



Give Me the Finger: Using Fingertick Blood Serum to Monitor Medication and Other Substance Use

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Titles and Affiliations

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Disclosures

Michael Sprintz, DO, DFASAM

- Consultant/Independent Contractor: Saluda Medical; Nanomedical Systems, Inc.; FirstTox, LLC; Assurance Medical Management, LLC; The Dean law Firm, PC; Mahantech
- Grant/Research Support: Ho-Chunk Nation (Tribal Nation). The interest is imputed, as I am CEO of Cellarian, Inc., who has partnered with HCN to to deploy software that helps providers identify patients at risk for substance abuse. I am a salaried employee of Cellarian and do not receive any money from this grant directly. All funds go to Cellarian.
- Honoraria: American Society of Addiction Medicine; Texas Pain Society; PAINWEEK; Texas A&M University System Health Center
- Advisory Board: Cellarian, Inc.; Cellarian Holdings, Inc.; Vitality Wellness Group, PLLC; Assurance Medication Management, LLC
- Stock Shareholder: Cellarian Holdings; Prosellus, Inc.; Vitality Wellness Group; Sprintz Center for Pain; Sprintz Center for Recovery; Vision Park Management Group; Titan Pharma; Indivior; RespireRx; Assurance Medication Management, LLC; NPSC

