

## SPECIFICITY STUDIES

### Introduction

The purpose is to perform specificity studies on DrugCheck® NxStep OnSite test kits utilizing lot numbers 801122706 (expiration June 2008) and 610010307 (expiration July 2008). Lot number 801122706 tests for Benzodiazepines (BNZ), Opiates (OPI 300), Methadone (MDN), Methylene dioxy-methamphetamine (MDMA), Oxycodone (OXY), Propoxyphene (PPX), and Tricyclic antidepressants (TCA). Lot number 610010307 tests for Amphetamines (AMPHS), Methamphetamine (MAMP), Benzoylcegonine (BE), Tetrahydrocannabinoids (THC), and Phencyclidine (PCP). The testing was performed between 1/9/07 and 1/25/07 at Kroll Laboratory in Gretna, LA.

### Materials and Methods

In the specificity studies, the test kits were exposed to a minimum of twenty positive patient samples at various levels based on GC/MS. The cups were then read as soon as readable results were possible. All samples were initially screened by CEDIA or DRI immuno assay and confirmed by Gas Chromatography/Mass Spectroscopy. The chemist performing the test was trained in the interpretation of on-site test results. All questionable samples were subjected to a second screening analysis with either CEDIA or DRI reagents.

### DATA

#### OPI300

Specificity Lot 801122706

#### Sample Confirmed Result

1. 2131143 Mor 574 Positive OPI
2. 2130925 Mor 712 Positive OPI
3. 2131295 Mor 565 Positive OPI
4. 2139146 Mor 754 Positive OPI
5. 2178624 Mor 639 Positive OPI
6. 2206217 Mor 547 Positive OPI
7. 2206218 Mor 763 Positive OPI
8. 2131869 Mor 249 Negative OPI
9. 2152617 Mor 242 Negative OPI
10. 2131044 Cod 383 Positive OPI
11. 2131115 Cod 4921 Positive OPI
12. 2131147 Mor 1579 Positive OPI
13. 2131422 Mor 57499 Positive OPI
14. 2130814 Oxy 2124 Negative OPI

15. 2127627 Hyc 1202 Positive OPI  
16. 2127924 Cod 2566 Positive OPI  
17. 2146421 Oxy 565 Negative OPI  
18. 2146980 Mor 2243 Positive OPI  
19. 2131242 Hyc 963 Positive OPI  
20. 2131862 Mor 3288 Positive OPI  
21. 2131125 Cod 4921 Positive OPI  
22. 2130742 Cod >5000 Positive OPI  
23. 2134827 Cod 1035 Positive OPI  
24. 2132263 Cod 92480 Positive OPI  
OPI2000  
Specifi city Lot 610010307  
Sample Screening Confi rmed Result  
1 1876939 >10,000  
165  
Cod =323 Mor =  
5520 THC = 93  
Positive Positive  
THC  
2 1877370 5205 Mor = 3562 Positive  
3 1877553 >10,000 Cod = 2669 Mor  
= 620  
Positive  
4 1877642 3680 Mor = 3562 Positive  
5 1877657 >10,000 Mor = 473 Positive  
6 1888935 2525 Cod = 275 Mor  
= 217  
Positive  
7 1890188 >40,000 Mor = 69001 Positive  
8 1891172 5383 Mor = 2102 Positive  
9 1891703 31530 Mor = 12523 Positive  
10 1892517 4071 Mor = 2267 Positive  
11 1892608 6230 Mor =6960 Positive  
12 1893325 >10,000 Hycd= 4631  
Hymr = 1167  
Positive  
13 1901302 5780  
180  
Cod = 400 THC  
= 77  
Positive Positive  
THC  
14 1905378 5035 Mor = 3778 Positive  
15 1905386 13200 Mor = 5267 Positive  
16 1845505 22925 Mor = 7413 Positive  
17 1874604 >10,000 Hymr = 2496 Positive

18 1906882 >10,000

>500

603

Cod = 1181 Mor

= 340

THC = >2000

Be = 429

Positive

Positive THC

Positive Be

Independent studies

verify the accuracy

of the DrugCheck®

NxStep OnSite test cup

Express Diagnostics, Int'l Inc. recently commissioned an independent study by Kroll Laboratory Specialists to determine the specificity and accuracy of the DrugCheck® NxStep Onsite test cup. As one of the foremost providers of drug testing analysis, Kroll Laboratory Specialists' studies set the standard for test evaluation through the collection of multiple samples and comprehensive statistical data. Following are their results.

