

Clinical Performance (Accuracy Study) of the nal von minden Drug-Screen® Urine Rapid Tests

Specimen Correlation

The specimen correlation studies were performed on urine specimens. All specimens were confirmed either by GC/MS, LC/MS, HPLC or other rapid test as stated in the respective tables. Specimens were randomized and tested with the nal von minden Drug-Screen® Urine Rapid Tests according to the instructions. The results are summarized in the tables. Unless otherwise stated, identical results were obtained for strip and cassette format.

AMP1000

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 132 | 9 |
| - | 4 | 155 |

Positive agreement with GC/MS: $132/(132+4) = 97\%$

Negative agreement with GC/MS: $155/(155+9) = 95\%$

Total agreement with GC/MS: $(132+155)/(132+4+9+155) = 96\%$

AMP500

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 92 | 2 |
| - | 2 | 84 |

Positive agreement with GC/MS: $92/(92+2) = 98\%$

Negative agreement with GC/MS: $84/(84+2) = 98\%$

Total agreement with GC/MS: $(92+84)/(92+2+2+84) = 98\%$

AMP300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 73 | 4 |
| - | 3 | 70 |

Positive agreement with GC/MS: $73/(73+3) = 96\%$

Negative agreement with GC/MS: $70/(70+4) = 95\%$

Total agreement with GC/MS: $(73+70)/(73+3+4+70) = 95\%$

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

Tel.: +49 941 29010-0
Fax: +49 941 29010-50

info@nal-vonminden.com
www.nal-vonminden.com

Geschäftsführer:
Sandra von Minden
Roland Meißner
Thomas Zander

Registergericht Kleve:
HRB 5679
Steuer-Nr. 244/133/00130
UST-ID-Nr. DE 189 016 086

Sparkasse
Regensburg
Kto: 840 017 073
BLZ: 750 500 00

Deutsche Bank
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BLZ: 350 700 24

Schnelltests

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BAR300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 122 | 4 |
| - | 10 | 156 |

Positive agreement with GC/MS: $122/(122+10) = 92\%$

Negative agreement with GC/MS: $156/(156+4) = 98\%$

Total agreement with GC/MS: $(122+156)/(122+10+4+156) = 95\%$

BUP10

| Drug-Screen Test Panel | LC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 55 | 2 |
| - | 1 | 168 |

Positive agreement with LC/MS: $55/(55+1) = 98\%$

Negative agreement with LC/MS: $168/(168+2) = 99\%$

Total agreement with LC/MS: $(55+168)/(55+1+2+168) = 99\%$

BUP5

| Drug-Screen Test Panel | LC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 50 | 2 |
| - | 2 | 46 |

Positive agreement with LC/MS: $50/(50+2) = 96\%$

Negative agreement with LC/MS: $46/(46+2) = 96\%$

Total agreement with LC/MS: $(50+46)/(50+2+2+46) = 96\%$

BZD300 (strip)

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 131 | 8 |
| - | 4 | 157 |

Positive agreement with GC/MS: $131/(131+4) = 97\%$

Negative agreement with GC/MS: $157/(157+8) = 95\%$

Total agreement with GC/MS: $(131+157)/(131+4+8+157) = 96\%$

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

Tel.: +49 941 29010-0
Fax: +49 941 29010-50

info@nal-vonminden.com
www.nal-vonminden.com

Geschäftsführer:
Sandra von Minden
Roland Meißner
Thomas Zander

Registergericht Kleve:
HRB 5679
Steuer-Nr. 244/133/00130
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Sparkasse
Regensburg
Kto: 840 017 073
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BZD300 (cassette)

