SV DIAGNOSTIC LAB

# ORAL TOXICOLOGY

## SPECIMEN COLLECTION AND TRANSPORT MANUAL

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## Introduction

The **SV Diagnostic Lab Specimen Collection and Transport Manual** has been developed to provide information about specimen collection, specimen identification, specimen submission, laboratory procedures, and specimen results reporting.

The meaningfulness of clinical laboratory results is directly related to the quality of the specimen submitted for analysis. Proper collection, labeling, storage, and shipment of specimens are the responsibility of the specimen collector.

If you have questions not adequately addressed in this manual, please call the laboratory for further information. Laboratory staff are available to help solve administrative and technical problems and answer questions.

This manual describes specimen requirements and information regarding toxicology testing performed at SV Diagnostic Laboratory. In most cases, turn-around time for toxicology results is 48-72 hours, excluding weekends and holidays.

This manual has been designed to aid the collection staff in proper patient preparation, specimen collection, and specimen transport properly to avoid specimen rejection. If problems arise concerning procedures, please do not hesitate to contact SV Diagnostic Laboratory.

> "A laboratory test is no better than the specimen and the specimen no better than the method by which it was collected."[1]

For questions regarding specimen requirements, please contact us at:

**SV Diagnostic Laboratory**
8628 Industrial Parkway, Unite E, Suite 107
Plain City, OH 43064

**Email:** info@svdiagnosticlabs.com
**Phone:** 937-421-8867

## Identifying Patients and Labeling Specimens

### *Patient Identification*

The patient should arrive at the collection station with a written order or requisition from an authorized caregiver. Please ensure the accuracy of the patient information and test(s) requested.

The person facilitating the oral collection (called the "collector" for the rest of this document) must positively identify the patient. This is most effectively done by asking the patient to state their full legal name and date of birth (DOB), while the collector verifies a match to the requisition form and any specimen labels provided.

It is **imperative** that the specimen container is labeled with at least two unique identifiers, such as patient name, DOB, social security number, barcode ID #, and/or medical record number. Less than two unique identifiers will result in specimen rejection when the specimen is processed by the laboratory.

Oral specimens must be collected in Quantisal oral fluid collection device with at least 4 ml of sample

### Patient Identification and Specimen Labeling Steps:

- ✓ Identify the patient: ask the patient to state their full name and date of birth. Compare with the information on the request form and specimen labels.
- ✓ Collection site collection guidelines can include requirements to secure handbags and parcels, remove waste receptacles, turn off water, observe collection, etc. Follow defined collection guidelines.
- ✓ Have patient collect the oral specimen for testing according to the collection instructions at the end of this manual.
- ✓ Label each specimen container with the appropriate barcoded label (if provided) and at least one other unique identifier.

***Note**: In the absence of an appropriate label, please write the patient's full legal first and last name (spelled correctly), patient's date of birth, and the date and time specimen was collected directly onto the cup label.*

***Note:** Specimen should be labeled on the cup part of the collection container, not the lid.*

### *Specimen Storage and Transport*

The specimens can be stored at room and refrigerator temperature. Samples are stable up to 14days.

At intervals decided on by the clinic, specimens should be shipped to the laboratory. Follow the instructions at the end of this manual to properly ship your specimens.

| Storage Temperature | Stability |
|---|---|
| Room temperature | 14days |
| 2-8°C (refrigerated) | 14days |

### *Improperly Identified Specimens*

Unlabeled or mismatched (name and patient ID number / DOB on specimen does not match name and patient ID number / DOB on requisition) specimens will be held for testing until proper documentation is received by the laboratory. A form will be provided for the clinician to fill out and return to the laboratory.

### *Specimen Collection / Submission / Rejection Policy*

To maintain patient specimen integrity and ensure accurate test results, the laboratory will only process specimens that follow the proper collection and transport protocol.

The laboratory makes every effort to minimize the specimen volume required for analysis, but because a test may have to be rerun it is ideal to submit at least twice the minimum required specimen volume of 4mL. The laboratory staff recognizes that this is not always possible and will make every effort to provide a result even if the specimen submitted is a small volume.

The laboratory will notify the ordering clinician or requesting client if a specimen is unacceptable by providing a patient report identifying the reason for rejection and recommend that the specimen be recollected. Exceptions may be made based upon client impact and/or for precious specimens. These exceptions are handled on an individual basis by the laboratory.

