Test Definition: CSMOF

Controlled Substance Monitoring Panel, 11 Drug Classes, Screen Only, Immunoassay, Oral Fluid

Overview

Useful For

Monitoring acute (ie, short-term) drug use in addiction treatment or pain management settings as part of a rotational drug testing strategy

Presumptive screening for amphetamine, methamphetamine, opioids/opiates (targeting morphine, oxymorphone, oxycodone, hydrocodone, 6-monoacetylmorphine, tramadol, buprenorphine, fentanyl, and methadone), PCP (phencyclidine), cocaine metabolite (targeting benzoylecgonine), benzodiazepines (targeting oxazepam, lorazepam, and clonazepam), zolpidem, barbiturates (targeting phenobarbital), methylphenidate, and THC-COOH (marijuana metabolite) in oral fluid specimens

This test is **not intended for** forensic or medico-legal purposes (ie, employee drug testing or settings where chain-of-custody is required).

Special Instructions

- Oral Fluid Specimen Collection Instructions for Controlled Substance Monitoring

Highlights

The oral fluid sample, collected with the Quantisal device, is screened using a competitive immunoassay.

Method Name

Competitive Chemiluminescent Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Fluid

Ordering Guidance

This oral fluid test only offers presumptive positive screening results without confirmatory testing. If specific drug identification is required, urine testing is recommended. Order CSMPU / Controlled Substance Monitoring Panel, Random, Urine, which uses high-resolution accurate mass spectrometry-based targeted testing.

Specimen Required

Patient Preparation:

1. If the patient has recently taken an oral medication or used an inhaled medication, wait 2 hours before collecting the specimen.
2. Patient must empty mouth of any gum, food, or tobacco prior to oral fluid collection. If patient's mouth is not empty immediately before collection, have them rinse their mouth with water (up to 4 oz) and wait 10 minutes before collection. The patient may discard or drink the water after rinsing.

Supplies: Quantisal Oral Fluid Collection Device (T980)
Note: Check expiration date on Quantisal packaging
Container/Tube: Quantisal collection device
Specimen Volume: 1 mL
Collection Instructions:
1. Review detailed instructions before specimen collection.
-Patient video: Oral fluid specimen collection for controlled substance monitoring.
-Practitioner video: Oral fluid specimen collection for controlled substance monitoring
-Printable instructions: Oral Fluid Specimen Collection Instructions for Controlled Substance Monitoring.
2. Peel open package and remove collector using its handle. Do not touch the collection pad with fingers before or after specimen collection. To expedite the collection process, move tongue side to side to accumulate saliva in mouth before starting. Keep the tip of the device pointed down.
3. Position collector under tongue and close mouth. Keep head down to allow gravity to help with saliva collection. **Important: Do not chew on pad, talk, or remove collector from mouth until indicator turns BLUE, or until 10 minutes has passed, whichever occurs first.**
4. Hold transport tube in an upright position and uncap by pushing up with thumbs. Do not stand tube on table. Do not spill or empty the liquid from tube.
5. Insert collector into the uncapped transport tube and replace cap. Do not place collector back in mouth after it has been placed in the transport tube.
6. **Snap cap firmly for transport**. Place center of specimen seal on top of tube and press down both sides.
7. Complete paperwork and send sample to laboratory.
8. Send in original tube. **Do not aliquot.**

Forms

If not ordering electronically, complete, print, and send a Therapeutics Test Request (T831) with the specimen.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Visibly bloody or pink specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fluid	Ambient (preferred)	7 days	
	Refrigerated	7 days	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Drug abuse is a major social and medical issue and usually requires costly interventions for the treatment and rehabilitation of abusers. This qualitative test screens for commonly prescribed and/or abused drugs/drug classes in human oral fluid specimens. It uses a noninvasive specimen collection method, which can be observed. This test may be used for screening samples for compliance monitoring of prescription drugs in a point of care setting.

Reference Values

Not detected

Positives are reported with a qualitative result.
Cutoff concentrations by competitive chemiluminescent immunoassay:
Opioids:
6-Acetylmorphine: 5 ng/mL
Morphine: 10 ng/mL
Hydrocodone: 10 ng/mL
Oxycodone: 10 ng/mL
Oxymorphone: 10 ng/mL
Methadone: 10 ng/mL
Fentanyl: 1 ng/mL
Tramadol: 5 ng/mL
Buprenorphine: 1 ng/mL

Benzodiazepines:
Oxazepam: 10 ng/mL
Clonazepam: 10 ng/mL
Lorazepam: 10 ng/mL

Non-Benzodiazepine: Zolpidem: 10 ng/mL

Stimulants:
Amphetamine: 20 ng/mL
Methamphetamine: 10 ng/mL
Methylphenidate: 100 ng/mL
Cocaine Metabolite (BE): 30 ng/mL

