

# Instructions for Performing Contingency Management Urinalysis

Obtaining the urine sample:

1. Ask the participant to give a urine sample, giving them the sample cup
2. Ask them to leave behind any coats, bags etc. that could be used to conceal false urine samples.
3. Escort them to the bathroom (if needed) and wait outside.

Checking for tampering/adulterated samples:

4. You can check that the urine is at the correct temperature to reduce the likelihood of the participant giving an adulterated sample. This should limit the chances of them either handing you someone else's urine or of diluting the sample with water.
5. The time from urination to temperature measurement should not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90 °F to 100 °F (32 °C to 38 °C), that is a reason to believe the donor may have altered or substituted the specimen.

Setting up the urinalysis machine:

6. Plug the urinalysis machine into the PC using a USB cable.
7. If you are using a CIRCLE laptop, log in with the profile *General User*
8. Double click on the CHR-110R icon on the desktop to open the program
9. Insert the RFID Tag into the urinalysis machine and select 'read tag'

Calibration:

10. Insert the Calibration cassette into the urinalysis machine
11. Click on *Settings > Gray Calibration*
12. A screen will appear with the phrase "*Calibration Success! Do you want this result saved as default one?*" Click on the Yes button
13. Remove the calibration cassette and insert the holder cassette for the marijuana test device

Analysing the urine sample:

14. Fill the pipette with urine (1ml) and release it into the dilution tube
15. Shake the tube to mix well
16. Put the marijuana test device into the holder cassette in the urinalysis machine drawer. The C and T marked on the side of the Cassette should match the C and T marked on the side of the cassette.
17. Use the Pipette again to draw some of this diluted urine and release 3 drops into the specimen well (indicated on the Cassette by the letter S).
18. Close the drawer and click on the Analysis Tab in the software
19. On the right side of the screen, you will find a button labelled 'min'. Just above, you will find a blank section. Write the number 5 in this blank section and then click 'min'

20. A screen will appear asking you to input some data. Fill the Patient ID and Operator (using your initials) sections and then press OK
21. The reader will wait 5 minutes and then perform the analysis

Following the analysis:

22. You will be given the THC concentration by the reader. Record the concentration in the participant intervention tracking sheet.
23. Based on the result (see next section), judge if the participant has passed during that session or not.
24. If possible, all materials, including urinalysis cassettes and urine sample, should be put in the clinical waste bag provided and disposed in the EI team's clinical waste. If clinical waste isn't available, such as at a participant's house, dispose of the liquid in the bathroom, and place the materials in the clinical waste bag. Either dispose of the clinical waste bag back at the service or ask the local clinical team about how they would recommend disposing of it.

# Judging Cannabis Use During Contingency Management Sessions

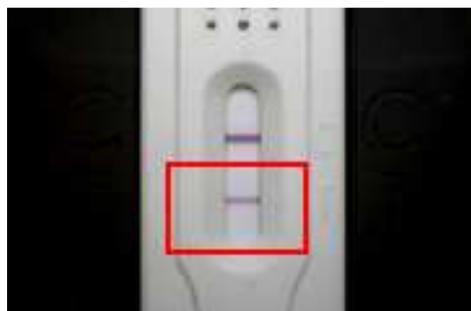
## Introduction

Urine THC concentration following cannabis use has a half-life. The half-life varies from person to person, but is typically about 8 days. So in an average person, roughly every 8 days their urine THC concentration will half. However, BMI, water/food consumption, level of exercise, metabolism and other factors influence the half-life length.

If someone has recently started to cut down or stop using cannabis, we should see a drop in urine THC concentration every week. If they have been using regularly and recently, concentration of THC should drop quickly at first but plateau after 2-3 weeks, and become undetectable after 3-4 weeks. This can take longer depending on individual factors, and may take considerably longer if the person is cutting down rather than being entirely abstinent. Once the THC concentration plateaus, you may see little difference week by week, or the THC concentration may appear to increase slightly. This could be due to many factors, including biological ones, but variation in results is normal.

