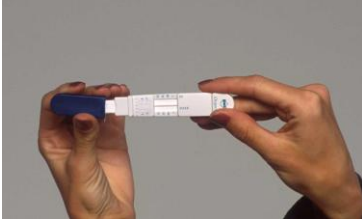



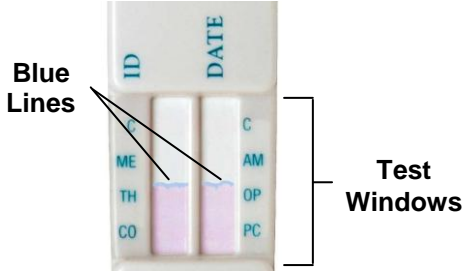



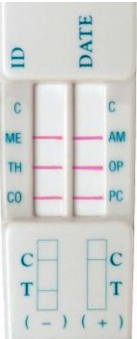




# Oratect® III Package Insert

The Oratect® III\* Oral Fluid Drug Screen Device is a simple one-step test for the detection of drugs of abuse in oral fluid.

<p>1. <b>Remove</b> the blue cap by holding the sides and pulling gently. This will expose the collection pad. <b>Make sure there is a blue line present in each window area indicating an unused device.</b></p> 	<p>2. <b>Open</b> mouth and gently <b>rub</b> the collection pad inside mouth against cheek in a circular motion several (approximately 15-20) times. Make sure to <b>keep head level.</b></p> 	<p>3. Gently <b>rub</b> the collection pad against the opposite cheek in circular motion several (approximately 15-20) times.</p> 
<p>4. Gently <b>rub</b> the collection pad <b>on top</b> of the tongue several (approximately 15-20) times. <b>Do not chew, suck, bite or bend the collection pad.</b></p>  <p>5. <b>Rub</b> the collection pad <b>underneath</b> the tongue several (approximately 15-20) times.</p>	<p>6. Place the collection pad underneath the tongue for approximately 30 seconds to collect saliva. Instruct the donor to hold the device in place with hand. <b>Sufficient amount of saliva collected is indicated by the flow of the blue lines. Repeat steps 2-6 until blue lines flow.</b></p> 	<p>7. <b>Remove</b> from mouth as soon as blue lines flow at both of the test windows. <b>Re-cap</b> the device.</p>  <p>8. Lay the device on a flat surface and <b>read results in approximately 5 minutes after removing the device from mouth. Do not read results after 30 minutes</b></p>

## Interpreting Test Results

<p><b>Invalid Result</b> When <b>no</b> colored band appears in the <b>CONTROL (C) region</b>, the test is <b>invalid</b> even if there is a band in the test region. <b>Repeat</b> the test with a new device.</p>  <p>Example Interpretation:</p> <p>ME: Invalid TH: Invalid CO: Invalid AM: Invalid OP: Invalid PC: Invalid</p>	<p><b>Negative Result</b> For each test, two colored bands should be observed:</p> <ul style="list-style-type: none"> <li>• <b>One in the CONTROL (C) region</b></li> <li>• <b>One in the specific TEST region</b></li> </ul> <p>The color of the test band may be slightly darker or lighter than the control band. Any visible band that can be seen is a <b>negative</b> result.</p>  <p>Example Interpretation:</p> <p>ME: Negative TH: Negative CO: Negative AM: Negative OP: Negative PC: Negative</p>	<p><b>Presumptive Positive Result</b> A colored band at the <b>CONTROL (C) region</b> should be observed. When there is no colored band at the specific <b>TEST region</b>, the test is presumptive positive for that particular drug.</p>  <p>Example Interpretation:</p> <p>ME: <b>Presumptive Positive</b> TH: Negative CO: Negative AM: Negative OP: Negative PC: Negative</p>
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\*Oratect® III is for forensic use only



Oratect® III Oral Fluid Drug Screen Device
ME25/TH40/CO20; AM25/OP10/PC4 or BZ5

Intended Use

The Oratect® III Oral Fluid Drug Screen Device is a one-step lateral flow immunoassay device for the qualitative detection of methamphetamine, MDMA, THC, cocaine, amphetamine, opiates, phencyclidine or benzodiazepines in human oral fluid. The Oratect® III Test detects these drugs at the following cut-off concentrations:

Table with 3 columns: Drug Abbreviation, Drug Name, and Concentration. Includes ME (d-Methamphetamine/MDMA), TH (Delta-9-Tetrahydrocannabinol), CO (Cocaine), AM (d-Amphetamine), OP (Morphine), PC (Phencyclidine), and BZ (Diazepam).

