

iCup[®]

Substance abuse screening device



PRODUCT TRAINING PROCEDURES



The information in this presentation is a general overview on using the iCup[®] substance abuse screening device.

Product Training Contents:

- iCup[®] overview
- Collection procedure
- Testing procedure
- Reading results
- Sending presumptive positives for confirmation



iCup[®] technical information

It is important to read the package insert before using the iCup[®] screening device.

Screening Results:

The iCup[®] is used for **Screening Only**. Positive results obtained with this device are presumptive.

Additional testing is necessary to **confirm** the presumptive positive results. Positive results should be “confirmed” by an **alternate method** such as GC/MS (Gas Chromatography/Mass Spectrometry) or LC/MS/MS (Liquid Chromatography/Tandem Mass Spectrometry).

Professional judgment should be applied to any drug of abuse test result, particularly with preliminary positive results.

The iCup[®] screening device is a rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For in vitro diagnostic use only.



Product overview



iCup[®] product overview

FEATURES & BENEFITS

- Available tests include: *AMP/BAR/BUP/BZO/ COC/THC/MTD/M-AMP/MDMA/MOP/OPI/OXY/ PCP/PPX/TCA
- Available with Specimen Validity Tests (S.V.T.) for Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine
- Self contained cup minimizes collector exposure to urine
- Performance comparable to laboratory screening methods
- Drug test results in 2-5 minutes
- All devices are FDA – 510(k) cleared to market, certain devices available CLIA waived



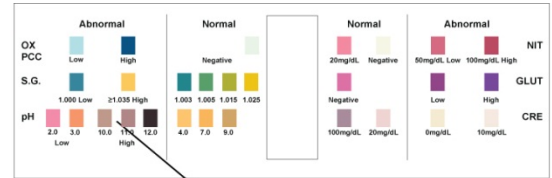
* See page 8 for abbreviations and cut-off levels



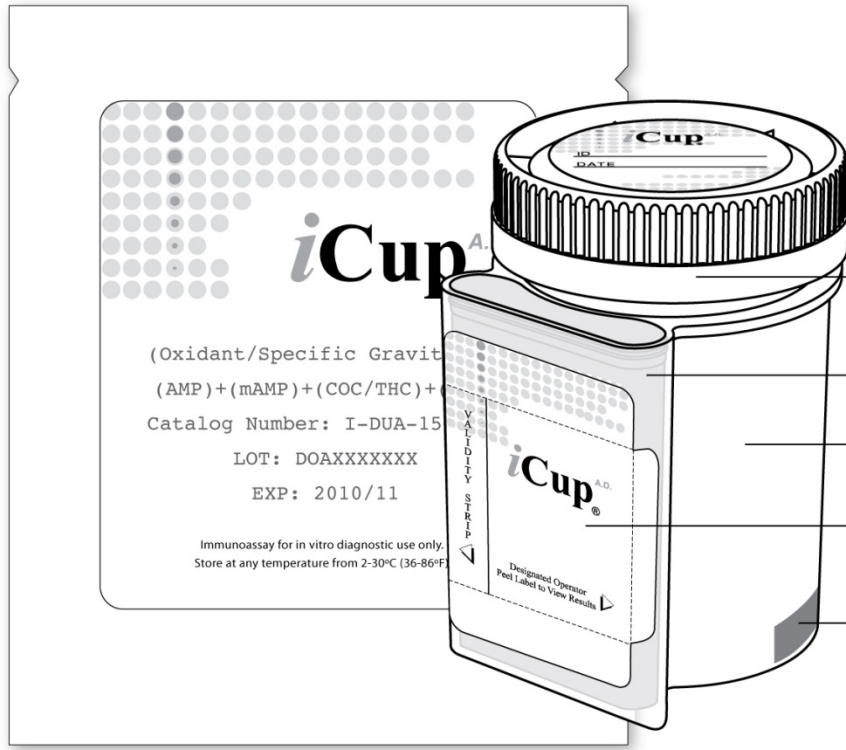
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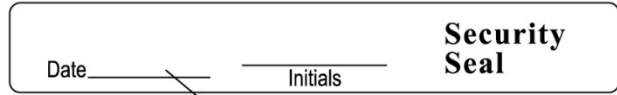
iCup[®] components