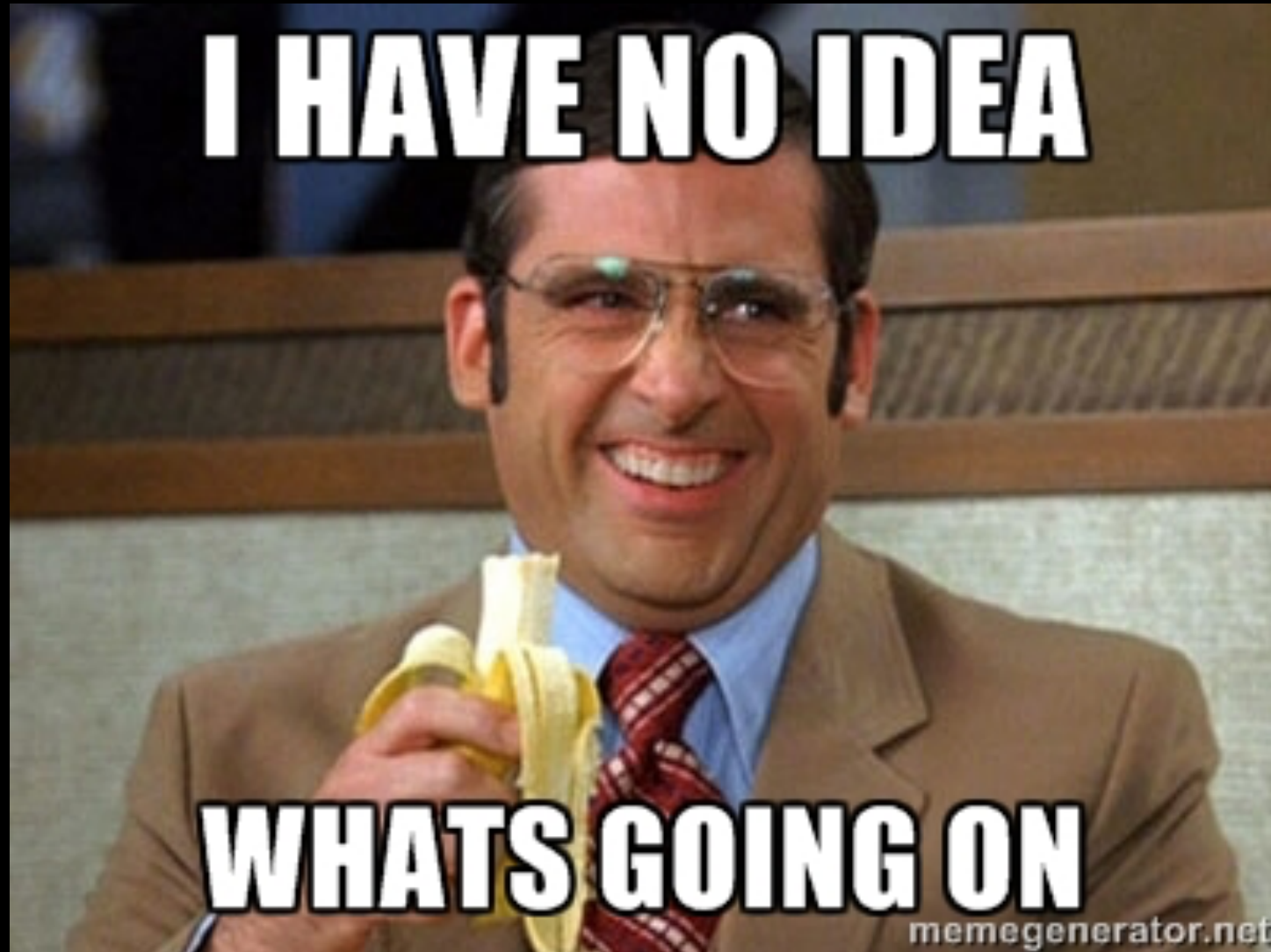
Michael C. Barnes, JD

- Nothing to disclose

Learning Objectives

1. Recognize some limitations of clinical urine drug testing.
2. Explore the clinical importance of monitoring steady state drug levels in patients.
3. Discuss using micro serum samples to measure steady state drug levels.
4. Identify the clinical implications of serum testing in patients with chronic pain or substance use disorders.

Once a patient leaves our clinic....



What We Tell Ourselves...

- “I know my patients”
- “I can tell which of my patients are abusing meds or illicit drugs ”
- “Billy’s a model patient. Never missed an appointment. He’s definitely not selling his oxycodone” (...or hydrocodone...or buprenorphine, etc)

Clinical Drug Testing Saves Lives

...But you MUST know how to use it

Drug testing is done for the patient,
not to the patient

-Gourlay and Heit 2013

Urine Drug Testing in Chronic Pain Medicine

- Monitor compliance for appropriately prescribed pain medications, including opioids
 - Protects patient by documenting patient adherence with medication treatment plan
 - Documentation also protects prescribers (along with PDMP and other precautions) by providing due diligence to identify and address potential SUD
- Early identification of substance use disorders (SUD)
- Detection of drug diversion



The Importance of Clinical Drug Testing



- A valuable tool to use as part of a comprehensive evaluation of patients
 - Improve diagnosis
 - Improve treatment
 - Improve outcomes
- Save billions in healthcare costs
- Improve public health
- Save YOU time, money, and your license



