

S26 Appendix. QDa mass spectrometer results

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Table S26 A. QDa mass spectrometer detailed performance breakdown.

<u>Samples</u>	Good quality samples available for specificity calculation: n=24			
	<u>0% and wrong API samples (n=19)</u>		<u>50% and 80% API samples (n=18)</u>	<u>All poor quality samples (n=37)</u>
	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Sensitivity (95% CI)
<i>Total, not through packaging (n=105)</i>	100 (93.3-100)	91.7 (73.0-99.0)	100 (91.6-100)	100 (96.2-100)
<i>Antimalarials (n=51)</i>	100 (87.7-100)	80.0 (28.4-99.5)	100 (81.5-100)	100 (92.3-100)
AMLN (n=24)	100 (79.4-100)	100 (15.8-100)	100 (54.1-100)	100 (84.6-100)
ART (n=14)	100 (54.1-100)	50 (1.3-98.7)	100 (54.1-100)	100 (73.5-100)
DHAP (n=13)	100 (54.1-100)	100 (2.5-100)	100 (54.1-100)	100 (73.5-100)
<i>Antibiotics (n=68)</i>	100 (86.3-100)	94.7 (74-99.9)	100 (85.8-100)	100 (92.7-100)
ACA (n=15)	100 (54.1-100)	100 (29.2-100)	100 (54.1-100)	100 (73.5-100)
AZITH (n=16)	100 (54.1-100)	100 (39.8-100)	100 (54.1-100)	100 (73.5-100)
OFLO (n=19)	100 (54.1-100)	85.7 (42.1-99.6)	100 (54.1-100)	100 (73.5-100)
SMTM (n=18)	100 (59.0-100)	100 (47.8-100)	100 (54.1-100)	100 (75.3-100)

Table S26 B. QDa mass spectrometer evaluation summary.

	<u>Samples</u>	<u>Sensitivity</u> <u>(95% CI)*</u>	<u>Specificity</u> <u>(95% CI)*</u>	<u>Comments</u>
Sensitivity and Specificity Results	<i>0% and wrong API</i>	100 (93.3-100)	91.7 (73.0-99.0)	N/A
	<i>50% and 80% API</i>	100 (91.6-100)		
	<i>All poor-quality samples</i>	100 (96.2-100)		
Strengths and Limitations	<p><i>Strengths:</i></p> <ul style="list-style-type: none"> -High accuracy in identifying samples with no or wrong API. - Correct identification of all 50% and 80% API medicines, with possibility of quantitation of API. <p><i>Limitations:</i></p> <ul style="list-style-type: none"> -Many consumable requirements include the need for a nitrogen-gas source. -Sample preparation required to obtain concentrations dilute enough to be within the quantitative range of the instrument. -Higher complexity and higher cost instrument. 			
User Satisfaction	<p><i>Plus:</i></p> <p>Highest sensitivity and specificity quantitative instrument tested with many other types of experiments possible.</p> <p><i>Minus:</i></p> <p>Intensive operation and set-up; chemicals and gases required; requires more experienced users.</p>			
Comparative Evaluation	<p>No significant differences in sensitivity compared to other devices to identify 0% and wrong API samples and lower specificity than all other devices except the C-Vue.</p>			

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