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TDM 및 남용약물검사 신빙도조사 결과보고(2009)

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Annual Report on External Quality Assessment in Therapeutic Drug Monitoring and Drug of Abuse in Korea (2009)

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We performed two trials of external quality assessment for Therapeutic Drug Monitoring (TDM) subcommittee of Korean Association of Quality Assurance for Clinical Laboratory (KAQACL) in 2009. The number of participating laboratories were 110, which is similar with that of previous 3 years. Average response rates were 97.8% in both trials, similar to those of previous years. Two kinds of control materials were requested to be tested in each trial so that each institution could find the possible systematic errors. The average drug item responded was 6.2 per institution, which was decreased slightly from 6.5 in recent 5 years. The most common test items were valproic acid, digoxin, carbamazepine, phenytoin, and theophylline which were peformed in more than 63.8% of participating laboratories, followed by phenobarbital, cyclosporine, tacrolimus, vancomycin, lithium, methotrexate, amikacin, gentamicin, acetaminophen, tobramycin, salicylate, free phenytoin, amitryptyline, ethosuximide, and primidone. The widely used TDM analyzers were Abbott AxSym (26.9%), followed by Abbott TDx/TDxFLx (24.8%), Roche Cobas Integra (15.1%), Siemens Diagnostics Viva-E (5.5%), Roche cobas c501 (5.1%), Siemens Diagnostics Dimension (3.4%), and many other analyzers. The inter-laboratory coefficients of variations showed similar tendency comparing with those of the previous years. The number of participating laboratories for drug of abuse (DOA) tests were 19, which was slightly increased compared to that of the previous year. Average DOA items were 3.8~4.2. We found the good performance of participating laboratories for DOA. In conclusion, the TDM and DOA external quality assessment of 2009 showed similar performance comparing with that of the recent 3 years.

Key Words : Quality assurance, External quality assessment, Therapeutic drug monitoring

서 론

대한임상검사정도관리협회 TDM분과위원회에서 1995년도부터 시작된 혈중 약물농도검사에 대한 신빙도 조사를 시작하여 첫 보고[1] 이후 2008년으로 14년의 역사가 되었다. 2007년부터 시작된[2] 약물남용검사 신빙도 조사는 3

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년째가 된다.

재료 및 방법

1. 관리물질

제1회 차에는 2009년 6월 7일에 TDM검사 인혈청(人血淸) 정도관리물질인 Lyphocheck® TDM Control (Bio-Rad Laboratories, Hercules, CA, USA) Level 1 (09-01) 및 Level 2 (09-02)의 두 종류의 물질을 총 112개 참여 기관에 발송하였다. 같은 날에 전혈(全血) 정도관리물질인 Lyphocheck® whole blood control (Bio-Rad Laboratories, Hercules, CA, USA) Level 1 (09-01WB) 및 Level 2 (09-02WB) 의 두 종류의 물질을 Cyclosporine 또는 Tacrolimus 검사를 시행하는 총 57개 기관을 대상으로 발송하였다. 그리고 약물남용 정도관리물질인 Liquicheck Qualitative Urine Toxicology Control (Bio-Rad Laboratories, Hercules, CA, USA) Negative (09-01Urine) 및 Positive (09-02Urine) 의 두 종류의 물질을 21개 기관에 발송하였다. 제2회 차에는 2009년 10월 20일에 TDM검사 정도관리물질 Lyphocheck® TDM Control (Bio-Rad Laboratories, Hercules, CA, USA) Level 2 (09-03) 및 Level 3 (09-04) 의 두 종류의 물질을 총 112개 참여 기관을 대상으로 발송하였다. 같은 날에 Lyphocheck® whole blood control (Bio-Rad Laboratories, Hercules, CA, USA) Level 2 (09-03WB) 및 Level 3 (09-04WB) 의 두 종류의 물질을 Cyclosporine 또는 Tacrolimus 검사를 시행하는 총 55개 기관을 대상으로 발송하였다. 그리고 약물남용 정도관리물질인 Liquicheck Qualitative Urine Toxicology Control (Bio-Rad Laboratories, Hercules, CA, USA) Negative (09-03Urine) 및 Positive (09-04Urine)의 두 종류의 물질을 18개 기관에 발송하였다.