The test is intended to be administered by a trained professional. It should not be used without supervision. This product is intended for forensic use only and is not for use in diagnostic procedures.

The Oratect® III Oral Fluid Drug Screen Device provides only preliminary drug test results. For a quantitative result or for a confirmation of a presumptive positive result obtained by the Oratect® III Oral Fluid Drug Screen Device, a more specific alternative method such as GC/MS or LC/MS must be used.

Summary and Explanation

Illegal drug consumption contributes to many accidents, injuries and medical conditions. Screening individuals for drugs of abuse is an important method in identifying those who may cause harm to themselves and to others.

Oratect® III Oral Fluid Drug Screen Device is developed to detect active drugs-of-abuse present in saliva. Studies on methamphetamine, MDMA, cocaine, opiate, amphetamine, phencyclidine, benzodiazepine and cannabinoid show that all of these drugs are detectable in oral fluid. Oratect® III Oral Fluid Drug Screen Device is designed to integrate oral fluid collection and lateral flow immunoassay screen testing for drugs-of-abuse in one single device.

Test Principle

The Oratect® III Oral Fluid Drug Screen Device is based on a competitive immunoassay procedure in which drug derivatives immobilized on the membrane compete with the drug(s) which may be present in oral fluid for limited antibody binding sites on the colored colloidal gold antibody conjugate. During testing, oral fluid is collected at the collection pad and migrates across the membrane. If no drug is present in the oral fluid, the colored colloidal gold antibody conjugate will bind to the drug derivatives on the membrane to form visible bands at specific test regions. Therefore, the presence of a purple-red band at a specific test region indicates a negative result. If any drug(s) is (are) present in the oral fluid, it competes with the immobilized drug conjugate for limited antibody binding sites of the colored colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug derivative on the membrane. Therefore, the absence of a purple-red band at the test region indicates a presumptive positive result for that particular test.

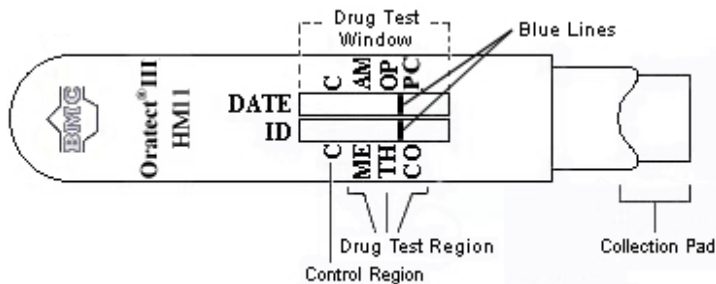


Fig. a Detail regions of Oratect® III Oral Fluid Drug Screen Device

The presence of a blue line in each window indicates that the device is unused. The flow of the blue lines indicates that a sufficient amount of oral fluid has been collected. A control band at the control region (C) indicates the test has performed properly. This control band should always appear regardless of the presence of drug or metabolite.

Reagents

The Oratect® III Oral Fluid Drug Screen Device contains two membrane strips and a collection pad. Each strip consists of a membrane, a colloidal gold conjugate pad, a sample pad and an absorbent pad.

Membrane: ME/TH/CO test strip: Methamphetamine, THC and Cocaine-protein conjugates are coated onto specific region on the membrane known as the "Test Region".

AM/OP/PC or AM/OP/BZ test strip: Amphetamine, Morphine, Phencyclidine or Amphetamine, Morphine, Benzodiazepine protein conjugates are coated onto the test region of the membrane.

Colloidal Gold Conjugate Pad: The colloidal gold conjugate pad for the ME/TH/CO test strip contains anti-methamphetamine, anti-THC and anti-cocaine antibody colloidal gold conjugates coated onto a fibrous pad. The colloidal gold conjugate pad for the AM/OP/PC or AM/OP/BZ test strip contains anti-amphetamine, anti-morphine, anti-phencyclidine or anti-amphetamine, anti-morphine, anti-benzodiazepine antibody colloidal gold conjugates.

