IMMUNALYSIS®

Quantisal®

Frequently Asked Questions

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1 What is Quantisal?

Quantisal is a device used to collect oral fluid for drug testing. It provides a simple, non-invasive, observed collection, avoiding issues with adulteration and dilution.

No bathroom is required for oral fluid collection, and it eliminates both the invasion of privacy and collector gender issues. Specimens can be collected anytime, anywhere.

2 Why is a collection device needed?

Studies have shown that expectoration was reported as distasteful by donors and collectors—both preferred Quantisal for collection and analysis. In addition, specimens collected with Quantisal contained higher drug levels and provided better detection rates than specimens collected by expectoration.

3 How is the specimen collected?

The Quantisal collection device pad is placed underneath the subject's tongue until the volume adequacy indicator located at the tip of the device turns blue. The device is then placed in the transport tube and secured for shipping to the laboratory.

4 How much oral fluid is collected and why is this important?

Quantisal collects 1 mL (± 10%) of oral fluid, ensuring sufficient quantity for screening, confirmation, repeat testing, and challenges. The volume adequacy indicator verifies that enough oral fluid has been collected, eliminating the potential for rejected samples caused by insufficient specimen volume—commonly referred to as "quantity not sufficient" (QNS).[5]

5 Why is there blue liquid in the transport tube?

The blue liquid or “buffer” assists in the extraction of drugs, if present, from the collection pad and stabilizes the drug compounds until testing.

6 How is oral fluid tested?

Just like urine testing, screening is performed by immunoassay, and confirmation is performed by mass spectrometry. GC-MS and LC-MS/MS** are two examples.

7 What is the stability of the sample after collection?

Samples collected with Quantisal can be stable for up to two weeks at room temperature and 30 days if refrigerated.

8 How are specimens shipped to the laboratory?

Specimens are shipped via overnight courier the day of collection. If this is not possible, specimens should be kept in a temperature controlled environment until shipping. If an oral fluid specimen cannot be shipped within two weeks of collection, and it has not been refrigerated, it should be discarded and recollected.

9 How is oral fluid different than urine?

Specimen volume is much lower with oral fluid. Drug concentrations are present in lower levels in oral fluid than urine; therefore lower screening and confirmation levels are required. Oral fluid identifies the parent drug and sometimes the drug metabolite. Urine testing is targeted at the drug metabolite.

**Gas chromatography mass spectrometry (GC–MS) and liquid chromatography tandem mass spectrometry (LC–MS/MS)

10 What drug classes are present in oral fluid that can be detected?

Illicit drugs and a wide range of prescription medications can be detected in oral fluid.

Immunalysis manufactures immunoassay screening reagents* for the following:

- Alcohol
- Amphetamine
- Barbiturates
- Benzodiazepines
- Buprenorphine
- Carisoprodol
- Cocaine
- Cotinine
- Dextromethorphan
- Fentanyl
- Fluoxetine
- K2 (Synthetic Cannabinoids-1)
- Ketamine
- Marijuana (THC)
- Methadone
- Methamphetamine
- Methylphenidate
- Naltrexone
- Opiates
- Oxycodone
- PCP
- Propoxyphene
- Sertraline
- Tramadol
- Tricyclic Antidepressants
- Zolpidem

11 What is the detection window?

Depending on the drug used, dose, and other individual factors, drugs are generally detected shortly after use and up to 48 hours or more in routine testing.

12 What do the results mean?

Drug levels in oral fluid are closely related to plasma drug levels and may provide evidence of “under the influence.” Oral fluid provides relevant information for monitoring programs since results reflect time frame consistent with dosing period, assuming equilibration has been achieved.

*For forensic use only

13 Can substances such as food, beverages, or mouthwash affect the test result?

The effects of a variety of commonly ingested substances have been studied and found to have no effect on the outcome of the result.[4]

14 Can a person dilute or adulterate an oral fluid specimen?

The subject should not have had anything to eat or drink, or have anything in his/her mouth for 10 minutes prior to collection. The collection is observed to ensure that the subject cannot introduce something to the specimen during the collection. If these collection procedures are followed, the chances of dilution and adulteration are virtually eliminated.

15 Does Quantisal use artificial stimulants to increase saliva production?

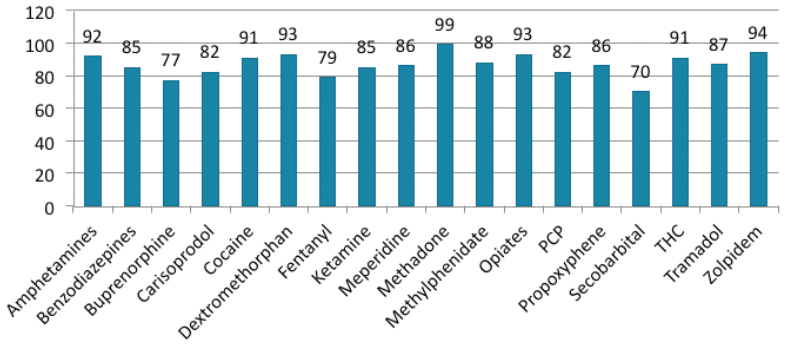
No, Quantisal does not contain artificial stimulants, such as citric acid. Studies show that drug levels in specimens collected after acidic stimulation may be lower than those collected without artificial stimulants.[2]

16 What is extraction efficiency and why is it important?

Extraction efficiency, also called “drug recovery,” is the percentage of drug that is recovered from the pad.

Recovery is calculated for each drug class by comparing the concentration of drug obtained from a collection device to the concentration of a standard not added to the pad and reported as a percent recovery. Good extraction efficiencies avoid false negatives by ensuring that low level positives at or around the cutoff level will be detected.[2]

Quantisal Extraction Efficiency by Drug Class[3, 4]



17 Does Quantisal contain gelatin?

Quantisal does not contain gelatin or any other substance that may be restricted for dietary reasons.

18 Is oral fluid collection considered a biohazard?

The Occupational Safety and Health Administration (OSHA) does not consider oral fluid collection hazardous.

1. Lee,D., Millman,G., Barnes, A.J., Huestis, M.A., Delta 9-Tetrahydrocannabinol (THC), 11-nor-9-Carboxy–THC (THCCOOH), Cannabidiol (CBD) and Cannabinol (CBN) in Oral Fluid Following Controlled, Smoked Cannabis. Proceedings of the 40th Annual SOFT Conference, 2010 Presentation #S26, Richmond, VA.
2. Crouch, D.J., Oral Fluid Collection: The Neglected Variable In Oral Fluid Testing. *Forensic Science Intl 2005;* 150: 165-73
3. O. Quintela, D.J. Crouch, D. Andrenyak, Recovery of Drugs of Abuse from the Immunalysis Quantisal Oral Fluid Collection Device. *Journal of Analytical Toxicology 2006*; 30: 614-16
4. Data on file at Immunalysis Corporation.
5. Heltsley, R. et al. Oral Fluid Drug Testing of Chronic Pain Patients. *Journal of Analytical Toxicology 2011*; 35: 529-40