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# PREVALENCE OF FALSE NEGATIVE RESULTS FOR HYDROCODONE IN ORAL FLUID TOXICOLOGY COMPARED WITH URINE TOXICOLOGY

Sarang Singh, Aakash Shah, Evan Chung, Joseph Valenza

Rutgers New Jersey Medical School - Department of Physical Medicine and Rehabilitation

## Introduction

Urine toxicology has been used in opioid drug test monitoring for chronic pain patients for decades [1]. The COVID-19 pandemic posed new challenges by limiting safe in-person testing. As a result, oral fluid toxicology emerged as a popular alternative due to the ability to remotely sample bodily fluid collection under virtual supervision while minimizing infringements on patient privacy. Early studies suggested oral fluid toxicology reported sensitivities between 65%-80% for hydrocodone while urine drug testing has been shown to have sensitivities ranging from 70-95% for hydrocodone [2,3]. Due to the ease in accessibility and cost-effectiveness of oral studies, some have suggested that they can be used as a sole alternative to urine toxicology. This study aims to compare the efficacy and reliability of oral fluid and urine toxicology studies in hydrocodone drug monitoring programs.

## Materials and Methods

Fourteen patients taking hydrocodone for  $\geq 10$  years were randomly selected within a Chronic Pain Center. All patients were formally evaluated by a pain management psychologist and board-certified pain management physician. Prescription Monitoring Program (PMP) reports were reviewed for each patient to observe pre-testing prescription trends. Results from oral fluid and urine samples from April 2021 to October 2021 were collected for each patient and used for comparison. All collection methods were validated and analyzed by a single nationally recognized toxicology lab. Hydrocodone levels were measured using enzyme-linked immunoassay (ELISA) and liquid chromatography–mass spectrometry (LC/MS). A positive test result with either ELISA or LC/MS indicated that their respective cutoff value was met. LC/MS had a lower cutoff value. Test results were then compared to each other to determine sensitivities of each test type. As the case report is devoid of patient identifiable information, it is exempt from IRB review requirements as per Rutgers New Jersey Medical School and Kessler Institute of Rehabilitation policies.

## Results/Case Report

Oral fluid testing had significantly lower sensitivities for detecting hydrocodone when compared with urine toxicology studies ( $p < 0.001$ ). The sensitivity of oral fluid testing was 71.4% with ELISA and 85.7% with LC/MS testing. The

sensitivity for urine testing was 100.0% in all subjects. With ELISA testing, 29% of subjects (4/14) had false negative oral fluid testing results compared to urine toxicology. LC/MS testing produced false negative oral fluid testing results in 14% of subjects (2/14). PMP reports did not reveal any aberrant drug-taking behavior in any of the patients. No unprescribed medications or illicit substances were detected in any of the oral fluid or urine samples.

## Discussion

This study suggests that oral fluid toxicology may have higher rates of false negative results compared to urine studies. In this study, oral fluid tests were 30% less sensitive than urine toxicology studies when both were performed with ELISA. Oral fluid testing with LC/MS was slightly more sensitive, but still 15% less sensitive than urine toxicology performed with LC/MS. While this suggests LC/MS could be a more reliable modality than ELISA in oral fluid testing, liquid chromatography has major barriers in currently being more expensive and less readily available in laboratory testing centers.

Chronic pain physicians utilize laboratory tests to monitor opioid compliance and to rule out the use of illicit and non-prescribed substances. Given the potential risks associated with any controlled substance, it is imperative that these studies accurately detect the presence of the specific tested compound. The low sensitivity, and large number of false negative results, in detection of hydrocodone in oral fluid toxicology may be higher than clinicians are currently aware [4,5]. While oral fluid testing may offer some advantages in specific circumstances, clinicians should approach these testing methods with caution as the research and understanding in this area continues to grow.

## References

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3. Roger L. Bertholf and others, Sensitivity of an Opiate Immunoassay for Detecting Hydrocodone and Hydromorphone in Urine from a Clinical Population: Analysis of Subthreshold Results, *Journal of Analytical Toxicology*, Volume 39, Issue 1, January/February 2015, Pages 24–28, <https://doi.org/10.1093/jat/bku109>
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## Disclosures

No

## Tables / Images

		Actual condition with confirmatory test	
		Positive	Negative
Predicted condition	Total population = n		
	Positive	True Positive (TP)	False positive (FP)
	Negative	False Negative (FN)	True Negative (TN)

		Urine study result	
		Positive	Negative
Oral fluid study result	Total population = 14		
	Positive	10	0
	Negative	4	0

		Urine study result	
		Positive	Negative
Oral fluid study result	Total population = 14		
	Positive	12	0
	Negative	2	0