

EVALUATION OF THE KONELAB 20XTi CLINICAL CHEMISTRY ANALYZER – AMPHETAMINES, CANNABINOIDS AND BENZODIAZEPINES IN URINE

Halonen T (1), Porkkala-Sarataho E (1), Lampinen H (2), Kurki M (2).

(1) Kuopio University Hospital, Department of Clinical Chemistry, Kuopio, Finland.

(2) Thermo Electron Corporation, Vantaa, Finland.

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INTRODUCTION

The Konelab 20XTi analyzer (Thermo Electron Corp., Finland) is a new flexible, fully automated, discrete, and selective clinical chemistry analyzer designed for small and medium size routine and special clinical chemistry laboratories. Konelab 20XTi is a complete system including optimized system reagents for routine clinical chemistry tests, specific proteins, therapeutic drugs and abused drugs as well system specified calibrators and controls. For electrolyte tests ISE technique is used.

The aim of the study was to evaluate the performance of the Konelab 20XTi clinical chemistry analyzer in three drug of abuse tests in urine: amphetamines (AMP), cannabinoids (THC), and benzodiazepines (BZO), and to compare the results with those measured by the Konelab 60i analyzer.

MATERIALS AND METHODS

Instruments

Konelab 20XTi, Thermo Electron Corporation, Vantaa, Finland
Konelab 60i, Thermo Electron Corporation, Vantaa Finland

Reagents

Kits for the qualitative or semiquantitative measurement of urinary abused drugs in Konelab 20XT, 30 and 60 analyzers:

Konelab™ AMPHETAMINES (REF 981629)

Konelab™ CANNABINOIDS (REF 981620)

Konelab™ BENZODIAZEPINES (REF 981622)

Methods

Kits for the analysis of abused drugs on Konelab analyzers are based on semiquantitative homogenous enzyme immunoassay principle. In the assay the drug-labeled enzyme, glucose-6-phosphate dehydrogenase (G_6PDH) and the free drug from the urine sample compete for the fixed amount of specific antibody binding sites. In the absence of free drug from sample, the specific antibody binds the drug-labeled G_6PDH and thus the enzyme is inhibited. There is a direct relationship between the drug concentration and the enzyme activity. The enzyme G_6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert NAD to NADH.

Samples

For the comparison of the Konelab 20XTi analyzer with the Konelab 60i analyzer, 78, 80 or 77 samples were chosen for analysis of amphetamines (AMP), cannabinoids (THC) and benzodiazepines (BZO), respectively. The samples were analyzed simultaneously in both analyzers. Cut-off values of the Konelab kits for AMP, THC and BZO are shown in the Table 1. Negative and positive quality controls [Konelab™ REF 981728 (AMP and BZO), Konelab™ REF 981744 (THC), and high positive serum pools AMP, THC, BZO)] (Table 1) were used in every run in order to evaluate within-run and between-days and total variations (CV%, range from 3 controls during 12-13 days, 2 runs a day with 2 replicates).

Table 1. The cut-off values, and the concentrations of negative and positive controls in the study

DRUG	CUT-OFF (µg/l)	NEGATIVE CONTROL (µg/l)	POSITIVE CONTROL I (µg/l)	POSITIVE CONTROL II (µg/l)
AMP	1000	750	1250	4400
THC	50	40	60	100
BZO	200	150	300	4900

RESULTS

Variations

Within-run, between-run and total coefficient of variation (CV%) near the cut-off values (negative control and positive control I) are shown in the Table 2.

Table 2. Coefficient variations of the Konelab 20XTi analyzer

DRUG	WITHIN-RUN (CV %)	BETWEEN-DAYS (CV %)	TOTAL (CV %)
AMP	1.5 – 2.5	4.3 – 4.6	5.1 – 5.5
THC	1.2 – 2.1	3.8 – 5.1	4.7 – 5.5
BZO	5.0 – 6.4	6.3 – 8.9	8.2 – 12.9

Correlation study of Amphetamines (n=78)

Correlation study from the urine samples showed excellent agreement (Table 3). Only exception was one sample near the cut-off limit (1000 µg/l) that was positive in the Konelab 60i but negative in the Konelab 20XTi (1195 µg/l in the Konelab 60i vs. 862 µg/l in the Konelab 20XTi).

Table 3. Amphetamine assay: correlation study with Konelab 60i

Konelab 20XTi	Konelab 60i			Total
	+	-		
+	35	0		35
-	1	42		43
Total	36	42		76

Correlation study of Cannabinoids (n=80)

Correlation study from the urine samples showed excellent agreement (Table 4). Only exception was one sample near the cut-off limit (50 µg/l) that was positive in the Konelab 60i but negative in the Konelab 20XTi (50 µg/l in the Konelab 60i vs. 45 µg/l in the Konelab 20XTi).

Table 4. Cannabinoid assay: correlation study with Konelab 60i

Konelab 20XTi	Konelab 60i			Total
	+	-		
+	33	0		33
-	1	46		47
Total	34	46		80

Correlation study of Benzodiazepines (n=77)

Correlation study from the urine samples showed also excellent agreement (Table 5). Only exception was one sample near the cut-off limit (200 µg/l) that was positive in the Konelab 20XTi but negative in the Konelab 60i (272 µg/l in the Konelab 20XTi vs. 169 µg/l in the Konelab 60i).

Table 5. Benzodiazepine assay: correlation study with Konelab 60i

Konelab 20XTi	Konelab 60i			Total
	+	-		
+	43	1		44
-	0	33		33
Total	43	34		77

CONCLUSIONS

1. The precision of the Konelab 20XTi methods for abused drugs was good near the cut-off values.
2. The AMP, THC and BZO results measured by the Konelab 20XTi analyzer were in excellent correlation with those measured by the Konelab 60i analyzer.
3. The Konelab 20XTi offers a convenient and reliable choice for measurement of abused drugs in small or medium size laboratories.