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 130 | 6 |
| - | 5 | 159 |

Positive agreement with GC/MS: $130/(130+5) = 96\%$

Negative agreement with GC/MS: $159/(159+6) = 96\%$

Total agreement with GC/MS: $(130+159)/(130+5+6+159) = 96\%$

BZD200

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 52 | 1 |
| - | 3 | 44 |

Positive agreement with GC/MS: $52/(52+3) = 95\%$

Negative agreement with GC/MS: $44/(44+1) = 98\%$

Total agreement with GC/MS: $(52+44)/(52+3+1+44) = 96\%$

BZD100

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 74 | 0 |
| - | 2 | 44 |

Positive agreement with GC/MS: $74/(74+2) = 97\%$

Negative agreement with GC/MS: $44/(44+0) = >99\%$

Total agreement with GC/MS: $(74+44)/(74+2+0+44) = 98\%$

COC300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 119 | 17 |
| - | 5 | 159 |

Positive agreement with GC/MS: $119/(119+5) = 96\%$

Negative agreement with GC/MS: $159/(159+17) = 90\%$

Total agreement with GC/MS: $(119+159)/(119+5+17+159) = 93\%$

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

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Regensburg
Kto: 840 017 073
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COC200 (strip)

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 60 | 3 |
| - | 5 | 52 |

Positive agreement with GC/MS: $60/(60+5) = 92\%$

Negative agreement with GC/MS: $52/(52+3) = 95\%$

Total agreement with GC/MS: $(60+52)/(60+5+3+52) = 93\%$

COC200 (cassette)

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 61 | 3 |
| - | 4 | 52 |

Positive agreement with GC/MS: $61/(61+4) = 94\%$

Negative agreement with GC/MS: $52/(52+3) = 95\%$

Total agreement with GC/MS: $(61+52)/(61+4+3+52) = 94\%$

COC100

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 56 | 2 |
| - | 4 | 48 |

Positive agreement with GC/MS: $56/(56+4) = 93\%$

Negative agreement with GC/MS: $48/(48+2) = 96\%$

Total agreement with GC/MS: $(56+48)/(56+4+2+48) = 95\%$

COT200

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 103 | 12 |
| - | 0 | 185 |

Positive agreement: $103/(103+0) = >99\%$

Negative agreement: $185/(185+12) = 94\%$

Total agreement with: $(103+185)/(103+0+12+185) = 96\%$

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Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

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EDDP100

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 135 | 5 |
| - | 5 | 155 |

Positive agreement with GC/MS: $135/(135+5) = 96\%$

Negative agreement with GC/MS: $155/(155+5) = 97\%$

Total agreement with GC/MS: $(135+155)/(135+5+155) = 97\%$

ETG500

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 50 | 9 |
| - | 4 | 57 |

Positive agreement with GC/MS: $50/(50+4) = 92.6\%$

Negative agreement with GC/MS: $57/(57+9) = 86.4\%$

Total agreement with GC/MS: $(50+57)/(50+4+9+57) = 89.2\%$

FYL10

| Drug-Screen Test Panel | Other FLY Rapid Test | |
|---------------------------|----------------------|-----|
| | | |
| | + | - |
| + | 124 | 0 |
| - | 0 | 161 |

Positive agreement with other rapid test: $124/(124+0) = >99\%$

Negative agreement with other rapid test: $161/(161+0) = >99\%$

Total agreement with other rapid test: $(124+161)/(124+0+161+0) = >99\%$

HRN10

| Drug-Screen Test Panel | LC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 153 | 2 |
| - | 2 | 128 |

Positive agreement with other rapid test: $153/(153+2) = 98.7\%$

Negative agreement with other rapid test: $128/(128+2) = 98.5\%$

Total agreement with other rapid test: $(153+128)/(153+2+128) = 98.6\%$

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

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info@nal-vonminden.com
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Geschäftsführer:
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Regensburg
Kto: 840 017 073
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Schnelltests

