POSTER

Precision and Comparability of Abuscreen OnLine Assays for Drugs of Abuse Screening in Urine on Hitachi 917 with other Immunochemical Tests and with GC/MS

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SUMMARY

Abuscreen OnLine assays for drugs of abuse screening in urine have recently been developed for use on Hitachi 917 analyzers (Roche Diagnostics GmbH). The assays are based on the kinetic interaction of microparticles as measured by changes in light transmission. Drug in a sample inhibits the formation of particle aggregates and diminishes absorbance change increases. It was the goal of this study to evaluate precision and comparability of the new assays with CEDIA drugs of abuse tests on Hitachi 917 in different laboratories (three European and three US). The assays were calibrated in the nonlinear mode with four to six standards (semiquantitative application). Initial within-run (21 replicates, four labs) and between-day (10 days, two labs) imprecision studies using Abuscreen OnLine tests and commercial negative (0.5 x cut-off) and positive (1.5 x cut-off) controls revealed the following median CVs [within-run neg./pos. control/between-day neg./pos. control]: amphetamines 1.9/1.3/3.4/2.4, barbiturates 3.0/1.6/3.9/3.1, benzodiazepines 4.7/1.5/3.0/3.0, cocaine metabolite 1.8/0.9/2.4/1.7, methadone 5.4/1.6/5.5/2.2, opiates 5.5/2.1/5.3/2.7, THC 8.9/9.0/21.8/12.1. CVs < 10% were obtained for the THC test using controls with concentrations closer to the cut-off. An identical set of 170 GC/MS analyzed urine samples was distributed to the six laboratories and measured with Abuscreen OnLine tests on Hitachi 917. The median values for each individual sample were calculated and compared with the results obtained on individual Hitachi 917 analyzers by Passing-Bablok regression analysis. A good agreement between the laboratories was found with less than ± 11% slope deviation and intercepts below 7% of the cut-off except for benzodiazepines (one slope 17%, one slope - 26%) and THC (one slope 34%, one slope - 18%). The comparability with CEDIA tests was analyzed by concordance plots using randomized routine samples in three laboratories. The following results were obtained in one of the participating laboratories [cut-off ng/mL] (No. of positive/negative/discrepant samples): amphetamines [500] 2/14/7/0, barbiturates [200] 1/14/6/0, benzodiazepines [100] 52/41/7, cocaine metabolite [300] 17/12/3/0, methadone [300] 113/34/2, opiates [300] 31/114/4, THC [50] 66/81/2. GC/MS was performed for clarification of the discrepant results. In summary, Abuscreen OnLine tests on Hitachi 917 give precise results which compare well when analyzed in different laboratories. They can be rated as convenient and flexible methods for drugs of abuse screening in the routine. (Clin. Lab. 2000;46:49-52)