We cannot guarantee that someone has or hasn't used in the previous week using urinalysis because there are so many factors that determine how THC is excreted. However, we can be very confident that someone is at least cutting down on their cannabis use each week by seeing a drop in urine THC concentration. So we are rewarding people for either: 1) substantially cutting down and eventually quitting cannabis, or 2) for being abstinent from the outset. You can say to participants that we want to see the amount of THC/cannabis in their urine drop each week, and that will mean that they will have to cut down substantially each week, and ideally stop altogether to guarantee achieving the reward.

On the next page are the rules for judging if someone has passed or failed. The urinalysis machine works in terms of intensity values. These intensity values describe how 'intense' the test line (see below) on the marijuana test device is. The darker the line, the less THC there is. So, **the higher the intensity value, the lower the concentration of THC.**



## Rules for deciding if someone passes or fails:

We use the following rules for judging if someone has been significantly reducing their use or has been abstinent over the previous week:



If someone's intensity value is:

1. **Above 70 – they always pass.** Urine THC is at a low level and they are very unlikely to have used at all in the last week.
2. **Between 40 and 70 – they pass as long as the value *hasn't significantly fallen* (approx. 15 or more) since the previous session.** Significant drops in intensity value indicate an increase in urine THC, that could be the result of cannabis use. If it looks like someone has used, you can discuss it with the participant and use your judgment to decide if they pass.
3. **Between 6 and 40 –** At this stage, their THC concentration should be falling each week. **So they would pass only if the intensity value *has risen* (approx. 10 or more) since the last session.** If it has dropped or remained at a similar value it indicates likely recent use (that they are using enough to maintain high urine THC concentration). However, you can discuss this with the participant and use your judgement to decide if they pass.
4. **Below 6 – they always fail.** Below 6 shows very high levels of urine THC, and they are unlikely to have made much effort to cut down on their cannabis use.

NB: An intensity value is a reading of THC concentration. It is the inverse of THC concentration. **The higher the intensity value, the lower the THC concentration. Normally significant changes in intensity values would be 10 or over.**

## Reward Schedule

Depending on the outcome, participants either receive a voucher of £5 (fail, i.e. positive urine) or a higher value (pass, i.e. negative urine).

### Passing a contingency management session

The table below demonstrates the rewards obtainable if participants pass every week:

Number of negative urines	Reward
1. Attending session	£5.00
2. Negative urine – pass	£10.00
3. Negative urine – pass	£10.00
4. Negative urine – pass	£15.00
5. Negative urine – pass	£15.00
6. Negative urine – pass	£20.00
7. Negative urine – pass	£20.00
8. Negative urine – pass	£25.00
9. Negative urine – pass	£25.00
10. Negative urine – pass	£30.00
11. Negative urine – pass	£30.00
12. Negative urine – pass	£35.00
Total amount	£240.00

### Failing a contingency management session

- If a participant fails a week they receive a £5 voucher.
- At the next session, if they fail again they receive £5, and will keep on receiving £5 for each subsequent week that they fail.
- If, having failed the previous week, they pass the next week they receive £10 for that session.
- If they pass the next session as well (i.e. the 3rd week after failing), they will return to the level they would have been on the week following the failed week, had they not failed.

For example, if a participant receives £20 in week 7, but in week 8 the urinalysis indicates that they had used cannabis, they would receive a £5 voucher in week 8. If they did not use in weeks 9 or 10 they would receive £10 in week 9 and £25 in week 10. If they passed in all subsequent weeks they would continue through the levels as previously:

Number of negative urines		Reward
1.	Attending session	£5.00
2.	Negative urine – pass	£10.00
3.	Negative urine – pass	£10.00
4.	Negative urine – pass	£15.00
5.	Negative urine – pass	£15.00
6.	Negative urine – pass	£20.00
7.	Negative urine – pass	£20.00
8.	Positive urine – fail	£5.00
9.	Negative urine – pass	£10.00
10.	Negative urine – pass	£25.00
11.	Negative urine – pass	£25.00
12.	Negative urine – pass	£30.00
Total amount		£190.00

The participant returns to the reward schedule at the level they would have been on the week following the failed week, had they not failed, i.e. week 8.

