

IMMUNALYSIS®

Quantisal®

Frequently Asked Questions



Laboratory Oral Fluid Testing



The information found in this booklet can help answer many common questions and assist you with integrating the Quantisal® collection device with laboratory-based oral fluid drug testing.

Oral fluid represents a paradigm shift in drug testing.

The simple, observable, and non-invasive nature of the collection means:

- No bathroom required
- Can be administered anytime, anywhere
- No gender-specific collectors necessary
- Minimized potential for adulteration or substitution

Drug concentrations in oral fluid are more comparable with blood levels than urine.

Please see Immunalysis product inserts and parameters for more information.

Immunalysis® enzyme-linked immunosorbent assay (ELISA) and HEIA® drug testing kits for oral fluid provide preliminary analytical test results only. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography mass spectrometry (GC-MS) or liquid chromatography mass spectrometry (LC-MS/MS) are the preferred confirmatory methods.

1 Why Quantisal®?

The Quantisal® collection device is widely used for laboratory-based oral fluid drug testing, combining unique scientific advantages with the efficiency of a simple, convenient specimen collection.

Key benefits include:

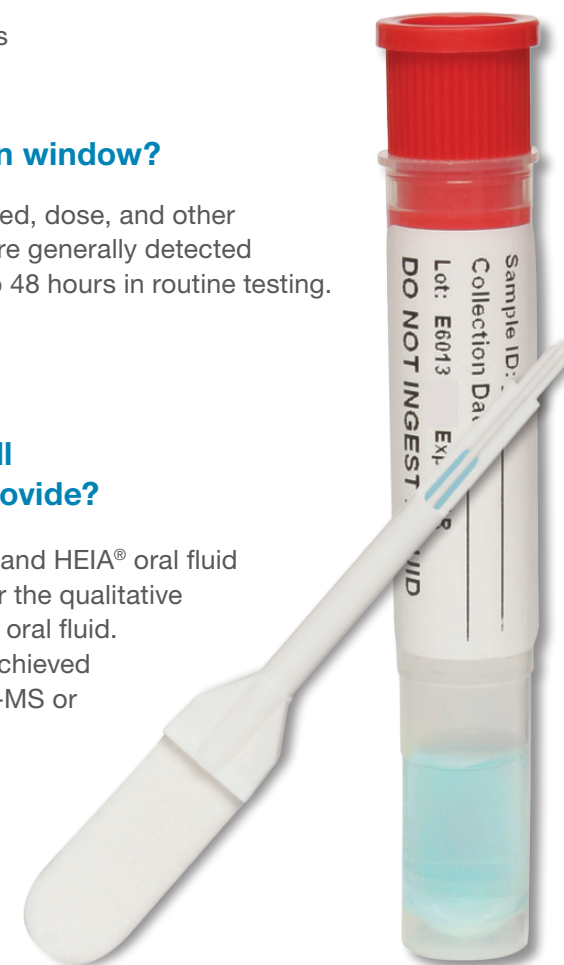
- Volume adequacy indicator
- Collects 1 mL \pm 10% oral fluid
- Excellent extraction efficiencies
- No artificial stimulants

2 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 in routine testing.

3 What information will the immunoassay provide?

The Immunalysis® ELISA and HEIA® oral fluid reagents are designed for the qualitative determination of drugs in oral fluid. Quantitative results are achieved with confirmation by GC-MS or LC-MS/MS methods.



4 What do the results mean?

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

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 much oral fluid is collected, and why is this important?

Quantisal collects 1 mL (\pm 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).¹

7 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

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

No, the entire collection is observed to ensure that the subject cannot alter the specimen during the process.

9 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.³

10 What is the stability of the sample after collection?

During transportation and for short-term storage, drugs are stable in the Quantisal collection system for 7 days without refrigeration. After 7 days, stored samples should be refrigerated.

11 How are specimens shipped to the laboratory?

Specimens should be shipped to the laboratory via overnight courier. No refrigeration is required during transportation. 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.

