1370
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Oral Fluid Pilot Project Data Analysis

January 2022 – July 2023

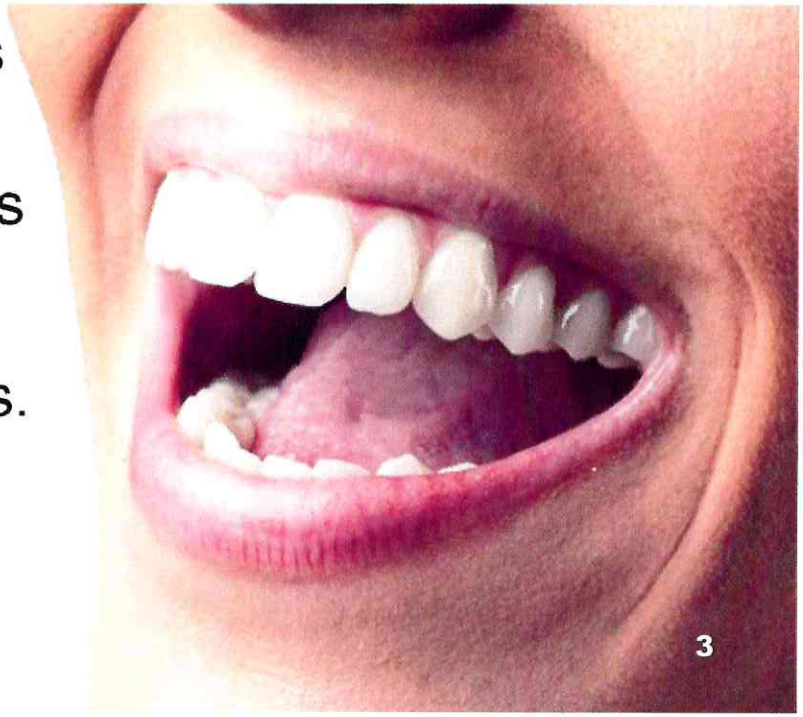
Oral Fluid Technical Advisory Committee Study Results

Oral Fluid Technical Advisory Committee

- Traffic Safety Resource Prosecutor (TSRP)
  - Kristi Pettit-Venhuizen
  - Aaron Birst
  - Peter Halbach
- Crime Laboratory Division
  - Janelle Portscheller
- ND DOT – Safety Division
  - Sandy Wilson
- Sheriff's Office
  - Shannon Wellen (DRE)
- NDHP
  - Trp. Tarek Chase (DRE)
  - Lt. Adam Dvorak (DRE)
- NDSU – Upper Great Plains Transportation Institute
  - Kimberly Vachal
  - Jaclyn Anderson
- Police Department
  - Matthew Woodley (DRE)
- Judicial Outreach Liaison
  - Judge John W. Grinsteiner

