

CareHealth
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DrugCheck[®] SalivaScan[™]

Training and Certification

DrugCheck[®] SalivaScan[™] Training

This training package is a general overview on operating and interpreting the DrugCheck[®] SalivaScan[™] test device.



- Training covers:
- Technical information
- Product overview
- Specimen collection and testing procedure
- Result interpretation
- Additional support services

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TECHNICAL INFORMATION

Please review the product's Instructions for Use (Package Insert) and Procedure Card prior to using this device.

The DrugCheck[®] SalivaScan[™] test device is a lateral flow chromatographic immunoassay device for the qualitative detection of multiple drugs and drug metabolites in oral fluid.

As with all immunoassay urine screens, the SalivaScan[™] only provides a preliminary analytical result. In order to obtain a confirmed analytical result a more specific laboratory method such as GC/MS (Gas Chromatography-Mass Spectrometry) or LC/MS/MS (Liquid Chromatography Tandem Mass Spectrometry) is required. Professional judgement and clinical consideration should be applied to any Drugs of Abuse (DOA) test result especially when preliminary positive results are obtained.

The SalivaScan[™] device is for Employment/Insurance or Forensic Use Only.

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PRODUCT OVERVIEW









This training applies to all versions of the DrugCheck[®] SalivaScan[™] device whether it is private label or a different configuration.

Features & Benefits:

- Tests for up to 10 drugs in saliva
- Flat panel device to photocopy or scan results
- Sponge saturation indicator ensures sufficient specimen volume
- Results in as little as 10 minutes
- Available in a wide variety of test configurations
- Made in the U.S.A.

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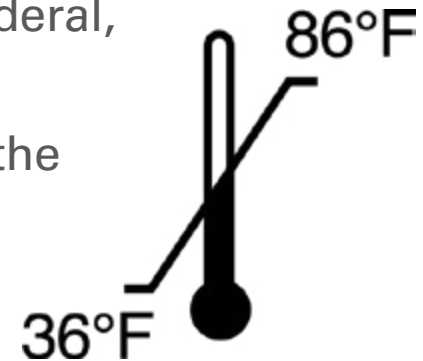
Test Strip	Drug	Cutoff
	Alcohol	0.02%
	Amphetamine	50
	Barbiturate	50
	Benzodiazepine	10
	Buprenorphine	5
	Cocaine	20
	Cotinine	50
	EDDP/Methadone	20
	Fentanyl	10
	K2	30
	Marijuana	15, 40, 50
	MDMA/Ecstasy	50

Test Strip	Drug	Cutoff
	Methadone	30
	Methamphetamine	40, 50
	Opiates	40
	Oxycodone	20
	Phencyclidine	10
	Propoxyphene	50
	6-Acetylmorphine	25
	K3	30

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PRODUCT STABILITY, STORAGE & PRECAUTIONS

- Test device must remain in sealed pouch until ready for use.
- Product should be stored at a temperature 36°F – 86°F.
- Do not freeze test devices or expose to heating sources.
- This device is for in-vitro diagnostic use only.
- Test device should be used according with applicable Federal, State or Municipal regulations.
- Product is stable through the expiration date printed on the test pouch. Do not use after the date of expiration.



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PERFORMING THE DRUG SCREEN – GATHER YOUR TESTING SUPPLIES

Materials Provided:

- 25 Individually Pouched Test Devices
- Security Seals
- Package Insert (Instructions for Use)
- Procedure Card

Recommended But Not Provided:

- Laboratory Custody and Control Forms (COC or CCF)
- Timer
- External Controls
- Gloves



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SPECIMEN COLLECTION & TESTING PROCEDURE

1. Have available for use a Chain of Custody Form (COC or CCF) or Test Results Template.
2. Require the donor to provide Photo ID.
3. Ask donor to remove any unnecessary clothing and empty all pockets.
4. Keep all backpacks, wallets and purses out of the restroom in a secure area (i.e. locked cabinet).
5. Ensure donor has not put anything in their mouth for 10 minutes prior to testing.
6. The device should be at room temperature prior to testing.



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SPECIMEN COLLECTION & TESTING PROCEDURE (CONTINUED)

7. Inspect test device pouch to ensure it has not been compromised.
8. Remove the test device/collection swab from pouch.
9. Place device upright on a level surface.



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TESTING PROCEDURE

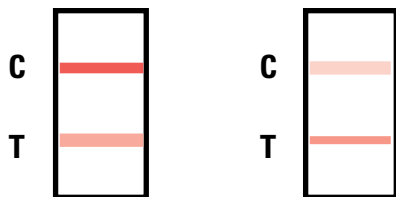
1. Place the sponge end of the collection swab into the mouth to collect oral fluid for about 3 minutes or until the red saturation indicator appears.
2. Do NOT chew or suck on the sponge.
3. If color saturation indicator has not appeared by 7 minutes, recollect using a new device.
4. Open the test device and insert the saturated collection swab.
5. Press the sponge down firmly until it reaches the bottom of the device tube then tightly close the lid to fully compress the sponge.
6. Read results at 10 minutes.



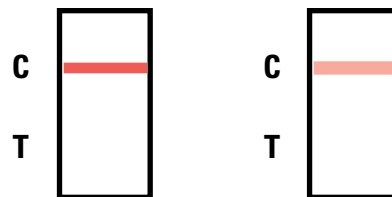
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INTERPRETING THE RESULTS

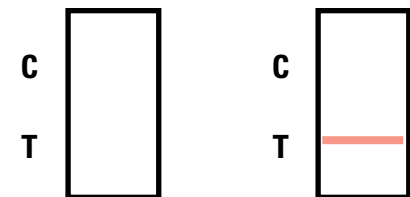
NEGATIVE Two lines appear. One line visible in the control region (C), and another apparent line adjacent visible in the test region (T). This negative result indicates that the drug concentration is below the detectable level. **NOTE:** The shade of color in the test line region (T) will vary, but it should be considered negative if a line is visible. There is no meaning attributed to the line color intensity or width.



POSITIVE One line appears in the control region (C). No line whatsoever appears in the test region (T). The lack of a line in the test region (T) indicates a preliminary positive result for the corresponding drug of that specific test region. Send this urine specimen to a certified laboratory for a more specific confirmation by GC/MS.



INVALID Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, contact your supplier for technical support.





ADDITIONAL SUPPORT

It is recommended that external controls be run with each new lot of test devices. For assistance in obtaining approved controls or other supplies please contact our Customer Service Department at 888-466-8433 or by emailing orders@drugcheck.com.



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