drugcheck.com

PROP

Specificity Study Lot 801122706

Sample Confirmed Result

1. 1844377 1402 Positive
2. 1844904 7487 Positive
3. 1845807 4352 Positive
4. 1903483 7913 Positive
5. 1903918 2591 Positive
6. 1903947 3793 Positive
7. 2019791 935 Positive
8. 1901595 5821 Positive
9. 1907519 1532 Positive
10. 1907873 >10000 Positive
11. 1911610 3590 Positive
12. 1915317 11676 Positive
13. 2102920 >1000 Positive
14. 2014312 >1000 Positive
15. 2013455 5386 Positive
16. 2014458 6003 Positive
17. 2018932 4126 Positive
18. 2020309 4106 Positive
19. 2020451 7133 Positive
20. 2021727 >10000 Positive

MDN

Specificity study LOT 801122706

Sample Confirmed Confirmed Result

1. 1844644 EDDP >40000 MDN 20378 Positive
2. 2014143 MDN >500 Positive
3. 1890400 EDDP 9931 MDN 3853 Positive
4. 1890836 EDDP 325 MDN >500 Positive
5. 1890845 EDDP 10679 MDN >10000 Positive
6. 1891127 EDDP 4394 MDN 6783 Positive
7. 1906815 EDDP 7021 MDN 6177 Positive
8. 1907008 EDDP 798 MDN >500 Positive
9. 1907566 MDN >500 Positive
10. 1907626 EDDP >800 MDN >500 Positive
11. 1915791 EDDP 10321 MDN >10000 Positive
12. 1916073 EDDP 527 MDN 493 Positive
13. 1916111 EDDP 12121 MDN >10000 Positive
14. 1916274 EDDP 389 MDN >500 Positive
15. 1916342 EDDP 7611 MDN >500 Positive
16. 1917098 MDN >500 Positive
17. 2012686 EDDP >16000 MDN >10000 Positive
18. 3007597 EDDP 1520 MDN 313 Positive
19. 2019557 EDDP >16000 MDN >10000 Positive
20. 2018765 EDDP >800 MDN >500 Positive

Oxycodone

Specificity study LOT 801122706

Sample Conformation Result

1. 2130814 2124 Positive
2. 2146421 565 Positive, F
3. 2146586 273 Positive, F
4. 2151562 4958 Positive
5. 2151995 2028 Positive
6. 2152443 4835 Positive
7. 2152536 3584 Positive
8. 2151446 513 Positive
9. 2152198 551 Positive, F
10. 2123839 8189 Positive
11. 2124604 2264 Positive
12. 2156988 470 Positive
13. 2161794 2782 Positive
14. 2160995 910 Positive, F
15. 2173837 1764 Positive
16. 2173946 583 Positive
17. 2174358 2965 Positive
18. 2190018 3919 Positive
19. 2190849 1395 Positive
20. 2191343 3678 Positive

BENZ

Specificity Study LOT 801122706

Sample Conformation Conformation

Result Rescreen

1. 201943 APAM 374 Positive
2. 2011942 NPAM 332 Positive
3. 2011938 APAM 520 Positive
4. 201939 OPAM 173 Negative <Cut Off
5. 201960 OPAM 563 TPAM

677

Positive

6. 201949 APAM 314 Positive
7. 201947 OPAM 563 Negative 889\*\*

8. 201946 OPAM

>50000

Positive

9. 1844602 APAM

>1000

Positive

10. 1844946 OPAM 449 Positive

11. 201953 NPAM 195 OPAM

569

Positive

12. 1891155 TPAM 651 Positive

13. 1876471 OPAM

>1000

Positive

14. 1876556 APAM 6334 Positive

15. 201954 OPAM 449 TPAM

807

Positive

16. 1840134 APAM 309 Positive

17. 1873942 APAM 451 Positive

18. 3470267 OPAM 303 Positive

19. 3472351 OPAM 842 TPAM

>2500

Negative 973\*\*

20. 3471559 OPAM 735 TPAM

311

Positive

MAMP

Specificity Lot 610010307

Sample Screening

Confirmed Result

1 1891978 2830 Amp=>200

Mamp=1875

Positive

2 1901691 2805 Amp=260

Mamp=1799  
Positive  
3 1893055 4985 Amp=1163  
Mamp=2827  
Positive  
4 1877191 11700 Amp=20588  
Mamp=1284  
Positive  
5 1891174 1051 Amp>200  
Mamp=598  
Positive  
6 203292 >25000 Amp=2794  
Mamp=7842  
Positive  
7 203299 1718 Amp=582  
Mamp=521  
Positive  
8 1890564 2223 Amp=365  
Mamp=1021  
Positive  
9 1906326 1599 Amp=357  
Mamp=783  
Positive  
10 1891157 3615  
>500  
Amp=768  
Mamp=3128  
THC=492  
Positive  
Positive  
THC  
11 1906355 2820 Amp=813  
Mamp=1649  
Positive  
12 1906619 >25000 Amp=19802  
Mamp=  
>100000  
Positive  
13 1906785 3006 Amp=284  
Mamp=1489  
Positive  
14 1906819 2350 Amp=1072  
Mamp=1546  
Positive  
15 1891708 2130 Amp=853  
Mamp=1222