2. 조사종목 및 방법

2009년도에 TDM분과에서 실시한 약물검사 신빙도 조사 종목은 acetaminophen, amikacin, amitriptyline, carbamazepine, digoxin, ethosuximide, free phenytoin, gentamicin, lithium, methotrexate, phenobarbital, phenytoin, primidone, salicylate, theophylline, tobramycin, valproic acid, vancomycin, cyclosporine, tacrolimus (FK-506) 등 20항목이었다. 제2회차에도 동일한 약물을 대상으로 실시하였다. 정도관리 물질로 검사하기 위해서 Lyphocheck® TDM control은 사용 시 검사 당일에 탈이온수를 정확히 5.0 mL을 넣어 용해시키며 실온에 15분간 세워 둔 후 잘 섞어 사용하도록 하였다. Lyphocheck® Whole blood control은 검사 당일에 탈이온수를 정확히 2.0 mL를 넣어 용해시키며 실온에 20분간 세워 둔 후 잘 섞어 사용하도록 하였다.

3. 결과분석 및 통계

결과분석 및 통계처리는 Microsoft Excel 2003, Microsoft Access 2003 및 Analyse-it Software (Version 1.68, Leeds, England, United Kingdom)을 사용하였다. 단위 및 유효숫자를 TDM분과위원회에서 제시한 것으로 하지 않고 임의대로 한 기관에 대해서는 본 위원회 제시안대로 일괄 환산 처리 하였다. 또한 검사장비코드를 기록하지 않은 기관은 전년도와 동일 코드로 처리하였으며 통계 분석은 각 검사 종목별로 장비의 차이를 고려하지 않은 전체 통계와 각 장비별(peer group)로 평균, 표준편차, standard deviation index (SDI) 값을 내되, SDI 값이 +3 또는 -3을 벗어나는 기관의 결과 값은 제외하고 다시 평균, 표준편차, 및 SDI 값을 계산하였다. 단, 참여 기관이 1 기관인 경우에는 통계에서 제외되었다. 또한 각 군별로 변이계수(coefficient of variation), 최저 값, 및 최대 값을 산출하였다. 본 분과위원회의 TDM 검사에서 수탁 기관으로서의 불인정 기준은 종전처럼 다음과 같이 처리하였다. 해당 연도에 정도관리사업의 참여가 전혀 없는 경우는 자동적으로 수탁 불인정 기관이 되지만, 그 외에 다음 두 경우에도 수탁 불인정으로 처리하였다.

(1) 어떤 약물의 두 가지 농도의 정도관리 검체에서 연속하여 장비별(peer group) SDI 값이 +3 이상 또는 -3 미만의 성적을 보인 경우가 2종목 이상이 발견되는 경우, 또는 (2) 어떤 약물의 두 가지 농도의 정도관리 검체에서 연속하여 장비별(peer group) SDI 값이 +2 이상 또는 -2 미만의 성적을 보인 경우가 4종목 이상이 발견되는 기관으로 하였다.

결 과

1. 참여기관 및 검사실시종목

약물검사 정도관리 결과보고 회신율은 1차에서 대상기관 112기관 중 110기관이 회신하여 98.2%였고, 2차에는 대상기관 111기관 중 108기관이 회신을 하여 97.3%였다. 이는 전년도와 유사한 수준으로 참가 기관 수는 최근 3년간 늘지 않은 것을 알 수 있었다(Table 1 및 Fig. 1). 또한 각 기관 당 검사 종목 수는 연평균 6.2 종목으로 최근 5개년 간(2004년~2008년)의 평균 종목 수와 유사하였다(Table 2).

약물검사의 종목 당 실시 기관수를 살펴보면 Table 3과 같았다. 대부분의 종목들이 작년과 유사한 응답률을 보였고, 최근 3년(2005년~2007년) 평균에 비해 Tacrolimus, Vancomycin 등이 증가 추세였다.

Table 1. Number of institution which responded in TDM proficiency testing in Korean Association of Quality Assurance and Clinical Laboratories (KAQACL) in the year of 2009 comparing with those of the previous years

Trial	N of institution participated	N of institution responded (response rate%)	Average response rate
First trial of 2007	110	109 (99.1%)	98.7%
Second trial of 2007	111	109 (98.2%)	
First trial of 2008	114	109 (95.6%)	97.8%
Second trial of 2008	108	108 (100.0%)	
First trial of 2009	112	110 (98.2%)	97.8%
Second trial of 2009	111	108 (97.3%)	