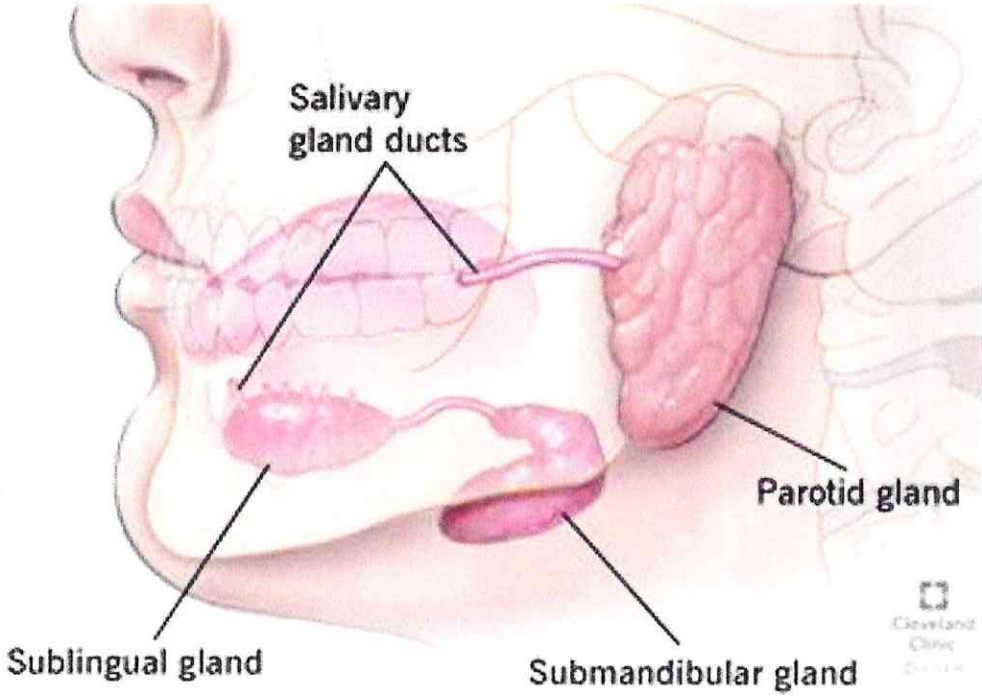
Terminology Oral Fluid vs. Saliva

- Physiologically different
- Saliva – fluid secreted from saliva glands
- Oral Fluid – encompasses not just the saliva but also nasal, bronchial secretions and other components such as bacteria, cellular elements, electrolytes, immunoglobins, proteins, and food debris.
- Saliva is a subcomponent of Oral Fluid



What is Oral Fluid

- 90% Saliva
- 3 major salivatory glands
  - Parotid
  - Submandibular
  - Sublingual
- Healthy adults produce 0.5 – 1.5 L of oral fluid per day
- Oral fluid pH 6.2 to 7.4



https://my.clevelandclinic.org/health/diseases/15749-sialadenitis-swollen-salivary-gland

How Drugs Enter Oral Fluid

- Unionized unbound drugs enter the oral fluid by passive diffusion across membranes from the blood to oral fluid
- Basic drugs will have a higher concentration in the oral fluid than in the blood due to ion trapping (e.g. Methamphetamine)
- Neutral and acidic drugs will have a lower concentration in the oral fluid than in the blood (e.g. Benzodiazepines)
- Drugs that are smoked, inhaled, snorted or taken as edibles appear rapidly in the oral fluid because of buccal cavity contamination
- Passive inhalation (will rapidly dissipate after source has been removed)
- Drugs that are administered orally in capsules do not contaminate the oral mucosa
- Drugs administered intravenously are detected in the oral fluid within minutes of injection

Why Test Oral Fluid?

- Samples can be collected on-site
- Samples can be collected with a collection device
- No medically qualified person needed
- Gender neutral sample collection
- Samples are difficult to adulterate
- Drug detection windows reflect recent drug use

Oral Fluid Impaired Driving Studies

- European Studies
  - ROSITA (1999 – 2000) & ROSITA-2 (2003 – 2005)
  - DRUID (2006 – 2011)
- Canadian Roadside Survey – 2008, 2010, 2012, 2014
- USA Studies
  - NHTSA National Roadside Survey – 2007 & 2013/2014
  - California & Washington Initiatives 2012 – 2014
  - Michigan Roadside Oral Fluid 2017-2018 & 2019-2020

Types of Oral Fluid Programs

Roadside Screening with Device (Probable Cause)

Applicable to presentation today

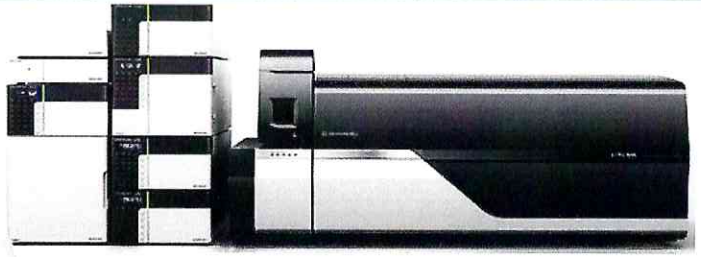
DrugWipe

SoToxa

Dräger Drug Test 5000

Laboratory Confirmation (Evidentiary)