Collection Pad: The collection pad consists of an absorbent material.

Materials Provided

Each Oratect® III Oral Fluid Drug Screen Device kit contains:

- 1. 1 Package Insert.
2. 25 test devices. Each device consists of a plastic holder and a detachable cap. The devices are packaged individually in a foil pouch with a desiccant.

Optional Materials

Upon customer request, the following item can be shipped:

- 1. 1 plastic vial containing buffer for confirmation testing

Warnings and Precautions

- The Oratect® III Oral Fluid Drug Screen Device is intended for forensic use only and is not for use in diagnostic procedures.
The test device should remain in its original sealed pouch until ready for use.
Discard the test device if package is ripped or torn.
Do not use the test device beyond the expiration date indicated on the kit.
Handle all oral specimens as potentially infectious. Proper handling and disposal methods should be established.

Product Storage

The Oratect® III Oral Fluid Drug Screen Device pouch should be stored at room temperature (15°-30°C). Do not open pouch until ready to perform the assay.

Specimen Collection and Handling

IMPORTANT: At least 10 minutes prior to administering the test, instruct the donor not to eat, drink, smoke or chew tobacco products.

Test Procedure

- 1. Remove the test device from the sealed pouch.
2. Carefully remove the blue cap by holding the sides and pull gently. This will expose the collection pad.
3. Ensure that the blue line is present in each test window.
4. The oral fluid collection process must be observed. Instruct the donor to hold the top portion of the device (above the test windows).
5. When placing device into the mouth, keep head level.
a. Open mouth and rub the collection pad inside mouth against one cheek gently in a circular motion several (approximately 15-20) times. (Fig. b)
b. Still keeping head level, gently rub the collection pad against the opposite cheek in a circular motion (approximately 15-20) several times. (Fig. b)

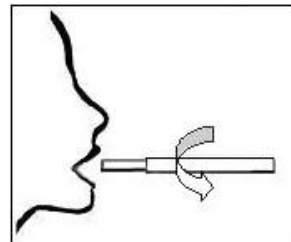


Fig. b Gently rub the collection pad against each cheek several (approximately 15-20) times.

- c. Rub the collection pad on top of the tongue several times and then underneath the tongue several (approximately 15-20) times. (Fig. c. and Fig. d.). Do not chew, suck, bite or bend the collection pad.

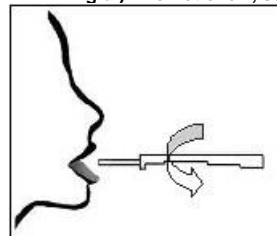


Fig. c Gently rub the collection pad on top of the tongue several (approximately 15-20) times.

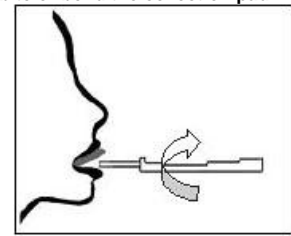


Fig. d Gently rub the collection pad underneath the tongue several (approximately 15-20) times.

- Place the collection pad underneath the tongue for approximately 30 seconds to collect saliva. Instruct the donor to hold the device in place with their hand.
  - The flow of the blue lines indicates the collection of a sufficient amount of saliva. If blue lines are present after placing the collection pad underneath the tongue for 30 seconds, repeat the instructions in steps 5 and 6 until the blue lines flow.
  - Remove the device from mouth as soon as the blue lines start moving at both test windows.
- Note: The flow of the blue lines should appear in the test windows within 5 minutes. If no flow is observed after 5 minutes in the mouth, discard the device, review procedures 4-7 above with the donor and repeat the test using a new device.
- Re-cap the device, lay it on a flat surface and **read results in approximately 5 minutes after removing device from mouth. Do not read results after 30 minutes.**

### Interpreting Test Results

#### Negative Results

For each of the test windows, purple-red colored bands should be observed; one band at the control region (C) and one band at the specific drug abbreviation (e.g. AM, OP, CO) in the test region. See example Fig e.

The color of the test band may be slightly darker or lighter than the control band. Any band that can be seen visually, no matter how faint, is a **negative** result. Read each test independently. Do not compare color intensity of one test to another.

