**S23 Appendix. Truscan RM Raman spectrometer results**



**Table S23 A. Truscan RM Raman spectrometer detailed performance breakdown.**

| | **Good quality samples available for specificity calculation: n=22** | | | |
|---|---|---|---|---|
| | **0% and wrong API samples (n=47)** | | **50% and 80% API samples (n=36)** | **All poor quality samples (n=83)** |
| **Samples** | **Sensitivity (95% CI)** | **Specificity (95% CI)** | **Sensitivity (95% CI)** | **Sensitivity (95% CI)** |
| ***Total, not through packaging (n=105)*** | 100 (92.5-100) | 100 (84.6-100) | 22.2 (10.1-39.2) | 66.3 (55.1-76.3) |
| ***Antimalarials (n=37)*** | 100 (84.6-100) | 100 (29.2-100) | 41.7 (15.2-72.3) | 79.4 (62.1-91.3) |
| AL (n=24) | 100 (79.4-100) | 100 (15.8-100) | 0 (0-45.9) | 72.7 (49.8-89.3) |
| ART (n=0)* | N/A | N/A | N/A | N/A |
| DHAP (n=13) | 100 (54.1-100) | 100 (2.5-100) | 83.3 (35.9-99.6) | 91.7 (61.5-99.8) |
| ***Antibiotics (n=68)*** | 100 (86.3-100) | 100 (82.4-100) | 12.5 (2.7-32.4) | 57.1 (42.2-71.2) |
| ACA (n=15) | 100 (54.1-100) | 100 (29.2-100) | 0 (0-45.9) | 50 (21.1-78.9) |
| AZITH (n=16) | 100 (54.1-100) | 100 (39.8-100) | 50 (11.8-88.2) | 75 (42.8-94.5) |
| OFLO (n=19) | 100 (54.1-100) | 100 (59-100) | 0 (0-45.9) | 50 (21.1-78.9) |
| SMTM (n=18) | 100 (59-100) | 100 (47.8-100) | 0 (0-45.9) | 53.8 (25.1-80.8) |

| | **Good quality samples available for specificity calculation: n=2** | | | |
|---|---|---|---|---|
| | **0% and wrong API samples (n=10)** | | **50% and 80% API samples (n=0)** | **All poor quality samples (n=10)** |
| **Samples** | **Sensitivity (95% CI)** | **Specificity (95% CI)** | **Sensitivity (95% CI)** | **Sensitivity (95% CI)** |
| ***Total, through packaging (n=12)†*** | 100 (69.2-100) | 100 (15.8-100) | N/A | 100 (69.2-100) |

| | **Good quality samples available for specificity calculation: n=1** | | | |
|---|---|---|---|---|
| | **0% and wrong API samples (n=6)** | | **50% and 80% API samples (n=6)** | **All poor quality samples (n=12)** |
| **Samples** | **Sensitivity (95% CI)** | **Specificity (95% CI)** | **Sensitivity (95% CI)** | **Sensitivity (95% CI)** |
| ***Total, through replacement packaging (n=13)‡*** | 100 (54.1-100) | 100 (2.5-100) | 33.3 (4.3-77.7) | 66.7 (34.9-90.1) |

* Not applicable – insufficient amount of powder (60 mg) to be tested directly with the device - ART samples were thus scanned through replacement packaging;
† Packaging available with medicine (blister or glass vial for one field collected ART sample) ;
‡ Insufficient genuine parenteral artesunate vials were available for testing and therefore borosilicate replacement vials were used.

**Table S23 B. Truscan RM Raman spectrometer evaluation summary.**

| | *Samples* | *Sensitivity (95% CI)** | *Specificity (95% CI)** | *Comments* |
|---|---|---|---|---|
| **Sensitivity and Specificity Results** | *0% and wrong API* | 100 (92.5-100) | 100 (84.6-100) | Developing API-specific algorithms could improve device performance to identify poor quality medicines with low API. |
| | *50% and 80% API*[†] | 22.2 (10.1-39.2) | | |
| | *All poor quality samples* | 66.3 (55.1-76.3) | | |
| **Strengths and Limitations** | *Strengths:*<br>-High accuracy in identifying samples with no or wrong API.<br>-Good performance through packaging (except through glass vial for ART samples) for 0% and wrong API identification.<br>-Good performance to identify 80% API DHAP samples.[†]<br><br>*Limitations:*<br>-Poor sensitivity to identify 50% API samples (except AZITH samples, 2 of the 3 DHAP and 2 of the 3 ART samples).[†]<br>-Poor sensitivity to identify 80% API (except DHAP samples).[†] | | | |
| **User Satisfaction** | *Plus:*<br>Several batches of the same reference sample can be added to the reference library to consider variability; easy to use for end user, step-by-step screen instructions; when sample fails to match the selected reference library spectrum, the whole library of spectra is searched by the device looking for the closest match; computer not needed for field-testing.<br><br>*Minus:*<br>Reference library creation cannot be accomplished to the device itself; initial set-up of master computer and software packages difficult, requiring IT skills; difficulties to scroll down with buttons when looking for the reference library; tablet holder not adapted to larger or smaller sized tablets; | | | |
| **Comparative Evaluation** | -No significant differences in sensitivity compared to other devices to identify 0% and wrong API samples; higher specificity than the C-Vue liquid chromatograph.<br>-Same total time per sample as Progeny spectrometer but slower than the NIRscan spectrometer (faster than 4500a FTIR spectrometer). | | | |

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

[†] Algorithms should be developed on an API basis to enhance detection of lower API samples (this was not performed in the present study; therefore, these results should be interpreted with caution)