### Specimens must:

- Be labeled properly, with the patient name, DOB and at least one other unique identifier, the date and time of collection, and the initials of the person collecting the specimen.
- Have matching requisition form/documentation and specimen container labels.
- Be collected in the proper specimen container.
- Have a minimum volume of 4mL.

- Be in a specimen container that is not compromised by cracks, or loose/improperly fitting lids.
- Be stored at the correct temperature prior to shipment to maintain specimen integrity.
- Be shipped with appropriate containment and preservation.
- Arrive in the laboratory within the specified time frame required for the specific tests ordered.

## Results Reporting

Oral Confirmation results will be available within 7- 10 days of the time the specimen is received in the laboratory. Any inquiries regarding results can be made by calling the laboratory.

Reports will be accessible from the client portal of the Laboratory Information System (LIS) as soon as they are reviewed and approved by a qualified laboratory scientist. An email will be auto-generated to notify the ordering clinician that their patients' results are ready to view.

Results can also be faxed or mailed via the United States Postal Service, upon request.

| Test | Turnaround Time |
|---|---|
| Oral Confirmation | 7 – 10 days. |

## Add-on Test Requests

If additional testing is desired after the specimen has been shipped to the laboratory within the specimen stability guidelines, you may send a test request to the laboratory. Be sure to record the correct date of collection on the requisition so that the specimen can be easily located.

Specimens are retained on site for 14 days after the receiving date. Add-on testing can be ordered for any specimen by submitting a requisition for this testing via mail or fax.

Verbal add-on test requests will not be accepted.

## References

1. Becton Dickinson and Company. Joseph Kleiner and the origins of the Vacutainer™. The Echo. Beckton Dickinson and Company, Franklin Lakes, NJ; 1991 (Spring; 11:3-5, 1991 (September); 11.5-7; 1996 (December); 16:1.

2. Bauer, JD "Collection and Preparation of the Specimen", Clinical Laboratory Methods, 9th Edition. CV Mosby Co., St. Louis.

3. College of American Pathologists, “So You're Going to Collect A Blood Specimen”, Chapter 3.

4. White, R, Moore, C. Detection of Drugs and Their Metabolites in Oral Fluid. Elsevier and RTI International, 2018.

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## SV Diagnostic Laboratory Oral Toxicology Test Menu

The following **analytes and cutoffs (ng/mL)** are analyzed and reported positive or negative with the quantitative concentration of the analyte recovered (for detected analytes) in patient oral specimens.