In the **Fig. e** below, the oral fluid sample is negative for Amphetamine, Opiate and Cocaine **because bands are visible in the AM, OP, and CO test regions.**

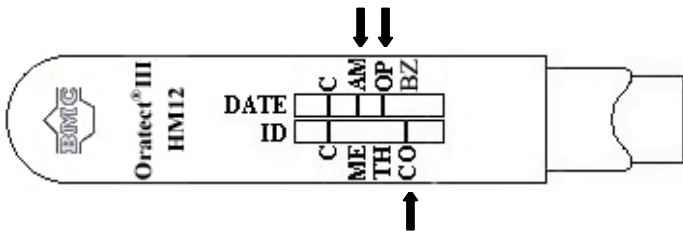


Fig e. Example of Negative Test Results

#### Presumptive Positive Results

When the control band is visible in the control region (C) and **no** band appears at the specific test region, the result is a **presumptive positive** for that particular drug. In **Fig. f** below, the oral fluid sample is presumptive positive for Phencyclidine, Methamphetamine (or MDMA) and THC **because no bands are visible in the test regions of PC, ME, and TH.**

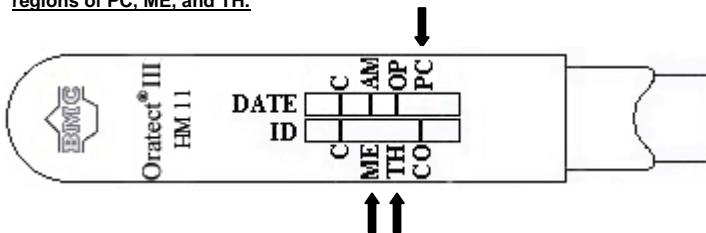


Fig. f Example of Presumptive Positive Test Results

#### Invalid Results

When **no** band appears in the control (C) region, **the test is invalid** regardless of the results in the test region. If the test is invalid, check testing procedures. **Repeat the test using a new device.** In **Fig. g** below, the test is invalid because there are **no bands in the control regions.**

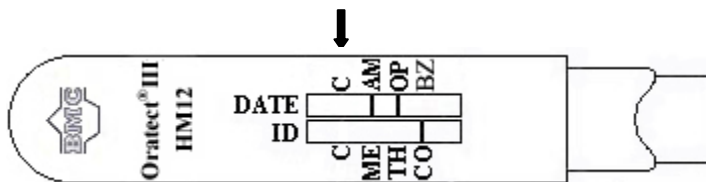


Fig. g Example of Invalid Test Results

**Important: Read each test independently. Do not compare color intensity of one test band to another.** When a faint purple-red band for a specific test is obtained in the test region along with the presence of the control line (C), the sample should be considered negative. The Oratect<sup>®</sup> III Oral Fluid Drug Screen Device only provides qualitative results for the presence of drug(s) at specified cut-off concentration(s). For confirmation of a presumptive positive result, a more specific quantitative method (GC/MS or LC/MS) must be used.

### Optional: Specimen Collection with Confirmation Vial & Handling for Confirmation Testing

- For device with any presumptive positive results, the collection pad should be removed and sent for confirmation test.
- Detach the collection pad with the blue cap by pulling. Be sure not to damage or distort the collection pad.
- Place the collection pad into the confirmation vial.
- Recap the vial and send it to a lab for confirmatory testing (Specimen should be stored at 15-30°C and tested within 2 weeks of collection).
- Follow standard chain of custody procedures.

### Quality Control

The Oratect<sup>®</sup> III Oral Fluid Drug Screen Device provides two built-in control bands at the control regions (C) to indicate that the test has performed properly. These control bands should always appear regardless of the presence of drugs. The flow of the blue lines indicates that a sufficient amount of oral fluid has been collected. The presence of the purple-red bands in the control regions verifies that proper flow was obtained. If the control bands do not appear, the test device should be discarded.

### Limitations of Procedure

- The assay is designed for human oral fluid use only.
- Positive results only indicate the presumptive presence of drugs and do not indicate or measure intoxication.
- Technical or procedural errors as well as substances in certain foods and certain medications may interfere with the test and cause false results.

