Introduction and study aims

The UK launch of the Quantum Diagnostics Six Test Rapid-Tox™ and Single Test Rapid-Tox™ heralded one of the first urine drug tests of abuse point-of-care devices (POCD) to include buprenorphine both in combination and in single drug form. With increasing use of POCD by drug treatment centres, our objective was to compare the performance of these devices against our routine buprenorphine method (Cozart™ ELISA). We assessed sensitivity and specificity above and below the 5.0 µg/L cut-off as well as the potential cross reaction with dihydrocodeine which has previously been identified as a potential interference with the antibody based Microgenics CEDIA™ method.

Method: sensitivity, specificity assessment and patient numbers

To assess the sensitivity of the Single Test Rapid-Tox™ we tested patient urine samples (n=24, range 0-10 µg/L by Cozart™) selected around the UKNEQAS cut-off (5.0 µg/L) for workplace and clinical drug testing. It is of note that the crossreactivity in the Cozart™ assay is 1% for norbuprenorphine but is not stated for the Single Test Rapid-Tox™.

Results: sensitivity and specificity

There were n=7 true negatives, n=16 true positives, n=1 false negative and no false positives using the 5.0 µg/L cut-off for the Single Test Rapid-Tox™. This gave a sensitivity of 94% and specificity of 100%. The Single Test Rapid-Tox™ performed well and is probably more sensitive than Quantum Diagnostics’ stated cut-off of 10.0 µg/L.

Method and Results: potential dihydrocodeine interference

Method. To assess the potential dihydrocodeine crossreactivity of the Six Test Rapid-Tox™, we tested positive and negative patient samples (n=27 by Cozart™) which were confirmed positive or negative for dihydrocodeine by TLC and GCMS (LOD 1.0 µg/L).

Results. There were: n=17 true negatives, n=4 true positives, n=1 false negative and n=5 false positives using the 5.0 µg/L cut-off. The Six Test Rapid-Tox™ gave good overall agreement with the Cozart™ ELISA with a sensitivity of 80% (increasing to 90% at 1.0 µg/L) and a specificity of 77%, all discrepancies being around the Cozart™ cut-off. The specificity of the Six Test Rapid-Tox™ increased to 95% by reducing the sensitivity to 1.0 µg/L and consequently one false positive. Detailed examination of the 5 false positives showed that the Cozart™ values of 2.3, 3.1, 2.1, 3.4 and 1.0 µg/L confirmed that the Six Test Rapid-Tox™ was more sensitive than the manufacturer’s stated cut-off of 10 µg/L.

Conclusions and observations

Both the Quantum Diagnostics Six Test Rapid-Tox™ and Single Test Rapid-Tox™ performed well and the latter is probably more sensitive than the manufacturer’s stated cut-off of 10.0 µg/L.

References

2. Quantum Diagnostics Ltd, Meridian Business Park, Fleming Road, Waltham Abbey, Essex, EN9 3BZ