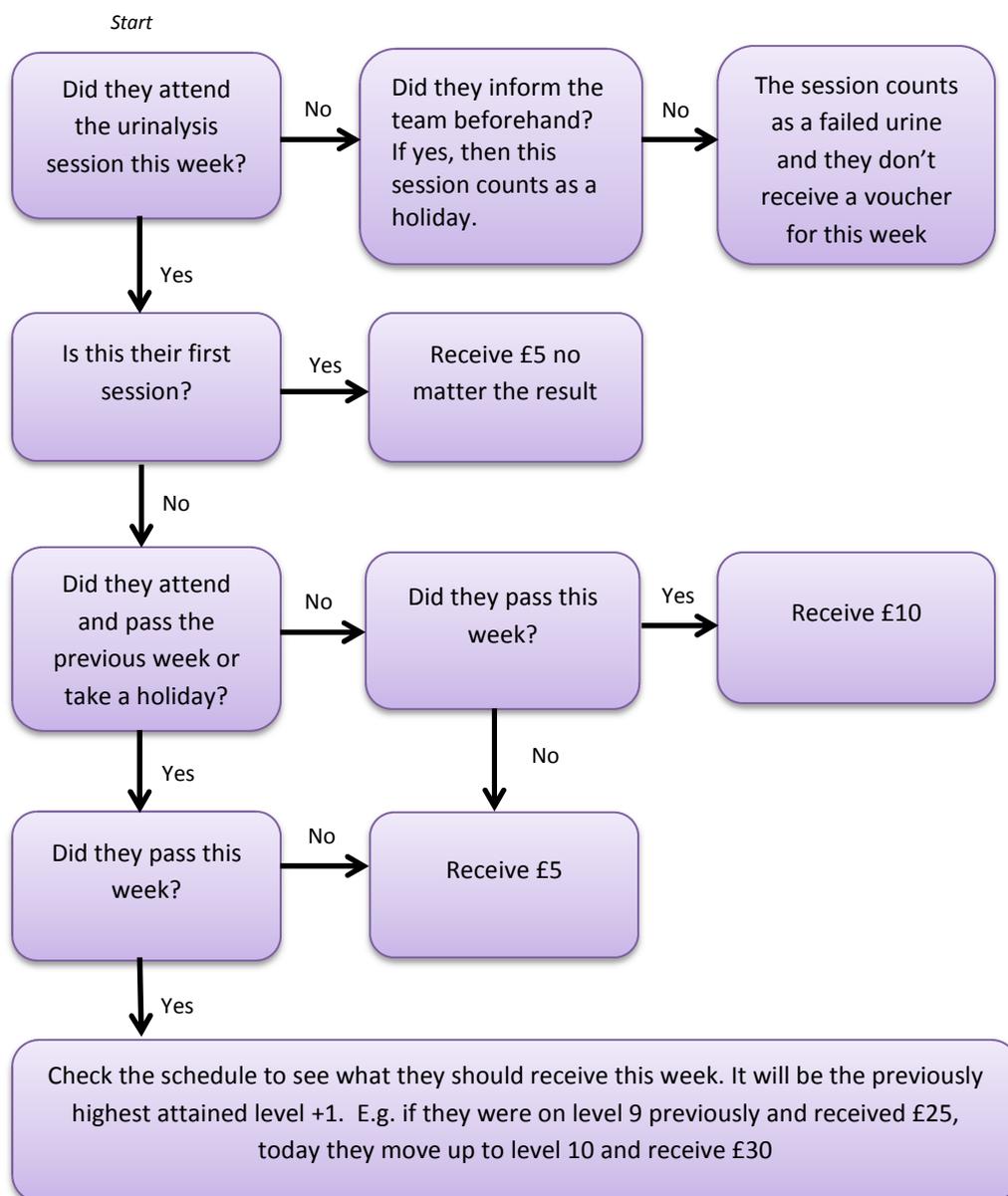
You can use the intervention tracking sheet and the decision flow chart below in order to keep track of what level of reward participants should be receiving each week.

