DTPM Study -

Performance of the new DTPM Branded16-Panel Point Of Care (POC) Cup in Comparison to a Currently Used Leading Alternate Brand 16-Panel POC Cup



ARTICLE INFORMATION

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STUDY OBJECTIVE

In this study, the new alternative *DTPM 16-Panel POC cup* was tested to ensure that its accuracy was equally comparable to the *leading alternate brand 16-Panel POC cup* we are currently providing to our clients. An accompanying objective was also to test if the DTPM 16-Panel POC cup was more accurate than the alternate brand 16-Panel POC cup and how each performed compared to the accuracy of an analyzer instrument.

BACKGROUND INFORMATION

For the last twenty years, POC testing and instrument testing has been the most common drug testing methods utilized in both clinical and laboratory settings. Many reliable sources have concluded that POC testing has an inconsistent accuracy rate due to a wide-range of factors including, POC product quality, sample collection, urine dilution/hydration, and tampering. Though instrument testing has an approximate rate of 95-99% accuracy, POC testing is the most convenient method for routine drug screening and is frequently utilized in clinical and laboratory settings.

METHOD AND MATERIALS

MATERIALS: A total of 24 POC cups were used in this comparison study: 12 of a leading alternate brand multi-drug urine test cups and 12 DTPM Multi-Drug Urine Test Cups were compared. Both brands of 16-Panel cups test for the following drugs of abuse (DOA):

THC, AMP, BAR, BUP, BZO, COC, MAMP, MDMA, MOP, MTD, OXY, PCP, ETG, FTY, TRA and K2.

A total of 12 urine samples were obtained: 10 of the 12 samples were positive for one or more of the above listed drugs of abuse and two of the 12 samples were negative for all drugs of abuse. (The samples were previously tested on an analyzer off site and the cut-off levels for each were obtained.) The same 12 samples were tested between both brands of cups. A timer was used to precisely alert to the five-minute mark

METHOD: The 12 samples were collected off-site then properly stored. As instructed per each brand of POC cup, the samples were screened at their appropriate temperature of between 90°F-100°F (32°C-38°C). *Instructions included*

DTPM POC Cup Instructions:

- 1. Sample collection can be collected at any time and for best results, specimens should be tested.
- 2. Read temperature immediately to verify that the urine temp is within the acceptable range 90°F-100°F
- 3. Peel of f the label and read the results. Drug Test Results should be read at 5 minutes.
- *The Drug Test Results remain stable for up to 30 Minutes.

Reading the Results

PRELIMINARY POSITIVE (+)

A Rose Pink band is visible in each control region. IF no color band appears in the appropriate test "T" region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.

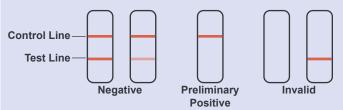
Negative (-)

If a rose-pink band is visible in each control region and the appropriate test "t" region. It indicates that the concentration of the corresponding drug if that specific test zone is absent or below the detection limit of the test.

Invalid

If a color band is not visible in the control "C" region or a color band is only visible in the test "T" region, the test is invalid and the process must be repeated.

IMPORTANT: There is no meaning attributed to line color intensity or width. This assay provides only a preliminary analytical test result.





Leading Alternate Brand Instructions:

- 1. Sample collection can be collected at any time and for best results, specimens should be tested.
- 2. Read temperature immediately to verify that the urine temp is within the acceptable range 90°F-100°F
- 3. Peel of f the label and read the results. Drug Test Results should be read at 1-2 minutes.
- *The Drug Test Results remain stable for 5 Minutes.

Reading the Results

PRELIMINARY POSITIVE (+)

A Rose Pink band is visible in each control region. IF no color band appears in the appropriate test "T" region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.

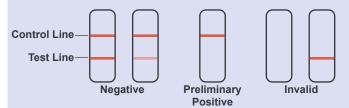
Negative (-)

If a rose-pink band is visible in each control region and the appropriate test "t" region. It indicates that the concentration of the corresponding drug if that specific test zone is absent or below the detection limit of the test.

Invalid

If a color band is not visible in the control "C" region or a color band is only visible in the test "T" region, the test is invalid and the process must be repeated.

IMPORTANT: There is no meaning attributed to line color intensity or width. This assay provides only a preliminary analytical test result.