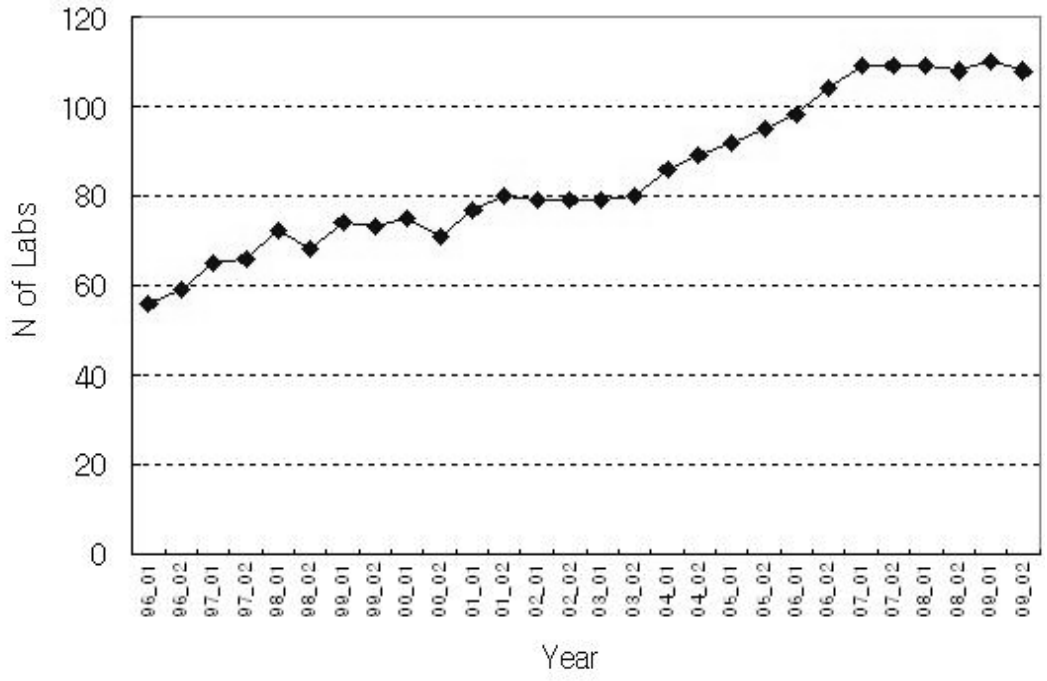

Fig. 1. Change of number of participating laboratories in TDM proficiency testing in KAQACL according to the trials of each year.

2. 검사장비별 이용 현황

2008년도에도 검사방법 및 장비코드는 전년도와 유사한 방법으로 조사하였다. 검사종목별 장비의 이용 현황을 보면 가장 많이 이용되는 장비는 Abbott사의 AxSym의 사용률이 꾸준하여 26.9%로 가장 많이 사용되었고, 반면에 Abbott사의 TDx(FLx)는 사용률이 줄어서 24.8%로 낮아졌고, 그 다음은 Roche사의 Cobas Integra 15.1%였다(Table 4). 한편 Dade Behring 사의 Viva E 및 Dimension RxL, Roche 사의 Modular P 와 Cobas 6000 의 사용률이 늘었다. Lithium검사의 경우에는 검사방법이나 장비의 사용에 있어서 전체 lithium검사기관의 97%인 30기관에서 ISE (Ion selective electrode)법이 이용되고 있어 작년과 유사한 비율이었다. Atomic absorption spectrophotometry (AAS)법 및 Flame emission spectrophotometry (FES)를 이용한 기관도 작년과 유사하였다(Table 5).

Table 2. Number of test items per laboratories of TDM proficiency testing of 2009 KAQACL comparing with those of recent five years