UDT only functions as a qualitative indicator of prescribed drug taken

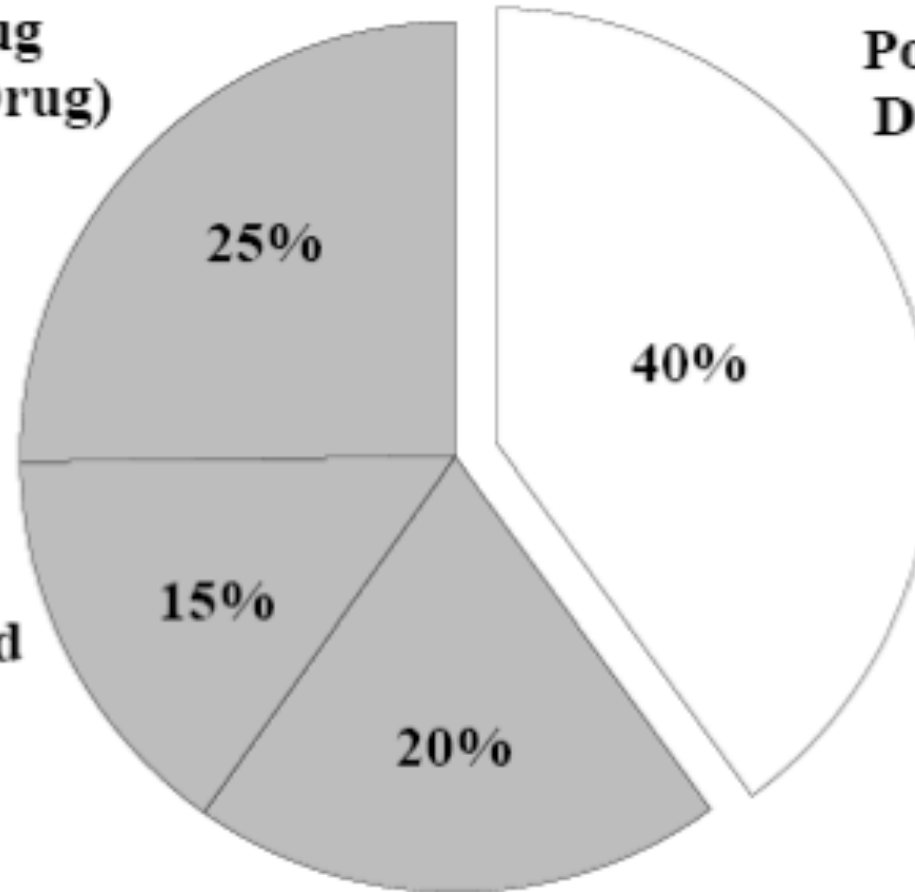
- Utilizing UDT for prescription drug monitoring only detects that patient **has or has not** taken prescribed drug within 3-7 days.
- UDT does NOT provide **how much** of a drug is present in the patient's system.

UDT drug concentration does not have correlation to dose taken

- UDT can not identify risk of unintentional overdose.
- UDT is a limited predictor of drug compliance.

**Negative for Any Drug
(Including Prescribed Drug)**

**Positive for Prescribed
Drug and Negative for
Other Drug**



**Negative for Prescribed
Drug and Positive for
Other Drug**

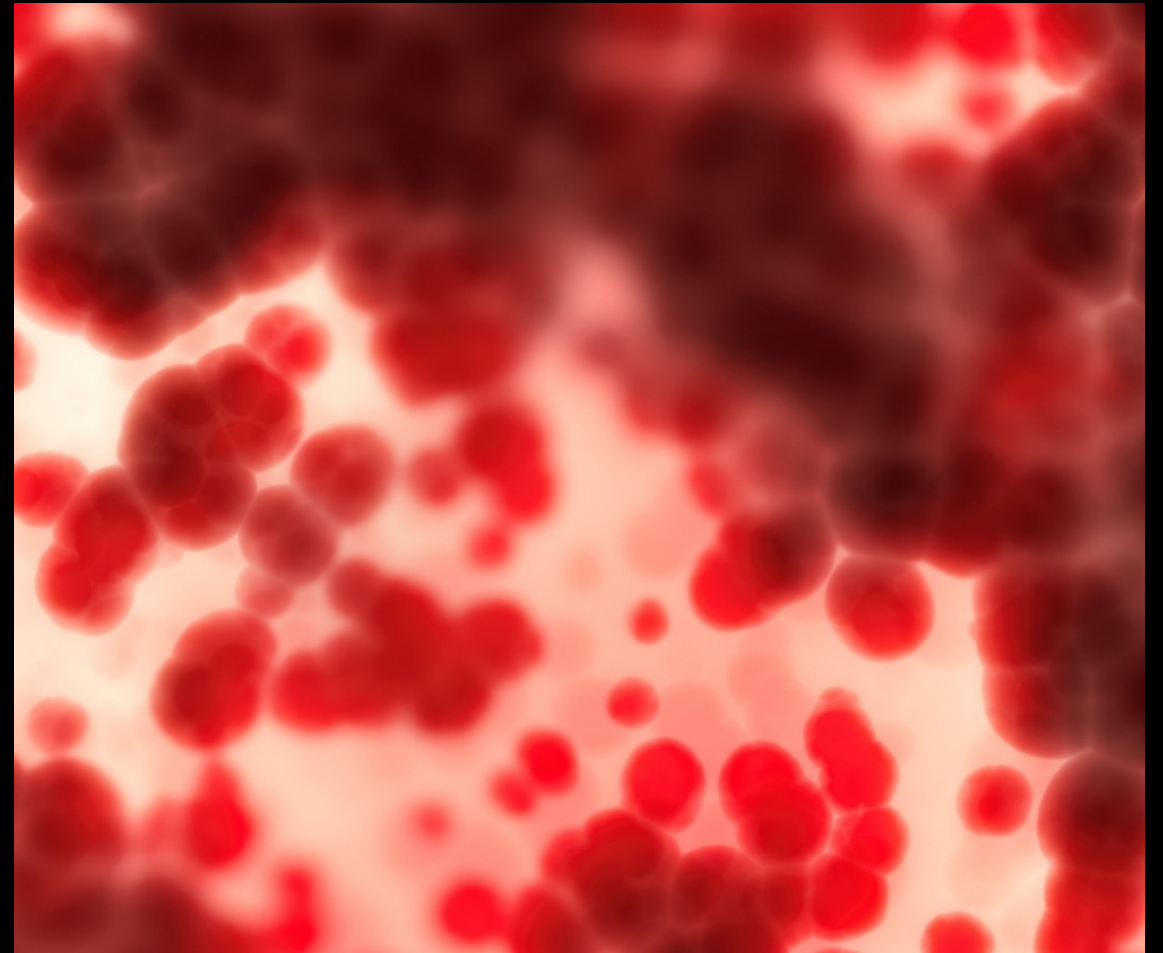
**Positive for Prescribed
Drug and Positive for
Other Drug**