Not Applicable to presentation today



Laboratory Equipment (ex. LC/MS/MS) used for Oral Fluid analysis

Oral Fluid Confirmation Specimen

Steps in the DUI Process

Vehicle in Motion → Personal Contact → Pre-Arrest Screening (SFSTs) → Field Screening Devices (Breath Alcohol or Oral Fluid Drug)

Evidential Sample Collection – Blood, Urine, or Breath → Consent/Search Warrant → Arrest → Probable Cause

Drug Influence Evaluation

https://publicaffairsresources.aaa.biz/wp-content/uploads/2020/07/AAA-Oral-Fluid-Drug-Screening-Handout.pdf

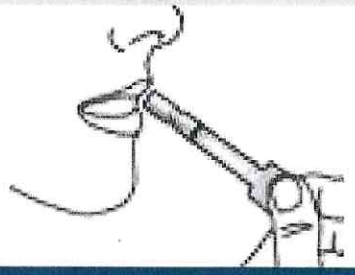
How the SoToxa Device Works

- Results are ready in 5 minutes
- Results are displayed as Positive or Negative for each test panel on the device
- The officer does not need to interpret the test results
- Test cartridges are disposed after use
- Test results stored on device and can be printed with a supplied external printer

HOW IT WORKS

1 Insert test cartridge into analyser.

2 Collect oral fluid sample.

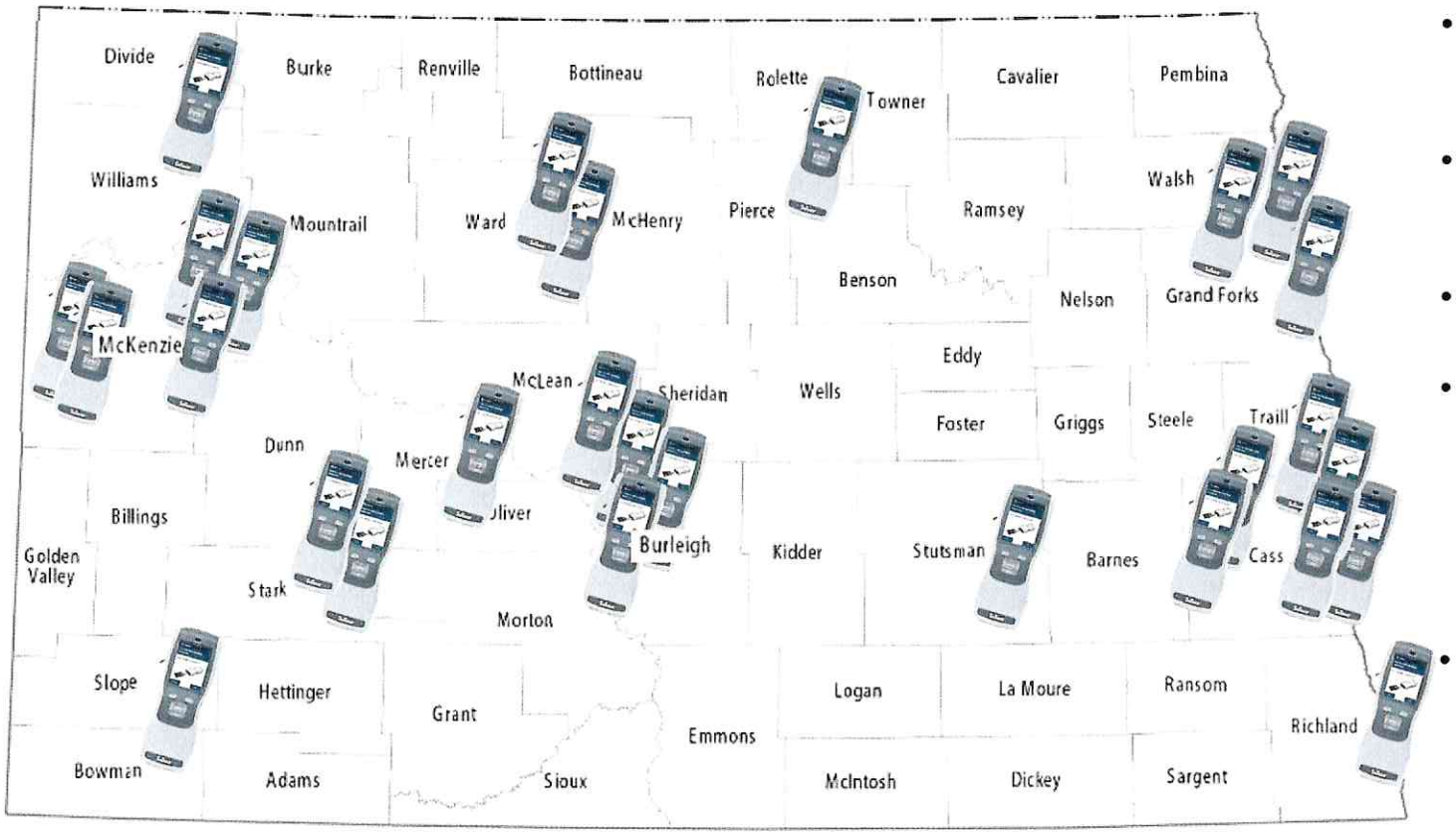


3 Insert collection device into test cartridge.

Principles of the SoToxa Device

- Lateral Flow Immunoassay which uses principles of Competitive Binding
- Test Panels:
  - Cocaine
  - Opiate
  - Methamphetamine/MDMA
  - Cannabis
  - Benzodiazepine
  - Amphetamine