12 What drugs can be tested?

Oral Fluid—HEIA®

Oral Fluid HEIA Kits	Catalog Number and Kit Volume		
Item Description	25 mL	100 mL	500 mL
Alcohol	503-0100*		
Amphetamine	309-0025	309-0100	309-0500
Benzodiazepines	314-0025	314-0100	314-0500
Buprenorphine	336OF-0025	336OF-0100	336OF-0500
Cocaine/Benzoyllecgonine (COC/BE)	312-0025	312-0100	312-0500
Methadone	332-0025	332-0100	332-0500
Methamphetamine	311-0025	311-0100	311-0500
Opiates	307-0025	307-0100	307-0500
Oxycodone	321-0025	321-0100	321-0500
Phencyclidine (PCP)	308-0025	308-0100	308-0500
THC	324-0025	324-0100	324-0500
Tramadol	325OF-0025	325OF-0100	325OF-0500

*Alcohol is available as an enzymatic assay. For more information, go to www.immunalysis.com/products/alcohol

Oral Fluid—ELISA

Oral Fluid ELISA Kits	Catalog Number and Number of Tests		
Item Description	480 Tests	500 Tests	4800 Tests
Alcohol	502-0500*		
Amphetamine	209-0480		209-4800
Barbiturates	210-0480		210-4800
Benzodiazepines	214-0480		214-4800
Buprenorphine	236-0480		236-4800
Carisoprodol	231-0480		231-4800
Cocaine/Benzoyllecgonine (COC/BE)	212-0480		212-4800
Cotinine (Nicotine Metabolite)	217-0480		
Dextromethorphan	238-0480		
Fentanyl	218-0480		218-4800
Fluoxetine	234-0480		
K2 (Synthetic Cannabinoids-1)	244-0480		244-4800
Ketamine	240-0480		
Meperidine	220-0480		220-4800
Methadone	232-0480		232-4800
Methamphetamine	211-0480		211-4800
Methylphenidate	219-0480		219-4800
Naltrexone	239-0480		
Opiates	207-0480		207-4800
Oxycodone	221-0480		221-4800
Phencyclidine (PCP)	208-0480		208-4800
Propoxyphene	237-0480		237-4800
Sertraline	235-0480		235-4800
THC	224-0480		224-4800
Tramadol	225-0480		225-4800
Tricyclic Antidepressants	222-0480		
Zolpidem	233-0480		

*Alcohol is available as an enzymatic assay. For more information, go to www.immunalysis.com/products/alcohol

13 May other manufacturers' products be used with the Quantisal oral fluid collection device?

No, the Quantisal device is intended for use in conjunction with Immunalysis controls, buffers, and reagents only. Do not attempt to use with reagents, buffers, or controls from other manufacturers.

14 What are the cutoff levels (calibrators) and bracketing controls?

OFC4-4 (4 mL) and OFC4-40 (40 mL)

Immunalysis Oral Fluid Multi-Analyte Calibrator and Control Set

OFC4-4 consists of 4 × 4 mL vials and OFC4-40 consists of 4 × 40 mL vials of the analytes at the levels indicated below.

Analyte	LOW Control Neat Oral Fluid (ng/mL)	Cutoff Calibrator Neat Oral Fluid (ng/mL)	HIGH Control Neat Oral Fluid (ng/mL)
Benzoylcegonine	10	20	40
d-Amphetamine	25	50	100
d-Methamphetamine	25	50	100
Methadone	25	50	100
Morphine	20	40	80
Oxazepam	10	20	40
Phencyclidine (PCP)	5	10	20
Propoxyphene	20	40	80
Secobarbital	25	50	100
THC	2	4	8

For concentrations in buffer, divide by 4



OFC-PM-10 (10 mL)

Immunalysis Oral Fluid Multi-Analyte PM Calibrator and Control Set

OFC-PM-10 consists of 4 × 10 mL vials of the analytes at the levels indicated below.

Analyte	LOW Control Neat Oral Fluid (ng/mL)	Cutoff Calibrator Neat Oral Fluid (ng/mL)	HIGH Control Neat Oral Fluid (ng/mL)
Buprenorphine	2.5	5	10
Carisoprodol	25	50	100
Fentanyl	0.5	1	2
Meperidine	25	50	100
Methadone	12.5	25	50
Oxazepam	5	10	20
Oxycodone	20	40	80
THC	4	8	16
Tramadol	25	50	100

For concentrations in buffer, divide by 4

15 Can calibrators and controls be mixed from different sets?

No, performance of the kit is optimized for the use of all calibrators and controls from the same set.

**16 Using Immunalysis HEIA® drug testing kits, can urine and oral fluid samples be run on the same automated chemistry analyzer?**

Yes, oral fluid can be run on the same equipment as urine samples. However, please note the following recommendations:

1

Batch oral fluid samples so that they are all run at the same time. Do not run urine and oral fluid samples together.

2

A maintenance wash is recommended between batches of urine and batches of oral fluid samples.