It's time to get our heads out of.....the sand

Serum or Plasma Testing

For over 40 years, serum or plasma has been utilized for therapeutic drug monitoring of a variety of prescription medications including anticonvulsants, tricyclic antidepressants, and blood testing for immunosuppressants. All Pharmacokinetic (PK) studies are documented with serum.



Advantages of Monitoring Plasma Drug Level Monitoring



- Concentrations are an accurate measurement of drugs and/or their metabolites in the body
- Serum or plasma provides steady-state levels for drug dose
 - Steady-state levels for prescription drugs at various doses are well-documented in literature
 - Can indicate diversion or treatment nonadherence if drug not at steady-state level for dose
- Indicates potentially toxic levels of drug
 - Identification can help prevent accidental overdose

Disadvantages of Micro-Serum vs Urine

- In-office presumptive screen (if medically necessary) still needs urine
- Potential exposure to blood (vs urine)
- Patient refusing fingerstick

Finger Stick Micro-Serum vs Urine for Drug Testing

Micro-Serum

- Determines steady state drug levels
- Hard to tamper with sample
- Optimizes clinical workflow efficiency
- Respects modesty and privacy
- Less stigmatizing

Urine

- Cannot determine medication compliance with accuracy
- Relatively easy to tamper with sample
- “Shy bladder” slows workflow
- Observed collection
 - Can worsen stigma, undermine therapeutic alliance
 - “Degrading” for patient
 - Requires same-identifiable-gender observer
 - Risk of claims of inappropriateness

What Does This Mean to You?

Using micro-serum drug testing instead of urine:

- Enables prescriber to determine if patient is actually taking meds as prescribed
- Less false negatives
- Less risk to patients and prescribers
- Very hard for patients to tamper with → Results are more reliable
- Improved clinical workflow efficiency