Year / No.of Test Items	Average '04~'08	2005 1st trial	2005 2nd trial	2006 1st trial	2006 2nd trial	2007 1st trial	2007 2nd trial	2008 1st trial	2008 2nd trial	2009 1st trial	2009 2nd trial	2009 Average
1	7.9	6	6	5	9	11	11	11	11	12	14	13
2	11.4	10	11	12	13	12	13	13	13	14	11	12.5
3	4.6	2	3	4	5	6	6	8	8	9	9	9
4	3.9	3	3	3	3	4	5	3	3	5	4	4.5
5	7.3	8	8	8	7	8	6	8	7	5	6	5.5
6	16.3	18	18	16	16	17	17	17	17	15	16	15.5
7	14.8	13	15	17	19	14	14	12	11	12	9	10.5
8	9.1	9	9	8	6	12	10	12	12	11	11	11
9	7.4	7	7	9	9	7	9	4	5	8	10	9
10	3.8	2	1	2	3	5	5	8	7	5	3	4
11	2.2	3	4	3	2	1	1	1	1	2	2	2
12	3.6	3	3	3	5	5	5	3	4	2	3	2.5
13	4.5	5	4	4	4	4	4	7	6	7	6	6.5
14	1.8	2	2	3	2	2	1	1	1	2	3	2.5
15	0.3	0	0	0	0	0	1	0	1	0	0	0
16	0.1	0	0	0	0	0	0	0	0	0	0	0
17	0.1	0	0	0	0	0	0	0	0	0	0	0
18	0.5	0	0	0	1	1	1	1	1	1	1	1
19	0.4	1	1	1	0	0	0	0	0	0	0	0
Total number of institutions	99.9	92	95	98	104	109	109	109	108	110	108	109
Average test items	6.5	6.7	6.6	6.7	6.4	6.3	6.3	6.3	6.3	6.2	6.2	6.2
No. of test items evaluated	20	20	20	20	20	20	20	20	20	20	20	20

Table 3. Distribution of test items in TDM proficiency testing in KAQACL in recent three years

Year / Name of Drug	2006 1st trial	2006 2nd trial	2007 1st trial	2007 2nd trial	2008 1st trial	2008 2nd trial	2009 1st trial	2009 2nd trial	Response Rate(%) of 2009		Response Rate(%) of '06~'08
Acetaminophen	6	6	7	6	7	7	7	7	6.4%	Inc*	6.1%
Amikacin	12	13	13	14	15	17	15	15	13.8%	Inc*	13.2%
Amitriptyline	3	2	2	2	1	1	1	1	0.9%		1.7%
Carbamazepine	80	81	83	79	76	77	74	73	67.4%		74.7%
Cyclosporine	39	42	44	47	46	46	48	48	44.0%	Inc*	41.4%
Digoxin	85	85	88	89	87	86	85	84	77.5%		81.6%
Ethosuximide	1	1	1	1	1	1	1	1	0.9%		0.9%
Free Phenytoin	4	3	3	3	3	3	3	4	3.2%	Inc*	3.0%
Gentamicin	7	7	7	7	7	8	8	8	7.3%	Inc*	6.8%
Lithium	32	32	34	36	34	33	33	34	30.7%		31.6%
Methotrexate	20	19	19	19	20	20	19	19	17.4%		18.4%
Phenobarbital	63	61	62	59	58	55	56	54	50.5%		56.2%
Phenytoin	73	71	74	73	72	71	72	70	65.1%		68.1%
Primidone	6	4	3	3	2	2	1	1	0.9%		3.1%
Salicylate	6	5	5	5	5	5	5	5	4.6%		4.9%
Tacrolimus (FK-506)	27	29	30	33	36	37	41	43	38.5%	Inc*	30.1%
Theophylline	74	74	76	73	74	73	70	69	63.8%		69.7%
Tobramycin	5	8	8	7	7	10	7	6	6.0%		7.1%
Valproic Acid	83	88	92	92	91	90	92	89	83.0%		84.1%
Vancomycin	29	34	36	38	39	40	41	41	37.6%	Inc*	33.9%
Total number of institution responded	98	104	109	109	109	108	110	108	31.0%		31.8%

* 'Inc' stands for the increase of both the number and the response rate of 2008 comparing with those of recent three years (2006 ~ 2008).