Adulteration Color Chart



- Cap
- Testing Chamber
- Urine Cup
- Peel Off Label
- Temperature Strip Label



Security Seal Label

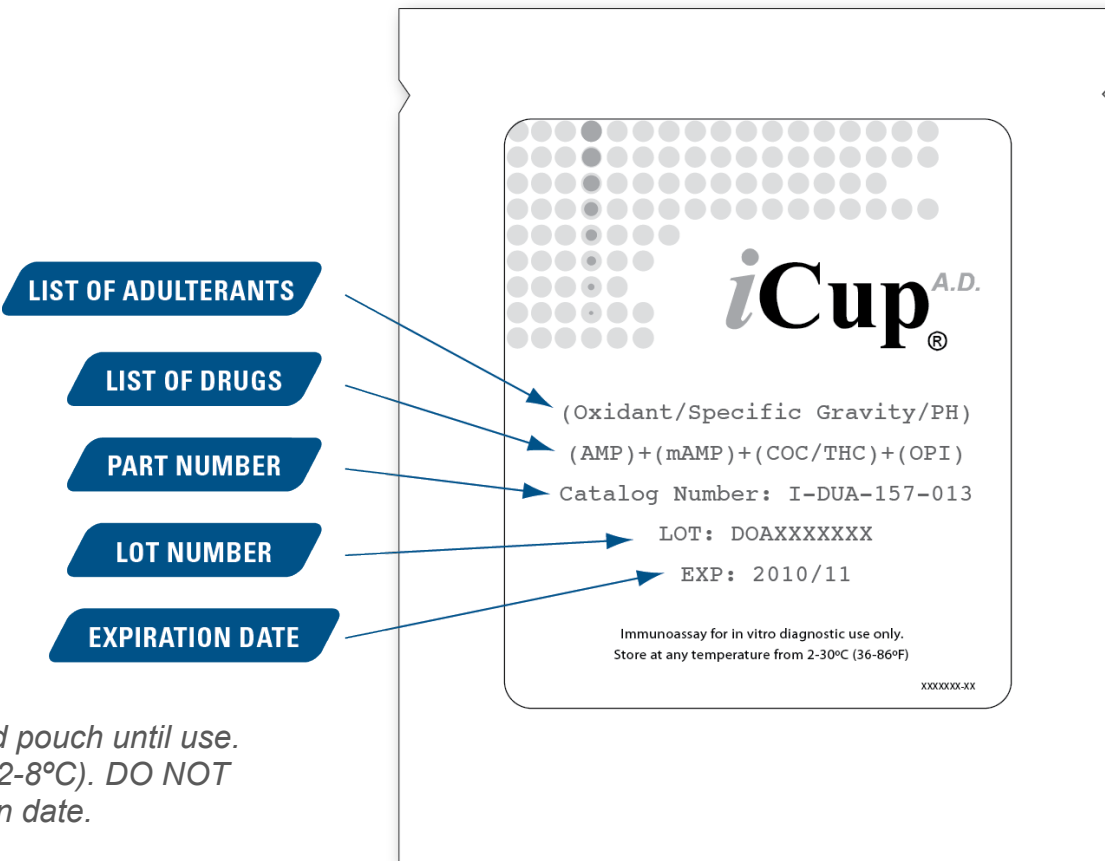
Pouch



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Alere™ iCup® foil pouch

The foil pouch contains the following information: list of adulterants, list of drugs* screened, part number, lot number and expiration date.



The test devices must remain in the sealed pouch until use. Storage temperature is between 36-86°F (2-8°C). DO NOT FREEZE. Do not use beyond the expiration date.