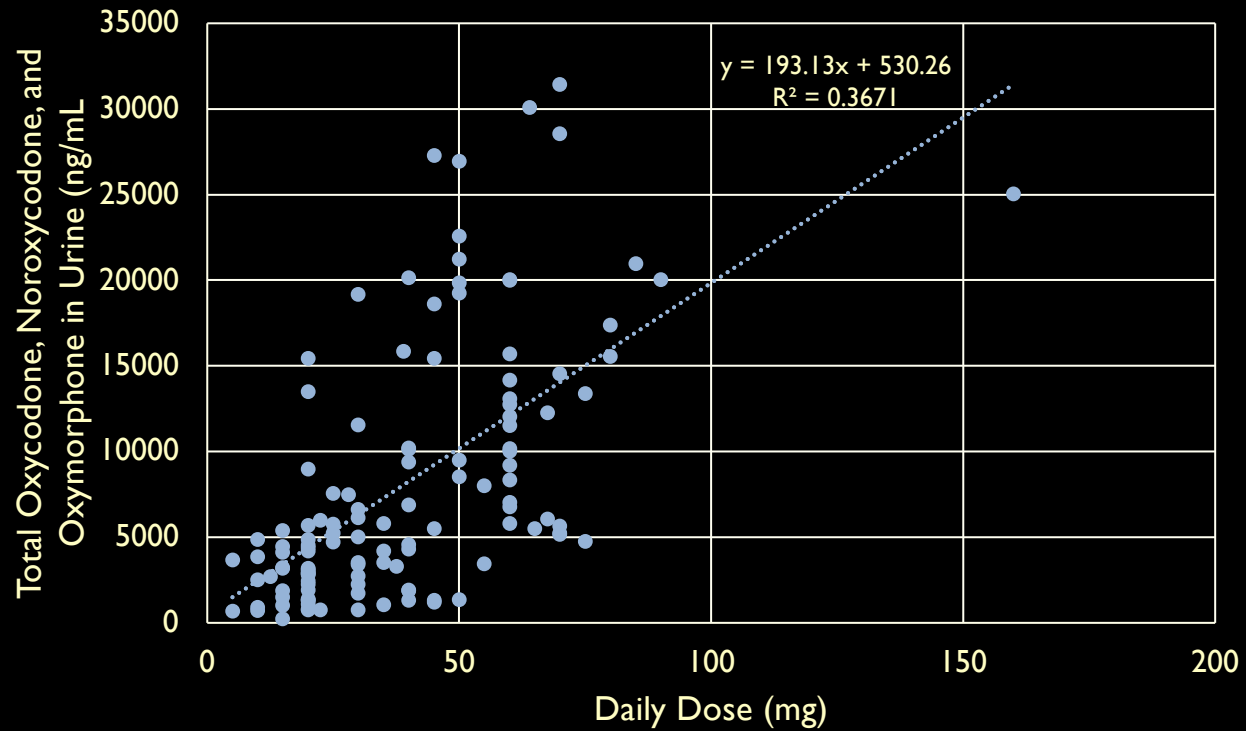
The Data: Clinical Study WIRB20180276

- IRB Approved Study comparing micro-serum vs urine for drug detection
 - ✓ Highly sensitive LC-MS/MS test for 35 drugs and their metabolites using 10 micro liter of serum or plasma from fingerstick blood.
 - ✓ Clinical study enrolled patients on opioids and collected both urine and fingerstick capillary blood.
 - ✓ Total of 1000 paired urine and plasma samples were analyzed to determine if their actual blood steady-state drug concentrations matched their predicted concentrations based on the prescribed dosing.