Positive

16 2049376 4565 Amp=1085

Mamp=1277

Positive

17 2049837 3180 Amp=342

Mamp=1264

Positive

18 2049880 2326 Amp=433

Mamp=975

Positive

19 2050012 21085 Amp=2231

Mamp=

>10000

Positive

20 2050134 1291

492

Amp>200

Mamp=853

Be=492

Positive

Positive

Be

21 2050222 1752 Amp=507

Mamp=1246

Positive

22 1904495 >25000 Amp=23931

Mamp=

>100000

Positive

\*\* Both of these samples are being re-analyzed by GC/MS to determine if degradation of the Benzodiazepines resulted in the negative reading with the on-site testing device.

AMP

Specificity Lot 610010307

Sample Screening Confirmed Result

1 1405001 2300 Amp = 1498 Positive

2 1889458 8215 Amp = 9108 Positive

3 1890741 13715 Amp =

>10000

Positive

4 1891688 1340 Amp = 1533 Positive

5 1891689 8935 Amp = 9220 Positive

6 1844762 1552 Amp = 1900 Positive

7 1844918 2494 Amp = 4172 Positive

8 2052790 1324 Amp = 1647 Positive

9 2052814 2545 Amp = 4394 Positive  
10 2046113 3512 Amp = 6404 Positive  
11 2046220 1345 Amp = 2169 Positive  
12 1903882 >100000 Amp = 7545 Positive  
13 1904374 1970 Amp = 2340 Positive  
14 1905151 3149 Amp = 5888 Positive  
15 1875438 2162 Amp = 3577 Positive  
16 1845264 4715 Amp = 6927 Positive  
17 1845427 15025 Amp =  
>10000

Positive

18 1872439 3140 Amp = 4694 Positive  
19 1874508 1524 Amp = 2354 Positive  
20 1874516 4006 Amp = 9682 Positive

THC

Specificity Lot 610010307

Sample Screening

Confirmed Result

1 203067 61 THC = 31 Positive  
2 203063 135 THC = 81 Positive  
3 2046415 84 THC = 39 Positive  
4 2046430 58 THC = 34 Positive  
5 2044944 85 THC = 39 Positive  
6 2045336 135 THC = 66 Positive  
7 2045513 93 THC = 74 Positive  
8 2045514 63 THC = 36 Positive  
9 2045518 58 THC = 34 Positive  
10 2045534 73 THC = 33 Positive  
11 2045571 >500 THC = 753 Positive  
12 2045703 92 THC = 148 Positive  
13 2046111 87 THC = 43 Positive  
14 2045706 91 THC = 119 Positive  
15 204241 42 THC = 22 Positive  
16 204399 75 THC = 22 Positive  
17 204259 180 THC = 89 Positive  
18 1838837 >500 THC = 839 Positive  
19 2046141 84 THC = 45 Positive  
20 2046686 52 THC = 32 Positive

Be

Specificity Lot 610010307

Sample Screening

Confirmed Result

1 2045475 317 Be = 243 Positive  
2 2045507 923 Be = 854 Positive  
3 2045513 374 Be = 285 Positive  
4 2045591 744 Be = 679 Positive



5 2045385 510 Be = 394 Positive  
6 2045202 605 Be = 603 Positive  
7 2044944 >25000 Be = 161932 Positive  
8 1844461 327 Be = 245 Positive  
9 1844476 645 Be = 449 Positive  
10 1844642 447 Be = 476 Positive  
11 1844643 330 Be = 384 Positive  
12 1844461 327 Be = 245 Positive  
13 1844720 590 Be = 555 Positive  
14 1844787 821 Be = 725 Positive  
15 1845249 431 Be = 292 Positive  
16 2043382 337 Be = 376 Positive  
17 1933567 897 Be = 700 Positive  
18 1844127 732 Be = 734 Positive  
19 1844130 1047 Be = 1001 Positive  
20 1844248 386 Be = 394 Positive