* See page 8 for abbreviations



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iCup[®] cutoff levels

Drug	Target Drug	Cutoff
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Amphetamine (AMP)	D-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10ng/mL
Cocaine (COC 300)	Benzoylcegonine	300 ng/mL
Cocaine (COC 150)	Benzoylcegonine	150 ng/mL
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (M-AMP 1,000)	D-Methamphetamine	1,000 ng/mL
Methamphetamine (M-AMP 500)	D-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxy-methamphetamine	500 ng/mL
Opiate (MOP 2,000)	Morphine	2,000 ng/mL
Opiate (OPI 300)	Morphine	300 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL



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Collection procedure

Remove cup from sealed pouch

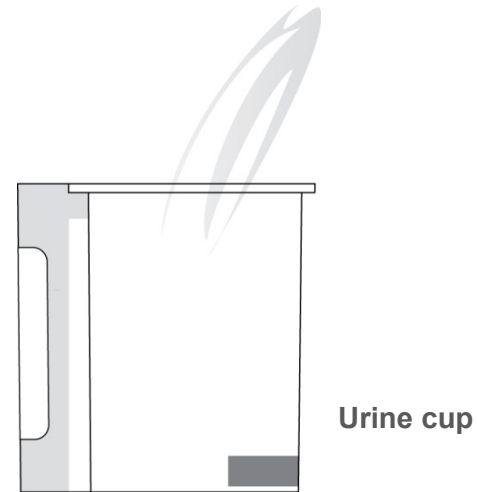
Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.

NOTE: The desiccant pouches are part of the packaging, they are not a part of the screening device.

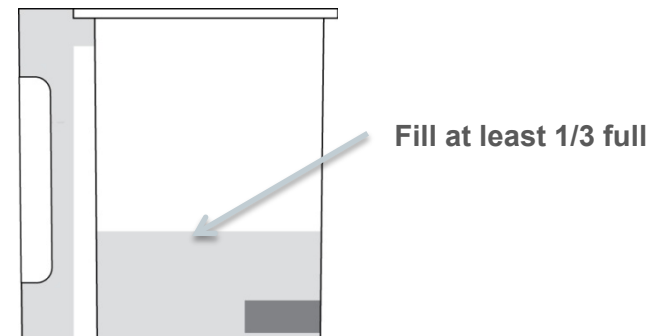


Collect urine specimen

Remove the cap from the urine cup.
Donor provides urine specimen in the collection cup.

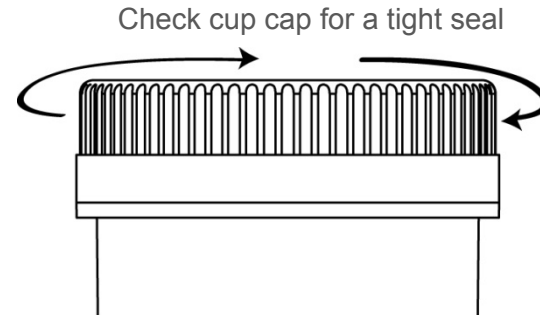


Fill the cup to at least 1/3 full.
This ensures sufficient specimen volume is available for initial screen and possible confirmation testing.



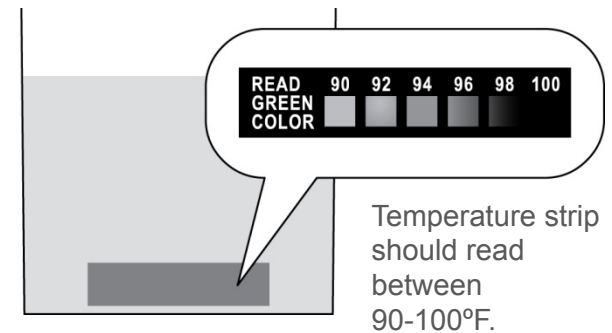
Collection procedure

Technician replaces and secures the cap while the cup is on a flat surface.



Temperature is read at 2-4 minutes.