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K2 (Spice) 50

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 91 | 0 |
| - | 0 | 20 |

Positive agreement with GC/MS: $91/(91+0) = >99\%$

Negative agreement with GC/MS: $20/(20+0) = >99\%$

Total agreement with GC/MS: $(91+20)/(91+20+0+0) = >99\%$

KET1000

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 135 | 9 |
| - | 2 | 154 |

Positive agreement with GC/MS: $135/(135+2) = 99\%$

Negative agreement with GC/MS: $154/(154+9) = 94\%$

Total agreement with GC/MS: $(135+154)/(135+2+9+154) = 96\%$

LSD10

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 44 | 2 |
| - | 0 | 54 |

Positive agreement with GC/MS: $44/(44+2) = 95.6\%$

Negative agreement with GC/MS: $54/(54+0) = >99\%$

Total agreement with GC/MS: $(44+54)/(44+2+54+0) = 98\%$

MDA500

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 57 | 0 |
| - | 0 | 63 |

Positive agreement with GC/MS: $57/(57+0) = >99\%$

Negative agreement with GC/MS: $63/(63+0) = >99\%$

Total agreement with GC/MS: $(57+63)/(57+0+63+0) = >99\%$

MDMA/XTC500

| Drug-Screen | GC/MS |
|-------------|-------|
|-------------|-------|

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

Tel.: +49 941 29010-0
Fax: +49 941 29010-50

info@nal-vonminden.com
www.nal-vonminden.com

Geschäftsführer:
Sandra von Minden
Roland Meißner
Thomas Zander

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| Test Panel | | + | - |
|------------|---|----|-----|
| | + | 88 | 3 |
| | - | 0 | 149 |

Positive agreement with GC/MS: $88/(88+0) = >99\%$

Negative agreement with GC/MS: $149/(149+3) = 98\%$

Total agreement with GC/MS: $(88+149)/(88+0+3+149) = 99\%$

MDPV500

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | 48 |
| | - | 0 |
| | - | 66 |

Positive agreement with GC/MS: $48/(48+0) = >99\%$

Negative agreement with GC/MS: $66/(66+0) = >99\%$

Total agreement with GC/MS: $(48+66)/(48+0+66+0) = >99\%$

MET1000 (strip)

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | 135 |
| | - | 10 |
| | - | 1 |
| | - | 154 |

Positive agreement with GC/MS: $135/(135+1) = 99\%$

Negative agreement with GC/MS: $154/(154+10) = 94\%$

Total agreement with GC/MS: $(135+154)/(135+1+10+154) = 96\%$

MET1000 (cassette)

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | 135 |
| | - | 12 |
| | - | 1 |
| | - | 152 |

Positive agreement with GC/MS: $135/(135+1) = 99\%$

Negative agreement with GC/MS: $152/(152+12) = 93\%$

Total agreement with GC/MS: $(135+152)/(135+1+12+152) = 96\%$

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

Tel.: +49 941 29010-0
Fax: +49 941 29010-50

info@nal-vonminden.com
www.nal-vonminden.com

Geschäftsführer:
Sandra von Minden
Roland Meißner
Thomas Zander

Registergericht Kleve:
HRB 5679
Steuer-Nr. 244/133/00130
UST-ID-Nr. DE 189 016 086

Sparkasse
Regensburg
Kto: 840 017 073
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Schnelltests

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MET500

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 57 | 1 |
| - | 1 | 53 |

Positive agreement with GC/MS: $57/(57+1) = 98\%$

Negative agreement with GC/MS: $53/(53+1) = 98\%$

Total agreement with GC/MS: $(57+53)/(57+1+1+53) = 98\%$

MET300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 45 | 9 |
| - | 3 | 99 |

Positive agreement with GC/MS: $45/(45+3) = 94\%$

Negative agreement with GC/MS: $99/(99+9) = 92\%$

Total agreement with GC/MS: $(45+99)/(45+3+9+99) = 92\%$

MOR/OPI300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 141 | 9 |
| - | 0 | 150 |

Positive agreement with GC/MS: $141/(141+0) = >99\%$

Negative agreement with GC/MS: $150/(150+9) = 94\%$

Total agreement with GC/MS: $(141+150)/(141+0+9+150) = 97\%$

MOR/OPI100

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 37 | 2 |
| - | 1 | 60 |

Positive agreement with GC/MS: $37/(37+1) = 97\%$

Negative agreement with GC/MS: $60/(60+2) = 97\%$

Total agreement with GC/MS: $(37+60)/(37+1+2+60) = 97\%$

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

Tel.: +49 941 29010-0
Fax: +49 941 29010-50

info@nal-vonminden.com
www.nal-vonminden.com

Geschäftsführer:
Sandra von Minden
Roland Meißner
Thomas Zander

Registergericht Kleve:
HRB 5679
Steuer-Nr. 244/133/00130
UST-ID-Nr. DE 189 016 086