3

Do not use bleach as a wash either between samples or between matrices.

17 Can urine, blood, oral fluid, and other matrices be run on the same ELISA equipment?

Yes, sample volumes and preincubation times can be preprogrammed on your equipment. There is no need to preprogram dilution factors for oral fluid, because everything is ready to use. Let your Immunalysis sales representative know if you need help programming your equipment.

18 If running the oral fluid HEIA® drug testing kit, how often should calibration be done?

Because HEIA oral fluid assays tend to be smaller in span than urine assays, we recommend daily calibration.

19 What should be used for the HEIA blank?

Use the Immunalysis synthetic negative oral fluid with buffer, catalog number NOFC-0100 or NOFC-0500, as the blank. The same negative oral fluid with buffer is also available in the OFC4-4, OFC4-40, or OFC-PM-10 control kits. Do not use extraction buffer, water, or deionized water as a blank.

20 What does it mean to “normalize” my results?

When “normalizing” results, cutoff concentrations for all assays are programmed on your instrument at a single value (either 0 or 100). All values below the cutoff are reported as negative, and all values above the cutoff are reported as positive.

21 How are the numbers obtained from qualitative analysis interpreted?

In qualitative analysis, the numerical values from the instrument do not represent the concentration of the drug in the control or specimen. These numbers should be used in a relative manner and not as absolute values.

22 How should neat saliva samples be diluted (e.g. proficiency samples) for use with Immunalysis ELISA or HEIA reagents?

To make dilutions, use the Immunalysis extraction buffer, EXTBUF-1000. For example, 250 µL of neat saliva can be added to 750 µL of extraction buffer to mimic the correct ratio in the Quantisal device. This incorporates the 1:4 dilution needed, which is 1 part oral fluid to 3 parts buffer.

23 Can I “dilute and shoot” the liquid from the Quantisal device directly into LC–MS/MS or GC–MS for confirmation testing?

No, the drugs must be extracted from the Quantisal device prior to confirmation. The liquid in the transport tube can lead to build up of salts and buffers on interior surfaces and columns of an LC–MS/MS instrument, leading to degradation.

24 Can Immunalysis help me develop mass spectrometry (MS) confirmation methods?

Immunalysis offers technical notes for GC–MS and LC–MS/MS, describing methods for the detection of drugs in oral fluid collected with the Quantisal device. These technical notes are available by contacting your Immunalysis sales representative.

Sample processing

Recommended Storage:

Refrigerate samples in capped glass tube or transport tube for up to one year. (Note: Never store the sample with the filter in the tube.)



1
Inspect to ensure security seal is intact and expiration date is within range.



2
Remove security seal and then the red cap by pushing up with thumb.



3
Scrape collection pad against the rim of the Quantisal tube until the pad is dislodged from the plastic stem.



4
Allow the pad to fall back into the buffer and discard the plastic stem.

Step 5—Option A

OR



5a
Aliquot buffer directly for screening, and follow instructions on kit insert for testing.

Step 5—Option B



5b
Before aliquoting the sample, press the pad to the bottom of the Quantisal tube with filter.



Decant liquid into borosilicate test tube.



Aliquot specimen and follow instruction on kit insert for testing.

Part numbers for Quantisal supplies

Item Description	Catalog Number	Quantity
Oral Fluid Collection Device	QS-0025	25
	QS-0500	500
Oral Collector Filters for Processing	QP-106	100
Oral Fluid Collector Filter Caps	QP-105	500

Item Description	Catalog Number	Volume
Calibrators and Controls (High, Medium, Low, and Negative)	OFC4-4	4 vials (4 mL each)
	OFC4-40	4 vials (40 mL each)
PM Calibrators and Controls (High, Medium, Low, and Negative)	OFC-PM-10	4 vials (10 mL each)
Extraction Buffer	EXTBUF-1000	1 L
Synthetic Negative Oral Fluid diluted with extraction buffer	NOFC-0100	100 mL
	NOFC-0500	500 mL

Notes

**The Advantage of Oral Fluid.
The Confidence of Quantisal.**





We are Toxicology.™

1. Heltsley R, DePriest A, Black DL, et al. Oral fluid drug testing of chronic pain patients. I. Positive prevalence rates of licit and illicit drugs. *J Anal Toxicol*. 2011;35(8):529-540.
2. Crouch DJ. Oral fluid collection: the neglected variable in oral fluid testing. *Forensic Sci Int*. 2005;150(2-3):165-173.
3. Data on file. Immunalysis Corporation.

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