### Performance Characteristics

#### Precision

For each specific drug test, artificial oral fluid solution was spiked with a drug standard at various concentrations (0%, 50%, 200% and 300%). For each concentration, a total of 20 tests were performed to validate the test performance. The results for each drug of the Oratect<sup>®</sup> III Oral Fluid Drug Screen Device Tests are summarized below:

Drug Test	Total # of Test/ Concentration	Concentration							
		0%		50%		200%		300%	
		-	+	-	+	-	+	-	+
ME	20	20	0	20	0	0	20	0	20
MDMA	20	20	0	20	0	0	20	0	20
TH	20	20	0	20	0	1	19	0	20
CO	20	20	0	20	0	0	20	0	20
AM	20	20	0	20	0	0	20	0	20
OP	20	20	0	20	0	0	20	0	20
PC	20	20	0	20	0	0	20	0	20
BZ	20	20	0	20	0	1	19	0	20

### Specificity

The specificity study for each drug test was evaluated by adding structurally related compounds to artificial oral fluid solution. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

Drug Test	Approximate Concentration (ng/ml)	Approximate % Cross Reactivity
<b>ME/MDMA</b>		
Desipramine	10000	0.25%
d,l-Ephedrine	1000	2.5%
1R, 2S l-Ephedrine	1000	2.5%
p-Hydroxymethamphetamine	1000	2.5%
MDEA	300	8.3%
MDMA	25	100%
d,l-Methamphetamine	30	83%
d-Methamphetamine	25	100%
l-Methamphetamine	500	5%
Methoxyphenamine	2500	1%
Phenylephrine	5000	0.5%
d-Pseudoephedrine HCl	5000	0.5%
Trimethobenzamide	4000	0.6%
<b>TH</b>		
Cannabinol	80	50%
Δ-8-Tetrahydrocannabinol	100	40%
Δ-9-Tetrahydrocannabinol	40	100%
11-nor-Δ-8-THC-9-COOH	10	400%
11-nor-Δ-9-THC-9-COOH	10	400%
11-Hydroxy-Δ-9-THC	400	10%