Verify the range is between 90-100°F.

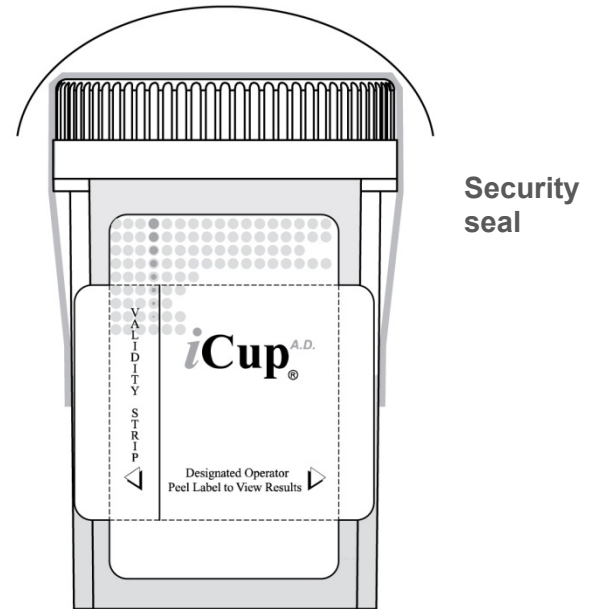


Collection procedure

Donor dates and initials the security seal.
(The technician/collector may also date or initial the security seal).

The technician attaches the security seal over the cup cap.

Date <u>9/14/09</u>	<u>CEM</u> Initials	Security Seal
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Reading results

Reading results

Technician peels off the label to reveal drug test strips.



Peel back label to reveal drug test strips

The technician peels off label to reveal adulteration strip(s), if applicable.



Reading adulteration results

(if applicable on your device)

FOR CUPS WITH ADULTERATION

Read adulteration test results between **2-5 minutes**. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results.

Compare the colors on the adulteration strip to the color chart.

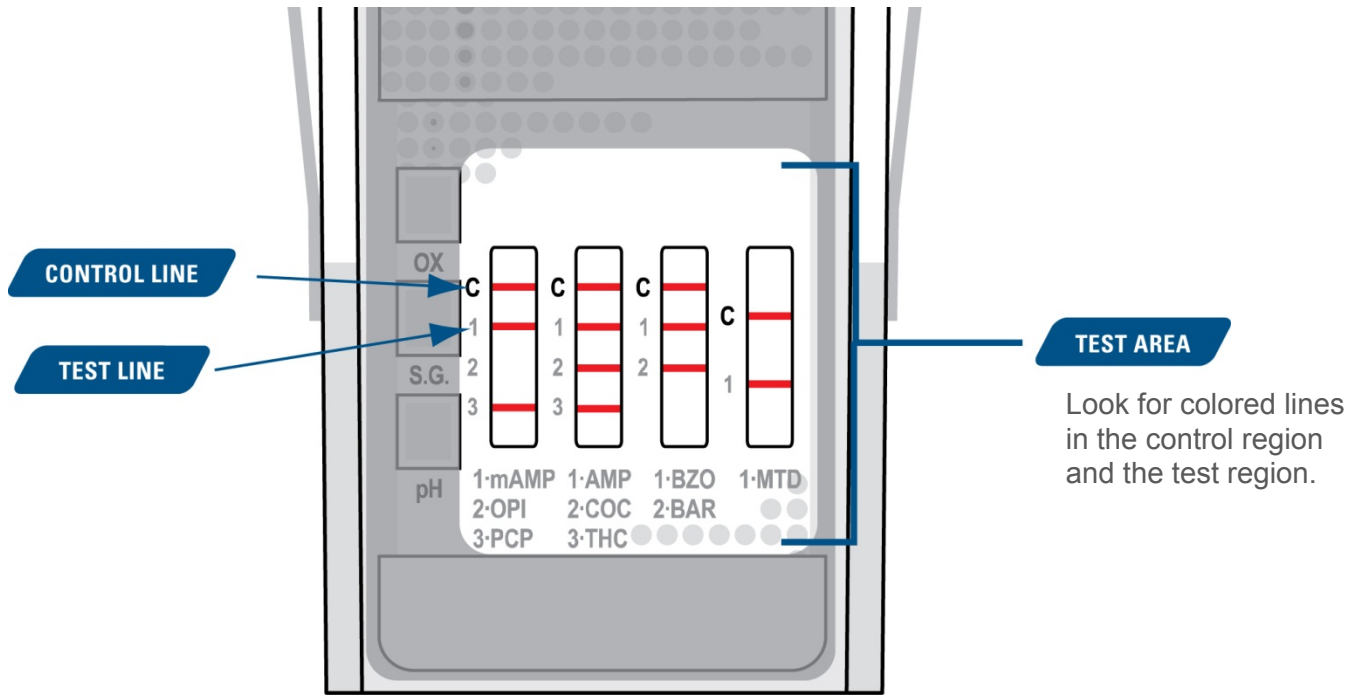
Substance	Abnormal	Normal
OX	Low (Light Blue), High (Dark Blue)	Negative (Light Green)
PCC	Low (Light Blue), High (Dark Blue)	Negative (Light Green)
S.G.	Low (Dark Blue), High (Yellow)	1.003 (Dark Green), 1.005 (Medium Green), 1.015 (Light Green), 1.025 (Yellow)
pH	Low (Pink), High (Black)	4.0 (Orange), 7.0 (Light Orange), 9.0 (Yellow)
NIT	50mg/dL Low (Red), 100mg/dL High (Dark Red)	20mg/dL (Pink), Negative (Light Yellow)
GLUT	Low (Purple), High (Dark Purple)	Negative (Pink)
CRE	0mg/dL (Light Orange), 10mg/dL (Orange)	100mg/dL (Purple), 20mg/dL (Light Purple)

