A COMPARISON BETWEEN THE *COZART*™ ELISA AND THE *QUANTUM DIAGNOSTICS*™ POINT OF CARE DEVICE FOR BUPRENORPHINE

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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 drugs 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 concentration 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[3].

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

Quantum Diagnostics Six Test Rapid-Tox™ (currently renamed QD E-Z Split Key Cup) tested with the AMP/BUP/BZO/COC /MTD/MOP combination

Quantum Diagnostics Single Test Rapid-Tox™ (currently renamed QD Single Drug Cassette) tested with Buprenorphine 10 µg/mL combination

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

3. Bottcher M and Beck O. *Evaluation of Buprenorphine CEDIA Assay versus GC-MS and ELISA using Urine samples from Patients in Substitution Treatment*. Journal of Analytical Toxicology 2005; **29**