Drug Test	Approximate Concentration (ng/ml)	Approximate % Cross Reactivity	Desipramine (except ME/MDMA assay)	Naloxone
<b>CO</b>			Dextromethorphan	Naltrexone hydrochloride
Benzoylcegonine	600	3.3%	Diazepam (except BZ assay)	d-Naproxen
Cocaine	20	100%	Dihydrocodeine (except OP assay)	Niacinamide
<b>AM</b>			4-Dimethylaminoantipyrine	Nitrazepam (except BZ assay)
d-Amphetamine	25	100%	Diphenhydramine	Nordiazepam (except BZ assay)
d,l-Amphetamine	40	62.5%	Dopamine (3-Hydroxytyramine)	Nordoxepin hydrochloride
l-Amphetamine	800	3.2%	Doxepin hydrochloride	d,l-Norephedrine hydrochloride
d,l-p-Chloramphetamine	200	12.5%	Doxylamine	Norethindrone
MDA	40	62.5%	Ecgonine	d-Norpropoxyphene
MDEA	100	25%	Ecgonine Methyl Ester	Nortriptyline hydrochloride
Phentermine	100	25%	l-Ephedrine	Oxalic Acid
β-Phenylethylamine	8000	0.3%	d,l-Ephedrine (except ME/MDMA assay)	Oxazepam (except BZ assay)
Tyramine	8000	0.3%	1R, 2S l- Ephedrine (except ME/MDMA assay)	Oxolinic acid
<b>OP</b>			1S, 2R d-Ephedrine	Oxycodone
6-Acetylcodeine	20	50%	l-Epinephrine	Papaverine
6-Acetylmorphine	12	83%	Erythromycin	Penicillin-G (Benzylpenicillin)
Codeine	10	100%	Estazolam (except BZ assay)	Pentazocine
Dihydrocodeine	10	100%	□-Estradiol	Pentobarbital
Ethyl morphine	60	17%	Estrone-3-sulfate potassium salt	Perphenazine
Heroin	15	67%	Ethanol	Phencyclidine (except PC assay)
Hydrocodone	60	17%	Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrrolidine Perchlorate salt	Pheniramine
Hydromorphone	70	14%	Ethyl Morphine (except OP assay)	Phenobarbital
Morphine	10	100%	Flunitrazepam (except BZ assay)	Phenothiazine
Morphine-3-beta-D-Glucuronide	25	40%	Flurazepam (except BZ assay)	Phentermine (except AM assay)
Nalorphine	100	10%	Furosemide	Phenylephrine (except ME/MDMA assay)
<b>PC</b>			Gentisic acid	β-Phenylethylamine (except AM assay)
Phencyclidine	4	100%	Glucose	d,l-Phenylpropranolamine hydrochloride
<b>BZ</b>			Glutethimide	Prazepam (except BZ assay)
Alprazolam	12	42%	Guaiacol Glyceryl Ether	Prednisolone
Bromazepam	3	167%	Hemoglobin	Procaine
Chlordiazepoxide	30	16.7%	Heroin (except OP assay)	Promazine
Clobazam	8	63%	Hippuric acid	Promethazine
Clonazepam	20	25%	Hydrochlorothiazide	d-Propoxyphene
Delorazepam	6	83%	Hydrocodone (except OP assay)	Protriptyline
Diazepam	5	100%	Hydrocortisone	d-Pseudoephedrine HCl (except ME/MDMA assay)
Estazolam	3	167%	Hydromorphone (except OP assay)	Quinidine
Flunitrazepam	10	50%	11- Hydroxy-Δ-9-Tetrahydrocannabinol (except TH assay)	Ranitidine
Flurazepam	10	50%	p-Hydroxymethamphetamine (Pholderin) (except ME/MDMA assay)	Riboflavin
Lorazepam	100	5%	Ibuprofen	Salicylic acid
Lormetazepam	15	33%	Imipramine	Secobarbital
Nitrazepam	20	25%	d,l-Isoproterenol	Serotonin
Nordiazepam	50	10%	l-Isoproterenol HCl	Sodium Chloride
Oxazepam	15	33%	Lidocaine	Sulfamethazine
Prazepam	15	33%	Lorazepam (except BZ assay)	Sulindac
Temazepam	10	50%	Lormetazepam (except BZ assay)	Temazepam (except BZ assay)
Triazolam	10	50%	MDMA (except ME/MDMA assay)	Tetracycline

#### Interference

The following compounds were spiked into artificial oral fluid solution and found not to cross-react with the Oratect® III Oral Fluid Drug Screen Device when tested at concentration of 10 µg/ml (10,000ng/ml)

Acetaminophen	Bilirubin
Acetoacetic acid lithium salt	Bromazepam (except BZ assay)
Acetone	d-Brompheniramine
Acetylsalicylic acid	Buprenorphine
6-Acetylcodeine (except OP assay)	Butalbital
6-Acetylmorphine (except OP assay)	Butethal
Albumin	Caffeine
Allobarbitol	Cannabinol (except TH assay)
Alphenal	Cannabidiol
Alprazolam (except BZ assay)	Chloral Hydrate
Amitriptyline	Chlordiazepoxide (except BZ assay)
Amobarbital	Chloroquine
Amoxapine	d-Chlorpheniramine
Amoxicillin	Chlorpromazine
d-Amphetamine (except AM assay)	Chloroamphetamine (DL-p-Hydrochloride (except AM assay)
d,l-Amphetamine (except AM assay)	Cholesterol
l-Amphetamine (except AM assay)	Clobazam (except BZ assay)
Ampicillin	Clomipramine
Apomorphine	Clonazepam (except BZ assay)
Aprobarbital	Cocaine (except CO assay)
l-Ascorbic Acid	Codeine (except OP assay)
Aspartame	Cortisone
Atropine	l-Cotinine
Barbital	Creatine
Benzillic acid	Creatinine
Benzocaine	Cyclobenzaprine
Benzoylcegonine hydrate (except CO assay)	Delorazepam (except BZ assay)
Benzoic acid	Deoxycortisone acetate

#### Bibliography of Suggested Reading

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5. Wong, R. On-site Oral Fluid Drug Testing by Oratect, in Drugs of Abuse: Body Fluid Testing, Wong, R and Tse, H ed., Humana Press, p146-158, 2005.

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