Table 4. Usage of the instrument for TDM KAQACL proficiency testing in 2009

Name of Instruments	2006	2007	2008	2009	Rank of Usage in 2009
Abbott AxSym	25.6%	26.4%	26.5%	26.9%	1
Abbott TDx/TDxFLx	38.9%	37.8%	35.3%	24.8%	2
Roche COBAS Integra	20.9%	18.8%	17.3%	15.1%	3
Siemens Diagnostics VIVA-E	0%	0%	3.0%	5.5%	4
Roche cobas c501 (Cobas 6000)	0%	0%	1.5%	5.1%	5
Siemens Diagnostics Dimension	1.1%	1.5%	2.7%	3.4%	6
Roche/Hitachi Systems	1.1%	1.1%	1.6%	2.8%	7
Toshiba chemistry analyzer	0%	0%	0%	2.6%	8
Abbott Architect i System	0%	0%	0.8%	2.6%	8
Abbott IMx	4.0%	4.2%	3.3%	2.3%	10
Siemens Diagnostics ADVIA Centaur	2.5%	1.8%	0.8%	2.2 %	11
Beckman UniCel DxC Synchron	0%	0%	0.9%	1.5%	12
BioMerieux VIDAS	0.5%	0.5%	0.6%	1.0%	13
Abbott Architect c system/Aeroset	0%	0%	0%	0.8%	14
Roche cobas e601/E170	0.3%	0.4%	0.5%	0.6%	15
Siemens Diagnostics Immulite /Immulite 1000, 2500	1.8%	2.1%	1.8%	0.5%	16
Waters	0%	0%	0%	0.5%	16
Other methods	1.2%	1.8%	0%	0.5%	16
Siemens Diagnostics Immulite 2000	0%	0%	0%	0.4%	19
Radioimmunoassay	0.3%	0.4%	0.3%	0.3%	20
Beckman Access/Access2	0.2%	0.2%	0.2%	0.2%	21
Vitros 5,1 FS Chemistry System	0%	0%	0.2%	0.2%	21
Roche cobas e411/Elecsys 1010,2010	0.4%	0.5%	0.3%	0.2%	21
Applied Biosystems	0%	0%	0%	0.1%	24
Sum	100%	100%	100%	100%	

Table 5. Distribution of the method of lithium determination in the year of 2008 in KAQACL proficiency testing

Principle of determination	2007 1st trial	2007 2nd trial	2008 1st trial	2008 2nd trial	2009 1st trial	2009 2nd trial	% of 2009
ISE	34	36	33	32	32	32	94.1%
AAS	1	1	1	1	2	2	5.9%
Sum	35	37	34	33	34	34	100.0%

Abbreviations: ISE, ion selective electrode method; AAS, atomic absorption spectrophotometric method.

3. 방법별 검사 결과치 및 검사실간 변이계수

2008년도 TDM분과에서 실시한 약물검사 신빙도조사의 항목별 검사실간의 변이계수(CV)값을 보면 Table 6, Table 7, 및 Table 8과 같이 각 농도별로 나누어 볼 때 일부 종목에서 검사실간 측정치의 차이가 커진 경우도 있었으나 대부분의 종목에서 약간씩 향상된 것을 볼 수 있었다.

각 검사 항목별 신빙도 조사 결과를 장비별 평균, 표준편차, 변이계수, 참가기관 검사결과를 Table 9-28에 정리하였다.

Table 6. Mean between-laboratory CV of each item using low-level control materials in recent 5 years

Item ＼ Trials	2006 (2nd)	2007 (2nd)	2008 (1st)	Average of recent 5 years	2009 (1st)	Number of institution participated
Acetaminophen	8.1	12.3	36.2	17.8	38.8	7
Amikacin	10.1	5.3	5.6	6.8	12.3	15
Amitriptyline	-	-	-	-	-	1
Carbamazepine	7.2	5.9	6.7	6.6	7.7	74
Cyclosporine	9.2	16.0	12.6	14.5	12.0	48
Digoxin	16.6	14.5	11.8	15.1	18.4	85
Free Phenytoin	7.9	8.4	6.2	13.2	20.9	3
Gentamicin	6.8	3.8	4.9	5.2	5.8	8
Lithium	15.4	17.0	19.7	19.9	18.9	33
Methotrexate	5.1	5.6	6.5	5.7	9.3	19
Phenobarbital	4.4	3.6	6.2	5.3	10.0	56
Phenytoin	5.5	6.4	7.3	6.9	7.3	72
Primidone	5.7	5.4	9.6	6.9	-	1
Salicylate	4.2	17.6	16.4	10.3	5.3	5
Tacrolimus (FK506)	17.6	25.1	16.7	18.7	27.5	41
Theophylline	6.8	4.7	5.6	5.5	6.4	70
Tobramycin	20.7	16.4	14.3	15.8	18.3	7
Valproic Acid	4.8	5.0	6.8	5.6	6.7	92
Vancomycin	8.1	7.1	9.5	8.5	7.5	41
Ethosuximide	-	-	-	-	-	-
Total mean CV	9.1	10.0	11.2	12.3	21.5	

All numbers are between-laboratory coefficient of variation (CV, %) regardless of methods. Several results of some institution was deleted for the calculation of CV since they were regarded as random errors.
-, CV could not be calculated since the number of institution responded was one or zero.

