

S12 Appendix. Mini-lab thin layer chromatography kit results

Table S12 A. Mini-lab thin layer chromatography kit detailed performance breakdown 1

Table S12 B. Mini-lab thin layer chromatography kit evaluation summary. 2

Table S12 A. Mini-lab thin layer chromatography kit detailed performance breakdown

<u>Samples</u>	Good-quality samples available for specificity calculation: n=24			
	<u>0% API and wrong API samples</u> <u>(n=53)</u>		<u>50% and 80%</u> <u>API samples</u> <u>(n=42)</u>	<u>All poor quality</u> <u>samples</u> <u>(n=95)</u>
	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Sensitivity (95% CI)
<i>Total, not through packaging (n=119)</i>	100 (93.3-100)	100 (85.8-100)	59.5 (43.3-74.4)	82.1 (72.9-89.2)
<i>Antimalarials (n=51)</i>	100 (87.7-100)	100 (47.8-100)	66.7 (41-86.7)	87 (73.7-95.1)
AL (n=24)	100 (79.4-100)	100 (15.8-100)	66.7 (22.3-95.7)	90.9 (70.8-98.9)
ART (n=14)	100 (54.1-100)	100 (15.8-100)	83.3 (35.9-99.6)	91.7 (61.5-99.8)
DHAP (n=13)	100 (54.1-100)	100 (2.5-100)	50 (11.8-88.2)	75 (42.8-94.5)
<i>Antibiotics (n=68)</i>	100 (86.3-100)	100 (82.4-100)	54.2 (32.8-74.4)	77.6 (63.4-88.2)
ACA (n=15)	100 (54.1-100)	100 (29.2-100)	83.3 (35.9-99.6)	91.7 (61.5-99.8)
AZITH (n=16)	100 (54.1-100)	100 (39.8-100)	33.3 (4.3-77.7)	66.7 (34.9-90.1)
OFLO (n=19)	100 (54.1-100)	100 (59-100)	50 (11.8-88.2)	75 (42.8-94.5)
SMTM (n=18)	100 (59-100)	100 (47.8-100)	50 (11.8-88.2)	76.9 (46.2-95)

Table S12 B. Mini-lab thin layer chromatography kit evaluation summary.

	<i>Samples</i>	<i>Sensitivity (95% CI)*</i>	<i>Specificity (95% CI)*</i>	<i>Comments</i>
Sensitivity and Specificity Results	<i>0% and wrong API</i>	100 (93.3-100)	100 (85.8-100)	N/A
	<i>50% and 80% API†</i>	59.5 (43.3-74.4)		
	<i>All poor quality samples</i>	82.1 (72.9-89.2)		
Strengths and Limitations	<p><i>Strengths:</i> -High accuracy to identify samples with no or wrong API. -Good sensitivity in identifying 50% API samples.</p> <p><i>Limitations:</i> -Most 80% API samples incorrectly identified as genuine. -Only three 80% API samples correctly identified as failing.†</p>			
User Satisfaction	<p><i>Plus:</i> All equipment necessary provided; well described, detailed and illustrated protocols; mains electricity not required.</p> <p><i>Minus:</i> Safety hazards and waste needed because of chemical reagents; destroys sample; large and heavy; sample testing requires a relatively long time.</p>			
Comparative Evaluation	<p>-No significant differences in sensitivity compared to other devices to identify 0% and wrong API samples. Higher specificity than the C-Vue liquid chromatograph. -Longest total time per sample compared to other devices. -Several samples of the same API can be run simultaneously.</p>			

* Sensitivity and specificity for quality assessment of the dosage unit not through the packaging.

† Because TLC experiments of the samples tested are run together with 80% and 100% API reference standard solutions, the Mini-lab TLC methods allow a range of 80 to 100 % API as the lower and higher acceptable limits. These results should be thus interpreted with caution.