Clinical Study WIRB20180276 Results

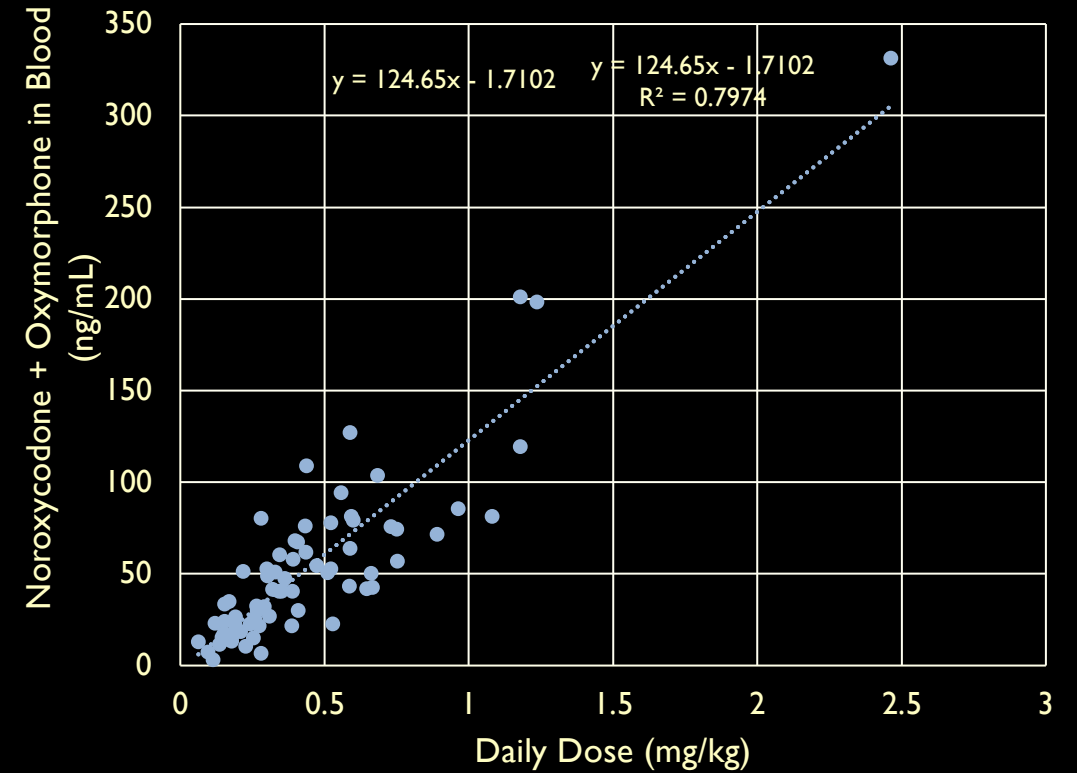
- ✓ Drug detection in urine verses micro serum was almost perfect with Cohen's Kapa Value of .96—Statistically urine and micro serum drug detection correlate
- ✓ Urine drug levels and metabolite concentrations did not correlate to the prescribed dose
- ✓ Serum drug levels and metabolites did correlate to the prescribed dose

Oxycodone + Metabolites in Urine



Urine Concentration does not correlate to dose

Noroxycodone + Oxymorphone



Serum Concentration correlates to dose

Summary

Serum Drug Testing: A Valuable Tool Helping Prescribers in the Opioid/Substance Abuse Epidemic

- 1. Know how much your patient is *really* taking**
 - Provides steady-state level and/or therapeutic ranges
 - Supports continued appropriate prescribing to compliant patients
 - Informs prescribers and enables early intervention
- 2. Prevent overdose and improve outcomes**
 - Identifies potentially toxic levels of drug prior to escalating opioid or other CNS suppressant drugs
 - Enables discussion with the patient about inconsistencies
- 3. Optimize clinical workflow**
- 4. Decrease risk**
 - Harder to tamper with blood and steady state drug levels
 - More information to protect providers and patients

Resources

- Clinical Study WIRB20180276
- Fingertick Plasma Drug Testing of Chronic Pain Patients: Comparison of Paired Fingertick Plasma and Urine Specimens: <https://openventio.org/wp-content/uploads/Fingertick-Plasma-Drug-Testing-of-Chronic-Pain-Patients-Comparison-of-Paired-Fingertick-Plasma-and-Urine-Specimens-TFMOJ-5-131.pdf>
- Mandatory Guidelines for Federal Workplace Drug Testing Programs: <https://www.federalregister.gov/documents/2017/01/23/2017-00979/mandatory-guidelines-for-federal-workplace-drug-testing-programs>

Resources continued

- Embarrassing, degrading, or beneficial: Patient and staff perspectives on urine drug testing in methadone maintenance treatment:
<https://www.tandfonline.com/doi/full/10.3109/14659890903431603?scroll=top&needAccess=true>
- Statement of Consensus on the Proper Utilization of Urine Testing in Identifying and Treating Substance Use Disorders: Final Report:
<http://udtconsensus.org/wp-content/uploads/2017/03/UDT-Consensus-Statement-151030.pdf>
- Clinical and Public Health Considerations in Urine Drug Testing to Identify and Treat Substance Use:
<https://www.tandfonline.com/doi/full/10.3109/10826084.2015.1135953>

Thank You

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