PCP

Specificity Lot 610010307

Sample Screening

Confirmed Result

1 216652 355

380

PCP = 373

THC = 163

Positive

2 3229701 59

>500

PCP = 51

THC = 317

Positive

3 3215326 236

87

PCP = 324

THC = 41

Positive

4 3224207 405

455

PCP = 359

THC = 272

Positive

5 3224898 188

215

>25000

PCP = 201

THC = 110

Be = 99508

Positive

6 3218906 226 235 Positive

7 3216453 >750 >1000 Positive

8 3220640 61 48 Positive

9 3220377 53 53 Positive

10 3215184 64 56 Positive

11 3208690 64 49 Positive

12 3222740 52 47 Positive

13 PCP 1 522 533 Positive

14 PCP 2 258

>3000

PCP = 229

Be = >3000

Positive

15 PCP 3 11884

1380

PCP = 97

THC = 1381

Positive

16 PCP 4 229 PCP = 200 Positive

17 PCP 5 54

742

PCP = 45

Be = 661

Positive

18 PCP 6 125 PCP = 101 Positive

Discussion

The specificity trials for Propoxyphene and Methadone returned positives above the stated cutoff across a wide range. The results were easy to read.

The specificity trial for Oxycodone returned positives above the stated cutoff. A few of the samples approaching the stated cutoff of 100 ng/mL appeared to have a very faint line present in the negative line area. Upon casual inspection the samples appeared positive, but upon close scrutiny, the samples may appear to test negative. The samples are designated with an "F" in the result column.

The specificity trial for BENZ returned positives on all of the samples above the stated cutoff off 300 ng/mL except for two samples. The two samples that returned negative results were rescreened. The rescreen results were above the stated cutoff for both samples. Both of the negative samples > cut

off are being re-analyzed by GC/MS to determine if degradation created the negative on-site test result. On the positive results, oxazepam and alphahydroxyalprazolam very near the cutoff returned good positives. The third negative result confirmed positive, but was under the stated cutoff, so a negative result was expected from this sample. The kits performed at an overall accuracy rate of 98.2%. The performance on THC, Cocaine, PCP, Amphetamine, Methamphetamine and OPI2000 was 100%. Several samples were run below the stated cut off and did return the expected negative result. The kits were easy to handle and interpret.

Pat Pizzo, Director of Toxicology

Kroll Laboratory Specialists

#### TIMED TRIALS

Introduction The purpose is to perform time trials on DrugCheck® NxStep OnSite test kits utilizing lot numbers 801122706 (expiration June 2008) and 610010307 (expiration July 2008). Lot number 801122706 tests for Benzodiazepines (BNZ), Opiates (OPI 300), Methadone (MDN), Methylene dioxy-methamphetamine (MDMA), Oxycodone (OXY), Propoxyphene (PPX), and Tricyclic antidepressants (TCA). Lot number 610010307 tests for Amphetamines (AMPHS), Methamphetamine (MAMP), Benzoylcegonine (BE), Tetrahydrocannabinoids (THC), and Phencyclidine (PCP). The testing was performed between 1/9/07 and 1/25/07 at Kroll Laboratory in Gretna, LA.

Materials and Methods In the time trials, six to ten test kits were exposed to positive patient urine at a level approximately two times the stated cutoff based on GC/MS results, certified negative urine and actual donor samples were used for the study. All samples were initially screened by CEDIA or DRI immuno assay and confirmed by Gas Chromatography/Mass Spectroscopy. The chemist performing the test was trained in the interpretation of on-site test results. All questionable samples were subjected to a second screening analysis with either CEDIA or DRI reagents.

#### DATA

Negative timed study with lot 801122706

Sample 5 minutes 30 minutes

1. Negative Lot# 88 Negative Negative

2. Negative Lot# 88 Negative Negative  
3. Negative Lot# 88 Negative Negative  
4. Negative Lot# 88 Negative Negative  
5. Negative Lot# 88 Negative Negative  
6. Negative Lot# 88 Negative Negative  
7. Negative Lot# 88 Negative Negative  
8. Negative Lot# 88 Negative Negative  
9. Negative Lot# 88 Negative Negative  
10. Negative Lot# 88 Negative Negative  
Negative timed study with lot 610010307  
Sample 5 minutes 30 minutes

1. Negative Lot# 88 Negative Negative  
2. Negative Lot# 88 Negative Negative  
3. Negative Lot# 88 Negative Negative  
4. Negative Lot# 88 Negative Negative  
5. Negative Lot# 88 Negative Negative  
6. Negative Lot# 88 Negative Negative  
7. Negative Lot# 88 Negative Negative  
8. Negative Lot# 88 Negative Negative  
9. Negative Lot# 88 Negative Negative  
10. Negative Lot# 88 Negative Negative

