

# Independent studies verify the accuracy of DrugCheck®

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. Express Diagnostics, Int'l Inc. recently commissioned an independent study by Kroll to determine the specificity and accuracy duration of DrugCheck® test devices. The results are as follows:



## 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 OPI OPI OPI 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 OPI OPI OPI Specificity Lot 610010307

|    | Sample  | Screening              | Confirmed  | Result                                  |
|----|---------|------------------------|--|---|
| 1  | 1876939 | >10,000<br>165         | Cod =323<br>Mor = 5520<br>THC = 93                 | Positive<br>Positive THC                |
| 2  | 1877370 | 5205                   | Mor = 3562   | Positive                                |
| 3  | 1877553 | >10,000                | Cod = 2669<br>Mor = 620                            | Positive                                |
| 4  | 1877642 | 3680                   | Mor = 3562   | Positive                                |
| 5  | 1877657 | >10,000                | Mor = 473  | Positive                                |
| 6  | 1888935 | 2525                   | Cod = 275<br>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<br>Hymr = 1167                          | Positive                                |
| 13 | 1901302 | 5780<br>180            | Cod = 400<br>THC = 77                              | Positive<br>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<br>>500<br>603 | Cod = 1181<br>Mor = 340<br>THC = >2000<br>Be = 429 | Positive<br>Positive THC<br>Positive Be |

**PROP** PPX PPX PPX  
**Specificity 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 |

**Oxycodone** OXY OXY OXY  
**Specificity 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    |

**MAMP** MET MET MET  
**Specificity Lot 610010307**

|    | Sample  | Screening    | Confirmed                       | Result                      |
|----|---------|--------------|---------------------------------|-----------------------------|
| 1  | 1891978 | 2830         | Amp=>200<br>Mamp=1875           | Positive                    |
| 2  | 1901691 | 2805         | Amp=260<br>Mamp=1799            | Positive                    |
| 3  | 1893055 | 4985         | Amp=1163<br>Mamp=2827           | Positive                    |
| 4  | 1877191 | 11700        | Amp=20588<br>Mamp=1284          | Positive                    |
| 5  | 1891174 | 1051         | Amp>200<br>Mamp=598             | Positive                    |
| 6  | 203292  | >25000       | Amp=2794<br>Mamp=7842           | Positive                    |
| 7  | 203299  | 1718         | Amp=582<br>Mamp=521             | Positive                    |
| 8  | 1890564 | 2223         | Amp=365<br>Mamp=1021            | Positive                    |
| 9  | 1906326 | 1599         | Amp=357<br>Mamp=783             | Positive                    |
| 10 | 1891157 | 3615<br>>500 | Amp=768<br>Mamp=3128<br>THC=492 | Positive<br>Positive<br>THC |
| 11 | 1906355 | 2820         | Amp=813<br>Mamp=1649            | Positive                    |
| 12 | 1906619 | >25000       | Amp=19802<br>Mamp=>100000       | Positive                    |
| 13 | 1906785 | 3006         | Amp=284<br>Mamp=1489            | Positive                    |
| 14 | 1906819 | 2350         | Amp=1072<br>Mamp=1546           | Positive                    |
| 15 | 1891708 | 2130         | Amp=853<br>Mamp=1222            | Positive                    |
| 16 | 2049376 | 4565         | Amp=1085<br>Mamp=1277           | Positive                    |
| 17 | 2049837 | 3180         | Amp=342<br>Mamp=1264            | Positive                    |
| 18 | 2049880 | 2326         | Amp=433<br>Mamp=975             | Positive                    |
| 19 | 2050012 | 21085        | Amp=2231<br>Mamp=>10000         | Positive                    |
| 20 | 2050134 | 1291<br>492  | Amp>200<br>Mamp=853<br>Be=492   | Positive<br>Positive<br>Be  |
| 21 | 2050222 | 1752         | Amp=507<br>Mamp=1246            | Positive                    |
| 22 | 1904495 | >25000       | Amp=23931<br>Mamp=>100000       | Positive                    |

**MDN** MTD MTD MTD  
**Specificity 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 |

**BENZ** BZO BZO BZO  
**Specificity Lot 801122706**

| Sample      | Conformation | Conformation | Result   | Re-screen |
|-------------|--------------|--------------|----------|-----------|
| 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 |           |

\*\* 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** AMP AMP 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** THC THC 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** COC COC COC  
**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** PCP PCP PCP  
**Specificity Lot 610010307**

|    | Sample  | Screening            | Confirmed                            | Result   |
|----|---------|----------------------|--------------------------------------|----------|
| 1  | 216652  | 355<br>380           | PCP = 373<br>THC = 163               | Positive |
| 2  | 3229701 | 59<br>>500           | PCP = 51<br>THC = 317                | Positive |
| 3  | 3215326 | 236<br>87            | PCP = 324<br>THC = 41                | Positive |
| 4  | 3224207 | 405<br>455           | PCP = 359<br>THC = 272               | Positive |
| 5  | 3224898 | 188<br>215<br>>25000 | PCP = 201<br>THC = 110<br>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<br>>3000         | PCP = 229<br>Be = >3000              | Positive |
| 15 | PCP 3   | 11884<br>1380        | PCP = 97<br>THC = 1381               | Positive |
| 16 | PCP 4   | 229                  | PCP = 200                            | Positive |
| 17 | PCP 5   | 54<br>742            | PCP = 45<br>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 alpha-hydroxyalprazolam 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 percent. The performance on THC, Cocaine, PCP, Amphetamine, Methamphetamine and OPI2000 was 100 percent.** 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 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 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   |

## 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

### 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 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 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 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 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 lot 801122706

| 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 |

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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