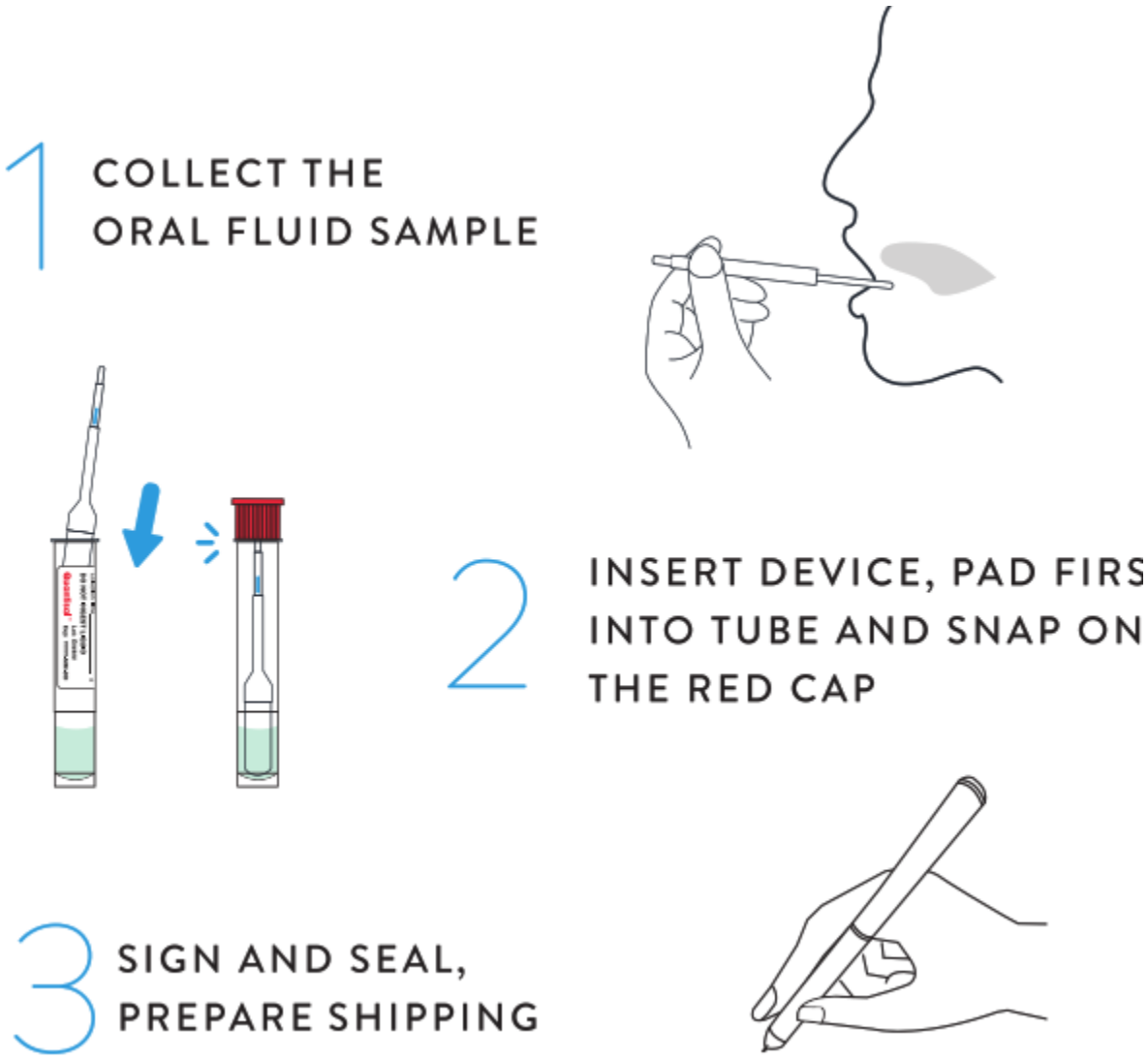
| Analyte | Cutoff (ng/mL) |
|---|---|
| 6-MAM | 2 |
| Alprazolam | 1 |
| Amitriptyline | 20 |
| Amphetamine | 20 |
| Benzoylecognine | 10 |
| Buprenorphine | 0.2 |
| Carisoprodol | 5 |
| Chlordiazepoxide | 1 |
| Clonazepam | 1 |
| Cocaine | 10 |
| Codeine | 5 |
| Diazepam | 1 |
| Dihyrocodeine | 5 |
| EDDP | 10 |
| Fentanyl | 0.2 |
| Flunitrazepam | 1 |
| Flurazepam | 1 |
| Gabapentin | 20 |
| Heroin | 2 |

| | |
|---|---|
| Hydrocodone | 5 |
| Hydromorphone | 5 |
| Ketamine | 20 |
| Lorazepam | 1 |
| MDA | 20 |
| MDMA | 20 |
| Meprobamate | 5 |
| Methadone | 10 |
| Methamphetamine | 20 |
| Methylphenidate | 2 |
| Midazolam | 1 |
| Mitragynine | 2 |
| Morphine | 5 |
| Naloxone | 0.5 |
| Naltrexol | 0.5 |
| Naltrexone | 0.5 |
| Norbuprenorphine | 1 |
| Nordiazepam | 1 |
| Norhydrocodone | 5 |

| | |
|---|---|
| Noroxycodone | 5 |
| Oxazepam | 1 |
| Oxycodone | 10 |
| Oxymorphone | 10 |
| PCP | 20 |
| Pregabalin | 20 |
| Tapentadol | 10 |
| Temazepam | 1 |
| THC | 5 |
| Tianeptine | 20 |
| Tramadol | 10 |
| Triazolam | 1 |
| Xylazine | 2 |
| Zolpidem | 10 |
| Amo-Pentobarbital | 20 |
| Butalbital | 20 |
| Phenobarbital | 20 |
| Secobarbital | 20 |

## Oral Specimen Collection Instructions for Specimen Collector

- 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
- Quantisal collects 1 mL (±10%) of oral fluid, ensuring sufficient quantity for screening, confirmation and repeat testing. The volume adequacy indicator verifies that the full 1 mL (±10%) of oral fluid has been collected.




Reference:

1. White, R, Moore, C. Detection of Drugs and Their Metabolites in Oral Fluid. Elsevier and RTI International, 2018.

INTENDED USE: The Quantisal Oral Fluid Collection Device is intended for the collection, preservation and transport of oral fluid specimens for analytical testing of drugs or drug metabolites. This device is for use only under observed collections.