METHOD: The urine specimens were individually poured into each of the two brands of test cups: The alternate brand test cups require a minimum of 25mL and are appropriately marked on the cup; the DTPM POC cups require a minimum of 20mL which is also appropriately marked on the cup. The POC cups were tested on a flat surface area at a room temperature of 65°F-86°F (18°C-30°C) and left for five minutes as directed per both brands of cup's specific test procedure. The round of 12 alternate branded POC cups was tested first and then individually photographed at their five-minute mark.

The DTPM POC cups were tested next with the same 12 specimens and read/photographed at the directed five-minute mark. The test results for each sample in each cup were documented at their five-minute mark. The results and accompanying data were compared and can be found summarized below.

RESULTS

Following the test procedures for the 12 leading alternate brand POC cups, the results showed that those cups produced nine of the 14 positive results giving them a 64.3% accuracy value. Following the test procedures for the 12 DTPM POC cups, the results showed those cups produced 10 of the 14 positive results giving the DTPM POC cups a 71.4% accuracy value. Upon further evaluation of the data, the alternate cups delivered five false positive results and five false negatives; the DTPM POC cup delivered three false positive results and four false negatives.

FIGURES AND CONCLUSION

As the data displays below, the DTPM 16-Panel POC cup performed at the same level and was more accurate than the leading alternate brand POC cup.

Analyzer: 14/14	100%
Leading Alternate Brand: 9/14	64.30%
DTPM Brand: 10/14	71.4%

Leading Alternate	5 False	5 False
Brand POC	Positives	Negatives
DTPM Brand POC	3 False Positives	4 False Negatives





RESULTS:

The 12 samples received for this study were previously run on an analyzer off-site; the results from the analyzer for each of the 12 samples were recorded on the chart along with the results from all 12 Alternate brand cups and DTPM POC cups.

A positive result was marked using an "X". If there were no positive results, the column was given an "X" in the "NEG" column. The chart shows the 14 positive test results given by the analyzer and how the cups compared against those 14 positives as well as compared to one another.

		NEG	тнс	AMP	BAR	BUP	BZO	coc	MAMP/MET	MDMA	МОР	MTD	ОХҮ	РСР	ETG	FTY/FYL	TRA	К2
	Sample:	NEG	IIIC	Alvir	DAIL	DOI	DEC	COC	IVIAIVII / IVIE I	IVIDIVIA	IVIOI	IVIID	OAT	rer	110	111/112	ш	IV.Z
	J																	
	Analyzer CUP1		Х						Х						Х			
	Alternate CUP1			Х					Х									
,	DTPM CUP1			Х					Х									
ı																		
	Analyzer CUP2														X			
	Alternate CUP2						Х								X			
	DTPM CUP2												_		Х			
ı	4 1 61100		V															
	Analyzer CUP3 Alternate CUP3		Х								Х							
	DTPM CUP3										X							
	DIT WI COLD																	
	Analyzer CUP4								Х									
	Alternate CUP4			х					Х									
	DTPM CUP4								X									
1																		
	Analyzer CUP5				Х													
	Alternate CUP5				Х													
	DTPM CUP5				Х													
	Analyzer CUP6			Х														
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ı	4 1 01107					V												
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	Analyzer CUP8														х			
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	Alternate CUP9								Х									
	DTPM CUP9								Х									
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	Analyzer CUP10				Х		v											
	Alternate CUP10				v		Х											
	DTPM CUP10				Х													
	Analyzer CUP11	Х																
	Alternate CUP11	X																
	DTPM CUP11	X																
	Analyzer CUP12	Х																
	Alternate CUP12	Х																
	DTPM CUP12	Х																

RESULTS:

Displayed are the cutoffs for each sample substance. The analyzer is the most accurate form of testing.

The DTPM POC cup is more accurate than the alternate brand.

	THC	AMP	BAR	BUP	BZO	сос	MAMP/MET	MDMA	МОР	MTD	ОХҮ	PCP	ETG	FTY/FYL	TRA	К2
CUTOFFS																
Analyzer:	50	500/1000	200	20	200	150	500	500	300	300	400	25	500	100	200	20/10
Alternate:	50	1000	200	10	100	300	1000	500	300	300	100	25	500	20	200	50
DTPM:	50	1000	300	10	300	300	1000	500	300	300	100	25	500	200	200	50

Analyzer: 14 out of 14 100% Alternate: 9 out of 14 64.30% DTPM: 10 out of 14 71.40%

Alernate: 5 False Positives
DTPM: 3 False Positives

Alternate: 5 False Negatives
DTPM: 4 False Negatives