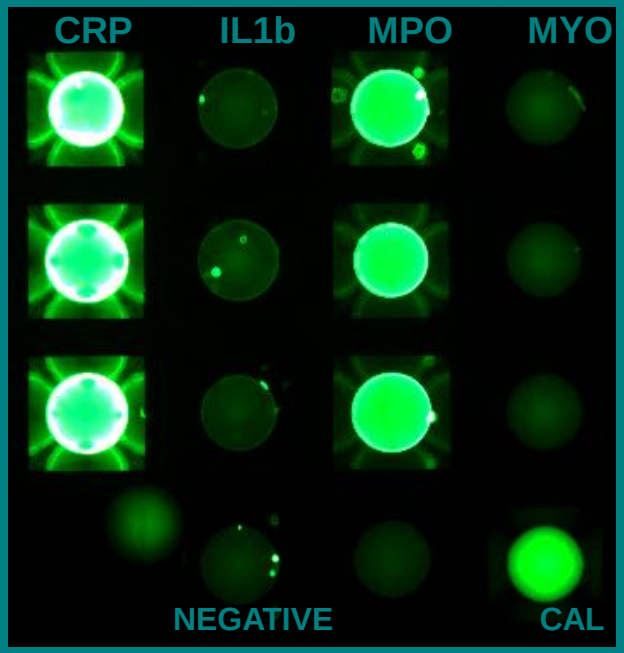


Ambulance Patient- EMS3



EMS Study

- Is there a role for salivary markers in the pre-hospital setting?
- Can they replace blood tests for definitive diagnosis by reducing time from diagnosis to treatment?

EMS Study

- Collect saliva samples from patients with ACS symptoms
- Evaluate for markers found in University of Kentucky MI study
- Correlate with diagnosis of STEMI/NSTEMI

EMS Study

- Faculty from UTHSCSA School of Health Professions Coordinate:
  - patient recruitment
  - patient history
  - collection of samples

  - Geoff Smith, LP
  - David Wampler, PhD, LP

SAFD Paramedics

- Danny Zamora
- Timothy Worley
- Christopher Velasquez
- Trenton Thames
- Greg Tetsch
- Hank Schott
- Robert Payne
- Mark Olson
- James Murray
- Michael Mumme
- Juan Morin
- Donald Merecka
- Jeremy McElroy
- Ray Mays
- Terrence D Lowe
- Mark Lerma
- Jonathan Hosek
- Alberto Garcia
- Joel Fox
- Marti Flores
- Robert Dugie
- Kenneth Dugger
- Michael Dixon
- Eli Dierkhising
- Kevin Cryus
- Kristy Crenshaw
- Kelvin Broadnax
- Peter Baron

Requirements for Study Enrollment

- IRB Training 1 Hour
- Study Training 1 Hour
- Review/Updates 1 hour, Group mtg
- Research Assistant– Bi-Weekly phone reminder

- Cooler issued
- Swab obtained
- Sampled delivered to VA

- Verbal consent by paramedic followed by formal consent post-event

EMS Study

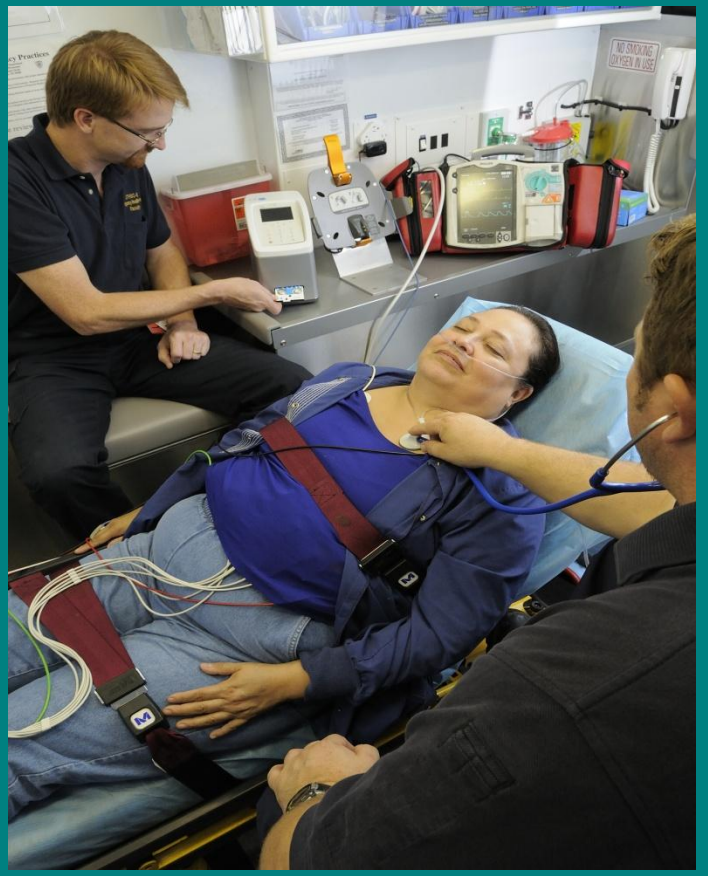
- Cardiologist will confirm patient diagnosis
- Salivary diagnostics lab will process samples for delivery to Rice University

EMS Study

- Markers will be analyzed using lab on a chip technology

EMS Study

- Potential Findings:
  - Increase accuracy of diagnosis in combination with ECG
  - Reduce diagnosis time
  - Alter treatment



Saliva ACS biomarker testing in ambulance

User: paramedics, highly trained

Environment: EMS vehicle, battery power, significant vibrations, compact

Accessories: used in connection with EKG, radio communications with hospital

12 lead EKG used by paramedics to transmit initial findings to emergency room physicians. EKG does not diagnose NSTEMI cases.

Saliva testing allows for identification of NSTEMI patients

Results

- Acute Coronary Syndrome/ Chest Pain

- Recruited 29/ 120 patients
- 7 Confirmed STEMI/NSTEMI
- 3 Heart Failure

- Is this important?
- Will it alter therapy?
- Does it improve outcomes?

Acknowledgements:

- San Antonio Fire Department
- Dr. Spencer Redding
- David Wampler, PhD
- Geoff Smith
- Chih-Ko Yeh
- Alan Lin
- Terry Baucher
- John McDevitt
- Funded Grant NIH "Development of a lab on a chip system for saliva based diagnostics""

Salivary Diagnostics Projects

- Four funded Groups
  - UT Austin-UTHSCSA-UK-UL
    - Cardiac disease
  - NYU
    - Tuberculosis
  - UCLA
    - Oral cancer
  - Tufts

Future


THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER
AT SAN ANTONIO