### Failure to attend (DNA), holidays, and suspending the CM intervention

- If someone misses a session without giving prior notice it generally counts as a fail and they don't receive a voucher at all for that week.
- Based on the discretion of the person delivering the CM, a session can be arranged for within the same week if the participant fails to attend or cancels. The session should be rearranged for as close to the original session as possible. Being too rigid may deter the participant from continuing in the scheme, but allowing too much time between sessions will result in the urinalysis being less reliable – the service user would be more able to still use cannabis but pass the test.
- A missed week will still count as a week in the CM scheme, i.e. the intervention will still run for a total of 12 weeks; the timescale will not be extended if someone doesn't attend one week whether an appointment was arranged or not.
- Participants can only take 2 'holidays' of 1 week during the 12 weeks, which normally need to be discussed with the team beforehand.
- If they pass the week following the holiday, they will receive a voucher for the holiday week as well.
- Holidays can cover any time when they are unable to attend that week.

- However, they cannot miss two consecutive weeks without one being classed as a failure to attend. This is because cannabinoids reduce significantly after 2 weeks.
- To prevent participants from being able to use cannabis but still appear to be abstinent during their participation, participants cannot miss 2 consecutive weeks of urinalysis without penalty.
- The intervention can only be suspended if they lose capacity, which would normally mean they are being seen by a crisis team or are hospitalised. This suspension can only last for up to 1 month, after which the participant would need to be withdrawn from the trial.

### Decision flow chart for urinalysis sessions



## Background to the Urinalysis

*\*Note: You are not required to have a full understanding of the theory of urinalysis, it is sufficient to understand and follow the guidelines above. The information below is provided in addition for anyone who wants or would benefit from a theoretical understanding of urinalysis testing for THC concentrations.*

### Testing for THC

The urine THC concentration from participants will vary dependent on the amount of cannabis consumed and the time since consumed. By taking a base rating and examining changes in the concentration of THC in the urine, we are better able to detect whether a person has used cannabis within the last week.

If someone has used cannabis within the last week, we can expect to see a **significant** increase in their THC level from the previous week; this will be expressed as a drop in the intensity value when analysed using the urinalysis machine (further information below). As previously mentioned, the precise concentration of THC within the urine will vary from person to person dependent on individual factors such as weight and water consumption. Despite these individual differences, certain concentrations of urine THC allow us to be very confident in our estimations of a person's recent cannabis use.

From the literature on THC concentrations and metabolism, it is understood that with  $\geq 350\text{ng/ml}$  of THC urine concentration there is a high likelihood that the participant has been using cannabis within the last week. A person who has  $\geq 50\text{ng/ml}$  of THC urine concentration has previously used cannabis, however they are unlikely to have used for the last 2-4 weeks at least.

The problem with examining changes in cannabis use from week to week using urine THC concentrations is that the test devices used to complete the urinalysis are very sensitive to THC. They are designed to pick up low levels of THC ( $50\text{ng/ml}$ ) as positive results (image 1.1). This makes it difficult to detect when your participant last used cannabis as it can show positive up to 4 weeks after cannabis abstinence.