Sparkasse
Regensburg
Kto: 840 017 073
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Schnelltests

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MOR/OPI2000

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 134 | 16 |
| - | 0 | 150 |

Positive agreement with GC/MS: $134/(134+0) >99\%$

Negative agreement with GC/MS: $150/(150+16) = 90\%$

Total agreement with GC/MS: $(134+150)/(134+0+16+150) = 95\%$

MPD150

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 147 | 2 |
| - | 3 | 123 |

Positive agreement with GC/MS: $147/(147+3) = 98\%$

Negative agreement with GC/MS: $123/(123+2) = 98.4\%$

Total agreement with GC/MS: $(147+123)/(147+3+2+123) = 98.2\%$

MQL300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 133 | 6 |
| - | 4 | 157 |

Positive agreement with GC/MS: $133/(133+4) = 97\%$

Negative agreement with GC/MS: $157/(157+6) = 96\%$

Total agreement with GC/MS: $(133+157)/(133+4+6+157) = 97\%$

MTD300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 122 | 10 |
| - | 1 | 167 |

Positive agreement with GC/MS: $122/(122+1) = 99\%$

Negative agreement with GC/MS: $167/(167+10) = 94\%$

Total agreement with GC/MS: $(122+167)/(122+1+10+167) = 96\%$

OPI

see MOR

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

Tel.: +49 941 29010-0
Fax: +49 941 29010-50

info@nal-vonminden.com
www.nal-vonminden.com

Geschäftsführer:
Sandra von Minden
Roland Meißner
Thomas Zander

Registergericht Kleve:
HRB 5679
Steuer-Nr. 244/133/00130
UST-ID-Nr. DE 189 016 086

Sparkasse
Regensburg
Kto: 840 017 073
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BLZ: 350 700 24

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OXY100

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 137 | 5 |
| - | 3 | 155 |

Positive agreement with GC/MS: $137/(137+3) = 98\%$

Negative agreement with GC/MS: $155/(155+5) = 97\%$

Total agreement with GC/MS: $(137+155)/(137+3+5+155) = 97\%$

PCM5000

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 150 | 0 |
| - | 6 | 164 |

Positive agreement with GC/MS: $150/(150+6) = 96.1\%$

Negative agreement with GC/MS: $164/(164+0) = >99\%$

Total agreement with GC/MS: $(150+164)/(150+6+164+0) = 98.1\%$

PCP25

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 50 | 5 |
| - | 0 | 157 |

Positive agreement with GC/MS: $50/(50+0) > 99\%$

Negative agreement with GC/MS: $159/(157+5) = 97\%$

Total agreement with GC/MS: $(50+157)/(50+0+5+157) = 98\%$

PGB500

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 74 | 0 |
| - | 0 | 79 |

Positive agreement with GC/MS: $74/(74+0) = >99\%$

Negative agreement with GC/MS: $79/(79+0) = >99\%$

Total agreement with GC/MS: $(74+79)/(74+0+79+0) = >99\%$

nal von minden GmbH

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47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
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Regensburg
Kto: 840 017 073
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PPX300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 122 | 10 |
| - | 1 | 167 |

Positive agreement with GC/MS: $122/(122+1) = 99\%$

Negative agreement with GC/MS: $167/(167+10) = 94\%$

Total agreement with GC/MS: $(122+167)/(122+1+10+167) = 96\%$

Spice50**K2 (Spice) 50****TCA1000**

| Drug-Screen Test Panel | HPLC | |
|---------------------------|------|-----|
| | | |
| | + | - |
| + | 35 | 20 |
| - | 0 | 167 |