- Cross Reactivity – Compounds with similar chemical structure can give a positive test result
  - Because of Cross Reactivity - False Positives & False Negatives are Possible
  - Therefore, they non-evidentiary Tests
  - Evidential Samples need to be collected and submitted to a laboratory for evidentiary testing

Pilot Study Numbers



- 31 DRE Officers were trained on the device
- 28 devices assigned to DRE Officers
- 16 Law Enforcement Agencies
- 13 State Counties
- 52 completed tests with SoToxa and Evidential Blood Specimen results were obtained
- Devices purchased with Federal DOT Grant Funds from NHSTA

ND Crime Laboratory Division Top 10 Drugs Detected from Impaired Driving Cases 2020 - 2023

2020	
1	THC-COOH
2	Amphetamine
3	Methamphetamine
4	Fentanyl
5	Norfentanyl
6	Diphenhydramine
7	Morphine
8	Alprazolam
9	7-Aminoclonazepam
10	Benzoylecgonine

2021	
1	Amphetamine
2	Methamphetamine
3	Δ^9-THC-COOH
4	Fentanyl
5	Norfentanyl
6	Δ^8-THC-COOH
7	Alprazolam
8	Diphenhydramine
9	Buprenorphine
10	EDDP (A Methadone Metabolite)

2022	
1	Δ^9-THC-COOH
2	Amphetamine
3	Methamphetamine
4	Fentanyl
5	Norfentanyl
6	Δ^8-THC-COOH
7	7-Aminoclonazepam
8	Alprazolam
9	Clonazepam
10	Benzoylecgonine

2023	
1	Δ^9-THC-COOH
2	Amphetamine
3	Methamphetamine
4	Δ^8-THC-COOH
5	Fentanyl
6	Quetiapine
7	Alprazolam
8	7-Aminoclonazepam
9	Cyclobenzaprine
10	Norfentanyl