Adulteration Test Region

Adulteration Color Chart

Reading drug test results

Read the drug test results at **5 minutes**. Do not interpret results after 60 minutes as false results may occur.



Result interpretation

NEGATIVE

The control line must be colored to indicate the test is valid.
Any visible line, even a faint line, indicates a negative result.
See example page 19.



NEGATIVE RESULT

C  *Test is valid*
DRUG  *Line is present*

POSITIVE

The control line must be colored to indicate the test is valid.
The test area must be snow white to be considered positive.
*See example page 20. *Additional testing is necessary to **confirm** the presumptive positive results. Positive results should be “confirmed” by an **alternate method such as GC/MS** (Gas Chromatography Mass Spectrometry).*

POSITIVE RESULT

C  *Test is valid*
DRUG  *Line is not present*

INVALID

When there is no line in the control line area, the result is invalid. If an invalid result is obtained repeat the test using a new test device.

INVALID RESULT

C  *Test is not valid*
DRUG 

If the problem persists, contact RTL Toxicology Support Services at:
(800) 255-2159, option 5.

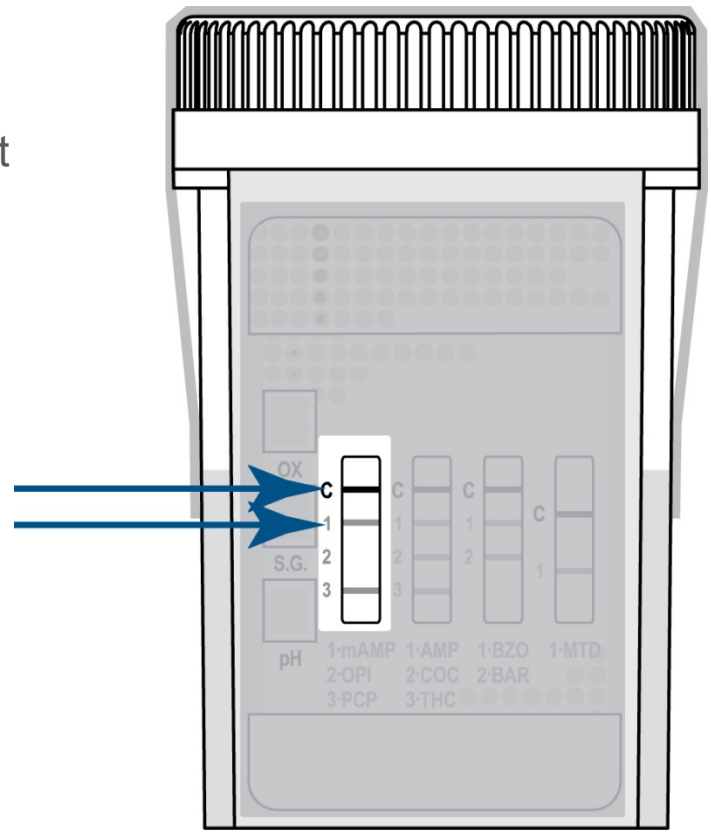


Reading results

Negative Example

NEGATIVE = line is present