### Dilution

In order to examine the important changes to THC urine concentration which help detect whether cannabis was used within the past week, the urine is diluted 1:7 with water. When the urine is diluted, a urine THC concentration of  $350\text{ng/ml}$  is required to return a positive test result on the marijuana test device (image 1:1). When the urine is diluted, anything less than a urine THC concentration of  $350\text{ng/ml}$  provides a line on the test device that the machine can read to provide a measure of THC concentration (image 1:2). This is useful in this study because we are interested in the window between recent, substantial use ( $>350\text{ ng/ml}$ ) and abstinence over the last few weeks

(<50ng/ml). What the urinalysis machine allows us to do is look at this window between 350ng/ml (corresponding an intensity value of 6) and 50ng/ml (intensity value of approximately 70). We can then monitor weekly change in THC concentrations to check if the person has been using or not.

Image 1:3 demonstrates how the test devices can show many different concentrations of THC in urine. What is important for the contingency management sessions is that the level of THC has not significantly increased, which would signal that the participant has been using cannabis during the past week (remembering to account for small increases which could be due to THC in fat cells etc., we are looking for a significant increase of around 10 or more).



Positive Result (Image 1:1)

Negative Result (image 1:2)

Range of THC concentrations (image 1:3)

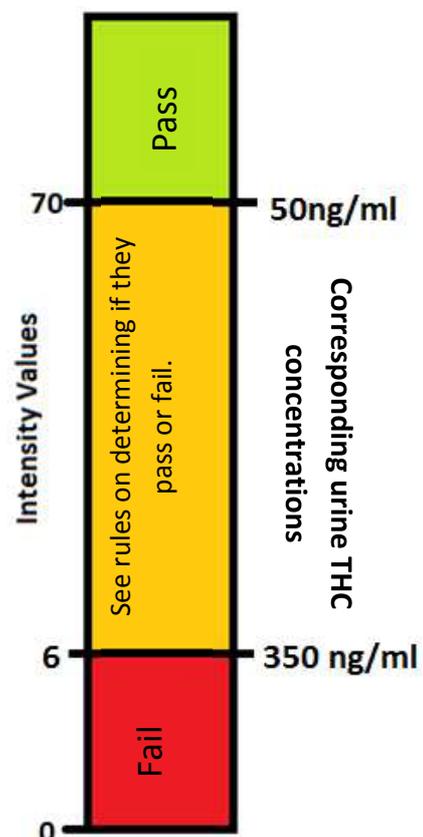
### THC concentrations and Intensity Values on the Urinalysis Machine

As shown in image 1:1 and image 1:2, a single line on the test device signals a positive result and urine THC concentration  $\geq 350\text{ng/ml}$ , two lines signals a negative result and THC concentrations  $<50\text{ng/ml}$ .

The urinalysis machine used in this study does not provide a value of urine THC concentration. Instead it provides an intensity value of the test line on the test device. **The higher the intensity rating the lower the THC levels in the urine (image 1:4).** So, as the intensity rating goes up we know that the THC in the urine has reduced.

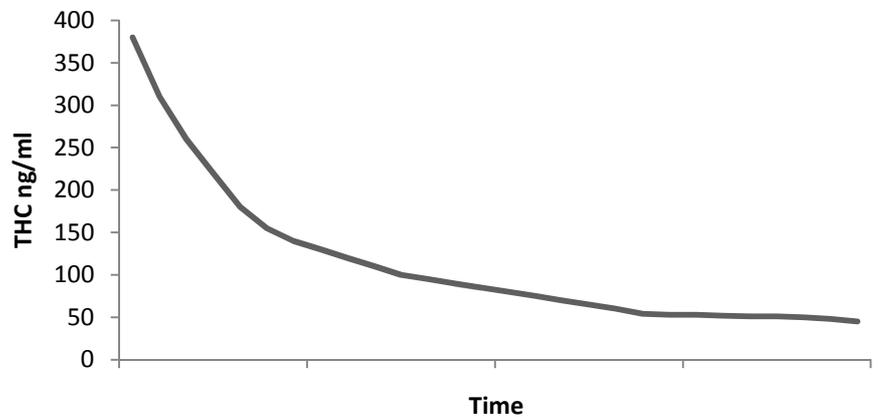
- An intensity rating of 70 or higher would signify  $\leq 50\text{ng/ml}$  THC in the diluted urine and, in turn, would inform us that the participant had NOT been using cannabis within the last week.
- An intensity rating of 6 or lower would signify  $\geq 350\text{ng/ml}$  THC in the diluted urine and, in turn, would inform us that the participant HAD been using cannabis within the last week.