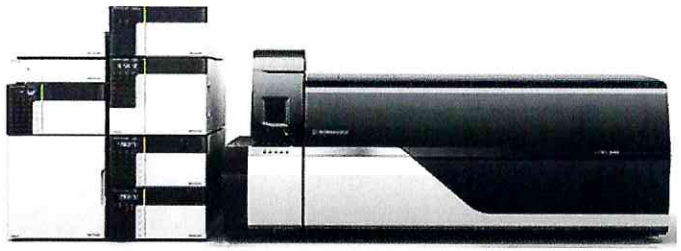
Drugs in Red Text = Drugs Detectable by the SoToxa Device

Note high percent of drugs present in drug impaired driving cases can be detected by the SoToxa Device

SoToxa Device Evaluation

- SoToxa results were compared to laboratory evidential blood specimen results for the same subject
- Each device test panel evaluated for Sensitivity, Specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), and overall Accuracy

Roadside Screening Device



Laboratory Test (ex. LC/MS/MS)

	Positive	Negative	
Positive	**True Positive (TP)**	**False Positive (FP)**	
Negative	**False Negative (FN)**	**True Negative (TN)**	
	Sensitivity $\frac{TP}{(TP+FN)}$	**Specificity** $\frac{TN}{(TN+FP)}$	
	PPV $\frac{TP}{(TP+FP)}$	**NPV** $\frac{TN}{(TN+FN)}$	**Accuracy** $\frac{TP+TN}{(TP+TN+FP+FN)}$

Device Evaluation Definitions

- **True Positive** (**TP**) – Test device and gold standard detect the drug
- **True Negative** (**TN**) – Test device and gold standard do not detect the drug
- **False Positive** (**FP**) – Test device detects a drug but the drug is not detected with the gold standard
- **False Negative** (**FN**) – Test device does not detect the drug but the gold standard detects the drug
- **Sensitivity** – A measure of the number of true positives as a rate of all positives (i.e. a positive is not missed)
- **Specificity** – A measure of the number of true negatives as a rate of all negatives (i.e. a negative is not missed)
- **Positive Predictive Value** (**PPV**) – A measure of the number of true positives as a rate of reported positives (i.e. a false positive is not missed)
- **Negative Predictive Value** (**NPV**) – A measure of the number of true negatives as a rate of reported negatives (i.e. a false negative is not missed)
- **Accuracy** – Measures the percentage of all samples correctly as classified by the tests

SoToxa Device Evaluation Summary

Test Panel	Sensitivity	Specificity	PPV	NPV	Accuracy
Cocaine	100% (91%)	98% (95%)	50% (67%)	100% (99%)	98% (94%)
Narcotic – Opiate	100% (94%)	100% (91%)	100% (35%)	100% (99.6%)	100% (91%)
Methamphetamine	100% (95%)	94% (95%)	90% (85%)	100% (99%)	96% (95%)
Cannabis	88% (86%)	100% (92%)	100% (96%)	90% (77%)	94% (88%)
Benzodiazepine	50% (34%)	100% (91%)	100% (40%)	84% (89%)	87% (83%)
Amphetamine	100% (84%)	71% (87%)	70% (69%)	100% (94%)	83% (86%)

Black Text = North Dakota data (SoToxa vs. Blood, Samples = 52)
Red Text = Michigan data (SoToxa vs. Blood, Samples = 584-597)

Conclusions

- Oral Fluid is a non-invasive sample collection method which allows for in field sample collection proximate to the time of driving
- Oral Fluid drug analysis represents recent drug use
- Roadside Oral Fluid Drug Screening Devices are an extra tool to assist officers in establishing probable cause
- A limited number of positive tests results were obtained for the Cocaine & Opiate test panels
- Low Sensitivity and Positive Predictive Values for Benzodiazepine test panel is a result of this class of drug not crossing from blood into the oral fluid and is not a device flaw
- The Sensitivity, Specificity, Positive Predictive Values, Negative Predictive Values, and device Accuracy for the remaining panels were similar to the results obtained by the Michigan Oral Fluid Study.
- The SoToxa device is therefore a good additional roadside tool to give officers to help establish probable cause for a drug impaired driving.