Any visible line, even a faint line, indicates a negative result.



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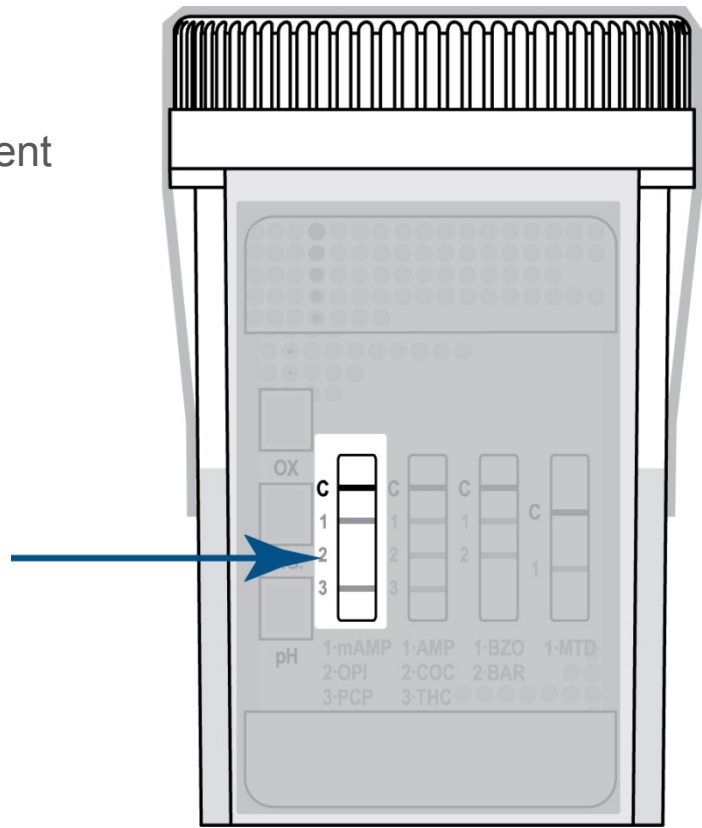


Reading results

Presumptive Positive Example

POSITIVE = No line is present

Presumptive positive for opiates (no line is present).



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Additional support services



Additional support services

SENDING SPECIMENS TO THE LABORATORY

» [Download PDF](#)

For instruction on how to send presumptive positive specimens to the lab, please review the next document in the training services: “Shipping & Labeling Protocol”.

COLLECTION AND REPORTING MANAGEMENT

» [Learn more](#)

Take advantage of RTL’s powerful collection and reporting system. Schedule donors, manage on-site tests, view reports and route presumptive positive specimens to the lab.

PRELIMINARY RESULT FORMS

» [Download PDF](#)

Log on-site results by downloading a Preliminary Result Form PDF. Printed form pads are available by request. These forms are not lab test request forms (for further confirmation testing).





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877-444-0049 screening devices
800-255-2159 laboratory services

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