For any intensity rating between 6 – 70 the clinician has to examine the direction of the change. An increase in intensity rating would signify that there is less THC in the participant’s urine than the previous session, while a decrease in intensity rating would signify that there is more THC. The rate at



which THC is metabolised varies from person to person, but as a general rule it is approximately halved every 8 days. So if participants have been using cannabis recently, their concentrations of THC should drop quickly at first (intensity ratings increasing). But after 3-4 weeks, are likely to plateau and the weekly drops in THC will become smaller.

This graph depicts roughly what will happen to urine THC concentration in the weeks following cannabis abstinence. For example THC could reduce from 380ng/ml to 140ng/ml in the first week; however by week 4 of abstinence THC concentrations might only reduce from 53ng/ml to 48ng/ml.



For this reason we would expect to see faster increases in intensity ratings (signalling reducing THC levels) in the first few weeks following cannabis abstinence, however we would expect much smaller, if any changes the longer the participant has been abstinent, this is reflected in the rules outlined previously.

### How Much Should Intensity Values Change?

The rate of change following abstinence is a little hard to define in terms of intensity values. There are biological factors, such as BMI or metabolic rates. But there are also factors related to the way the marijuana test devices work. For example, it takes time for them to react to urine THC. As a rule, we leave 5 minutes between when the urine goes on the device and when the machine performs the analysis as that gives the most accurate result. However, urinalysis with the same used test device can provide slightly different results depending on the time period between when the diluted urine was pipetted onto the test device and when the urinalysis was performed. It is likely to return a different result 2 minutes after the urine has been put on the device compared to 5 minutes. Furthermore, for intensity values over 70 or 80, intensity values results can vary a lot with the same test device. Cannabis use is likely to be associated with big drops in intensity values at higher intensity values, and smaller changes at lower values. Meanwhile, abstinence will be associated with big increases in intensity values at lower values, and smaller changes at higher values.

As a general rule, in the window between 6 and 70, intensity values that have changed by 5 or less since the previous session may be a product of the urinalysis process itself, or very small changes in use – such as the person changing the time of day they use before the reward session. We can say any change in intensity value that is less than 10 generally indicates a small change in use, but that THC concentration hasn't changed much. Between 10 and 20 indicates moderate change at lower intensity values or abstinence at higher intensity values. Over 20 indicates a big change – either that they had been using a lot recently, and have now substantially cut down (for lower intensity values);

or that they have definitely used since the last session at higher intensity values. Below are a number of examples of participant urinalysis results over the course of 12 weeks.

The highlighted figures are those for which the reward voucher was provided to participants, the non-highlighted boxes were provided only with the £5 standard payment as their results suggested recent cannabis use. Line C is a typical pattern of results for a participant who has continued to use cannabis throughout the trial. Line B shows a pattern which would be found in a participant who became abstinent at near the start of the trial and remained abstinent, as demonstrated by the consistently high ( $\geq 70$ ) intensity ratings. Line A is depicting a participant who initially became abstinent from cannabis but returned to cannabis use after week 7 when the intensity ratings fell from 95.92 to 21.92.

	1	2	3	4	5	6	7	8	9	10	11	12
A	18.78	40.34	80.85	75.8	78.7	113.93	95.92	21.92	11.48	8.68	4.24	28.29
B	31.82	65.82	62.82	56.65	111.34	90.12	71.28	73.44	88.76	76.94	93.3	83.86
C	3.1	3.89	1.83	3.53	3.24	4.09	2.52	5.14	3.56	1.9	0.89	3.83