THC timed study lot 610010307  
Sample Confirmation 5 minutes 30 minutes

1. THC  
2132197  
87 Positive Positive  
2. THC  
2132203  
86 Positive Positive  
3. THC  
2131130  
72 Positive Positive  
4. THC  
2134930  
74 Positive Positive  
5. THC  
2133127  
76 Positive Positive  
6. THC  
2132422  
79 Positive Positive  
7. THC  
2131971  
83 Positive Positive

THC timed study with lot 801122706  
Sample Confirmation 5 minutes 30 minutes

1. THC  
2132197  
87 negative negative

2. THC  
2132203  
86 negative negative

3. THC  
2131130  
72 negative negative

4. THC  
2134930  
74 negative negative

5. THC  
2133127  
76 negative negative

6. THC  
2132422  
79 negative negative

7. THC  
2131971  
83 negative negative

Be timed study lot 610010307  
Sample Confirmation 5 minutes 30 Minutes

1. BE  
2128513  
837 Positive Positive

2. BE  
2131153  
621 Positive Positive

3. BE  
2130813  
559 Positive Positive

4. BE  
2132143  
649 Positive Positive

5. BE  
2132215  
542 Positive Positive

6. BE  
2135863  
594 Positive Positive

7. BE  
2135616  
584 Positive Positive

Be timed study with lot 801122706  
Sample Confirmation 5 minutes 30 Minutes

1. BE 2128513 837 negative negative
2. BE 2131153 621 negative negative
3. BE 2130813 559 negative negative
4. BE 2132143 649 negative negative
5. BE 2132215 542 negative negative
6. BE 2135863 594 negative negative
7. BE 2135616 584 negative negative

AMPHS timed study lot 610010307

Sample Confirmation 5 Minutes 30 Minutes

1. AMPHS 2129583 2453 Positive Positive
2. AMPHS 2131827 2417 Positive Positive
3. AMPHS 2133282 2548 Positive Positive
4. AMPHS 2134385 2029 Positive Positive
5. AMPHS 2131994 2056 Positive Positive
6. AMPHS 2148944 1933 Positive Positive
7. AMPHS 2132172 2719 Positive Positive

AMPHS timed study with lot 801122706

Sample Confirmation 5 Minutes 30 Minutes

1. AMPHS 2129583 amp 2453 negative negative
2. AMPHS 2131827 amp 2417 negative negative
3. AMPHS 2133282 amp 2548 negative negative
4. AMPHS 2134385 amp 2029 negative negative
5. AMPHS 2131994 amp 2056 negative negative
6. AMPHS 2148944 amp 1933 negative negative
7. AMPHS 2132172 amp 2719 negative negative

MAMP timed study 610010307

Sample Confirmation 5 minutes 30 Minutes

1. MAMP 2134918 2353 Positive Positive
2. MAMP 2135563 2293 Positive Positive
3. MAMP 2151242 1903 Positive Positive
4. MAMP 2132037 1491 Positive Positive
5. MAMP 2153642 5043 Positive Positive
6. MAMP 2131870 1132 Positive Positive

MAMP timed study with lot 801122706

Sample Confirmation 5 minutes 30 Minutes

1. MAMP 2134918 mamp 2353 negative negative
2. MAMP 2135563 mamp 2293 negative negative
3. MAMP 2151242 mamp 1903 negative negative
4. MAMP 2132037 mamp 1491 negative negative
5. MAMP 2153642 mamp 5043 negative negative
6. MAMP 3426136 mamp 1974 negative negative

OPI300 timed study

Sample Confirmation 5 Minutes 30 Minutes

1. 2131143 Mor 574 Positive OPI Positive OPI
2. 2130925 Mor 712 Positive OPI Positive OPI
3. 2131295 Mor 565 Positive OPI Positive OPI

4. 2139146 Mor 754 Positive OPI Positive OPI
5. 2178624 Mor 639 Positive OPI Positive OPI
6. 2206217 Mor 547 Positive OPI Positive OPI
7. 2206218 Mor 763 Positive OPI Positive OPI

Discussion

Both lots performed as expected in the timed trials with the negative lot.

The time trials for THC, BE, AMPHS, and MAMP with lot 610010307, tested as expected. The results were easy to read and did not change over time. The time trial for lot 801122706 tested as expected. The results were easy to read and did not change over time. The kits performed at an overall accuracy rate of 100% at both 5 and 30 minutes.

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