Positive agreement with HPLC: $35/(35+0) > 99\%$

Negative agreement with HPLC: $167/(167+20) = 94\%$

Total agreement with HPLC: $(35+167)/(35+0+20+167) = 95\%$

THC25

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 119 | 22 |
| - | 3 | 156 |

Positive agreement with GC/MS: $119/(119+3) = 98\%$

Negative agreement with GC/MS: $156/(156+22) = 88\%$

Total agreement with GC/MS: $(119+156)/(119+3+22+156) = 92\%$

THC50

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 64 | 0 |
| - | 0 | 56 |

Positive agreement with GC/MS: $64/(64+0) = >99\%$

Negative agreement with GC/MS: $56/(56+0) = >99\%$

Total agreement with GC/MS: $(64+56)/(64+56+0+0) = >99\%$

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47445 Moers
Deutschland

Friedenstraße 32
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Kto: 840 017 073
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Deutsche Bank
Kto: 056 998 800
BLZ: 350 700 24

Schnelltests

Labordiagnostika

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THC150

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 118 | 22 |
| - | 4 | 156 |

Positive agreement with GC/MS: $118/(118+4) = 97\%$

Negative agreement with GC/MS: $156/(156+22) = 88\%$

Total agreement with GC/MS: $(118+156)/(118+4+22+156) = 91\%$

THC200

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 49 | 0 |
| - | 2 | 54 |

Positive agreement with GC/MS: $49/(49+2) = 96.1\%$

Negative agreement with GC/MS: $54/(54+0) = >99\%$

Total agreement with GC/MS: $(49+54)/(49+54+2+0) = 98.1\%$

TIL300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 74 | 2 |
| - | 2 | 77 |

Positive agreement with GC/MS: $74/(74+2) = 97.4\%$

Negative agreement with GC/MS: $77/(77+2) = 97.5\%$

Total agreement with GC/MS: $(74+77)/(74+2+77+2) = 97.4\%$

TML100

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|-----|
| | | |
| | + | - |
| + | 136 | 4 |
| - | 4 | 156 |

Positive agreement with GC/MS: $136/(136+4) = 97\%$

Negative agreement with GC/MS: $156/(156+4) = 98\%$

Total agreement with GC/MS: $(136+156)/(136+4+4+156) = 97\%$

nal von minden GmbH

Carl-Zeiss-Straße 12
47445 Moers
Deutschland

Friedenstraße 32
93053 Regensburg
Deutschland

Tel.: +49 941 29010-0
Fax: +49 941 29010-50

info@nal-vonminden.com
www.nal-vonminden.com

Geschäftsführer:
Sandra von Minden
Roland Meißner
Thomas Zander

Registergericht Kleve:
HRB 5679
Steuer-Nr. 244/133/00130
UST-ID-Nr. DE 189 016 086

Sparkasse
Regensburg
Kto: 840 017 073
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TZD25

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 60 | 0 |
| - | 1 | 49 |

Positive agreement with GC/MS: $60/(60+1) = 98.3\%$

Negative agreement with GC/MS: $49/(49+0) = >99\%$

Total agreement with GC/MS: $(60+49)/(60+1+49+0) = 99.1\%$

ZAL100

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 58 | 0 |
| - | 1 | 61 |

Positive agreement with GC/MS: $58/(58+0) = >99\%$

Negative agreement with GC/MS: $61/(61+0) = >99\%$

Total agreement with GC/MS: $(58+61)/(58+1+61+0) = >99\%$

ZOP300

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 39 | 0 |
| - | 0 | 40 |

Positive agreement with GC/MS: $39/(39+1) = 97.5\%$

Negative agreement with GC/MS: $40/(40+0) = >99.9\%$

Total agreement with GC/MS: $(39+40)/(39+1+0+40) = 98.8\%$

ZOL25

| Drug-Screen Test Panel | GC/MS | |
|---------------------------|-------|----|
| | | |
| | + | - |
| + | 49 | 1 |
| - | 1 | 47 |

Positive agreement with GC/MS: $49/(49+1) = 98.0\%$

Negative agreement with GC/MS: $47/(47+1) = 97.9\%$

Total agreement with GC/MS: $(49+47)/(49+1+47+1) = 97.9\%$

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47445 Moers
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93053 Regensburg
Deutschland

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