PCP, Phencyclidine: 5 ng/mL
Marijuana metabolite (THC-COOH): 10 ng/mL
Barbiturates, Phenobarbital: 50 ng/mL

Interpretation

This test is intended to screen for amphetamine, methamphetamine, opioids/opiates (targeting morphine, oxymorphone, oxycodone, hydrocodone, 6-monoacetylmorphine, tramadol, buprenorphine, fentanyl, and methadone), PCP (phencyclidine), cocaine metabolite (targeting benzoylecgonine), benzodiazepines (targeting oxazepam, lorazepam, and clonazepam), zolpidem, barbiturates (targeting phenobarbital), methylphenidate, and THC-COOH (marijuana metabolite) in oral fluid specimens. The limit of detection for each of these drug groups varies (see Reference Values). A positive finding for one of these drugs or metabolites is an indication for the presence of the drug of abuse or cross reactivity with other structurally similar commonly prescribed drugs.

Cautions

It is possible that substances other than those investigated may interfere and cause a false-positive screening result. If specific drug identification is required, urine testing is recommended; order CSMPU / Controlled Substance Monitoring Panel, Random, Urine, which uses high-resolution accurate mass spectrometry-based targeted testing.

In instances where an oral fluid specimen cannot be collected (eg, dry mouth), providers should consider alternative specimen collection methods (eg, urine).

This test is not appropriate for use in forensic or employment settings (ie, medico-legal, chain-of-custody).

Clinical Reference

1. Jannetto PJ, Bratanow NC, Clark WA, et al. Executive Summary: American Association of Clinical Chemistry Laboratory Medicine Practice Guideline-Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients. J Appl Lab Med. 2018;2(4):489-526. doi:10.1373/jalm.2017.023341
2. Bosker WM, Huestis MA. Oral fluid testing for drugs of abuse. Clin Chem. 2009;55(11):1910-31. doi:10.1373/clinchem.2008.108670.
3. Huestis MA, Verstraete A, Kwong TC, Morland J, Vincent MJ, de la Torre R. Oral fluid testing: promises and pitfalls. Clin Chem. 2011;57(6):805-10. doi:10.1373/clinchem.2010.152124

Performance

Method Description

The oral fluid sample, collected with the Quantisal device, is screened using a competitive immunoassay to indicate the presence of any of the drugs/drug classes or their cross reactivity with other structurally similar commonly prescribed or abused drugs. Screening for amphetamine, methamphetamine, opioids/opiates (targeting morphine, oxymorphone, oxycodone, hydrocodone, 6-monoacetyl morphine, tramadol, buprenorphine, fentanyl, and methadone), phencyclidine (PCP), cocaine metabolite (targeting benzoylecgonine), benzodiazepines (targeting oxazepam, lorazepam, and clonazepam), zolpidem, barbiturates (targeting phenobarbital), methylphenidate, and THC-COOH (marijuana metabolite) is accomplished using a competitive chemiluminescent immunoassay.(Unpublished Mayo method)

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PDF Report
No

Day(s) Performed
Monday, Wednesday, Friday

Report Available
2 to 4 days

Specimen Retention Time
2 weeks

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
80307

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CSMOF	Controlled Substance Panel, OF	20787-8

Result ID	Test Result Name	Result LOINC® Value
621486	Opioids, Morphine, OF	32100-0
621485	Opioids, 6-acetylmorphine, OF	32099-4
621487	Opioids, Hydrocodone, OF	32080-4
621488	Opioids, Oxycodone, OF	69356-4
621489	Opioids, Oxymorphone, OF	104692-9
621490	Opioids, Methadone, OF	72626-5

621491	Opioids, Fentanyl, OF	87815-7
621492	Opioids, Tramadol, OF	74110-8
621493	Opioids, Buprenorphine, OF	73942-5
621494	Benzodiazepines, Oxazepam, OF	72614-1
621495	Benzodiazepines, Clonazepam, OF	61039-4
621496	Benzodiazepines, Lorazepam, OF	61044-4
621497	Non-Benzodiazepine, Zolpidem, OF	87820-7
621498	Stimulants, Amphetamine, OF	40799-9
621499	Stimulants, Methamphetamine, OF	40804-7
621500	Stimulants, Methylphenidate, OF	87805-8
621501	Stimulants, Cocaine Metabolite (BE), OF	40802-1
621502	PCP, Phencyclidine, OF	40808-8
621503	Marijuana metabolite (THC-COOH), OF	40801-3
621504	Barbiturates, Phenobarbital, OF	32108-3
621484	Controlled Substance Interpretation	69050-3