Table 7. Mean between-laboratory CV of each item using medium-level control materials in recent 5 years

Item / Trials	2007 (1st)	2008 (1st)	2008 (2nd)	Average of recent 5 years	2009 (2nd)	Number of institution participated
Acetaminophen	24.7	13.1	12.9	13.1	7.3	7
Amikacin	4.2	3.8	7.5	4.8	7.0	15
Amitriptyline	-	-	-	-	-	1
Carbamazepine	7.7	6.2	6.4	6.6	5.8	73
Cyclosporine	6.6	8.1	8.9	9.2	7.7	48
Digoxin	11.2	8.2	10.0	10.0	9.3	84
Free Phenytoin	6.3	8.3	13.2	11.8	28.6	4
Gentamicin	6.1	8.1	10.0	9.1	7.7	8
Lithium	22.2	17.4	13.0	18.9	14.1	34
Methotrexate	12.7	7.0	8.7	23.9	8.3	19
Phenobarbital	4.0	6.2	8.0	5.2	8.1	54
Phenytoin	6.8	4.7	4.1	5.7	4.6	70
Primidone	5.5	11.5	6.4	6.1	-	1
Salicylate	3.6	2.1	2.9	3.2	3.8	5
Tacrolimus (FK506)	8.3	11.3	14.9	12.8	7.8	43
Theophylline	5.0	5.1	4.3	4.9	4.1	69
Tobramycin	9.9	10.9	15.2	11.3	15.9	6
Valproic Acid	4.1	6.3	4.3	5.0	5.5	89
Vancomycin	8.4	5.9	7.6	7.4	7.5	41
Ethosuximide	-	-	-	-	-	-
Total mean CV	8.7	8.0	8.8	9.4	9.0	

All numbers are between-laboratory coefficient of variation (CV, %) regardless of methods. Several results of some institution was deleted for the calculation of CV since they were regarded as random errors.
-, CV could not be calculated since the number of institution responded was one or zero.

Table 8. Mean between-laboratory CV of each item using high-level control materials in recent 5 years

Item / Trials	2007 (2nd)	2008 (2nd)	Average of recent 5 years	2009 (1st)	2009 (2nd)	Number of institution participated
Acetaminophen	5.3	6.2	10.9	6.7	5.5	7
Amikacin	5.8	6.4	5.1	6.1	8.0	15
Amitriptyline	-	-	-	-	-	1
Carbamazepine	7.5	7.7	8.3	7.1	5.6	73
Cyclosporine	9.6	8.4	9.5	9.3	6.3	48
Digoxin	9.6	8.8	9.5	9.9	8.9	84
Free Phenytoin	14.0	16.1	15.5	26.4	28.1	4
Gentamicin	10.4	8.2	10.1	10.0	6.9	8
Lithium	15.5	13.5	17.2	16.2	16.3	34
Methotrexate	3.2	5.3	4.7	11.0	6.7	19
Phenobarbital	6.6	9.2	7.1	7.7	7.6	54
Phenytoin	4.9	4.8	4.7	5.3	5.6	70
Primidone	2.0	7.0	4.2	-	-	1
Salicylate	0.8	1.2	2.0	5.3	2.3	5
Tacrolimus (FK506)	12.1	14.0	12.2	9.7	8.6	43
Theophylline	4.3	4.6	5.5	3.8	5.3	69
Tobramycin	10.5	15.2	10.7	16.5	17.5	6
Valproic Acid	3.9	4.6	4.9	7.0	5.4	89
Vancomycin	8.3	8.2	10.0	10.9	7.6	41
Ethosuximide	-	-	-	-		-
Total mean CV	7.5	8.3				

All numbers are between-laboratory coefficient of variation (CV, %) regardless of methods. Several results of some institution was deleted for the calculation of CV since they were due to random error.
-, CV could not be calculated since the number of institution responded was one or zero.

Table 9. Acetaminophen proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	7	7.56	2.93	38.8	7	96.41	6.45	6.69	7	32.56	2.39	7.34	7	96.93	5.29	5.46
Roche Integra	5	7.78	0.44	5.63	5	94.38	2.87	3.04	5	32.08	0.73	2.27	5	94.64	1.76	1.86
Abbott TDx	1	12	-	-	1	110	-	-	1	37.5	-	-	1	108.3	-	-
Cobas 6000	1	2	-	-	1	93	-	-	1	30	-	-	1	97	-	-

Table 10. Amikacin proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	15	3.61	0.44	12.25	15	33.21	2.02	6.09	15	16.17	1.14	7.02	15	34.36	2.75	7.99
Abbott(TDx)	7	3.51	0.42	11.9	7	33.25	2.74	8.24	7	16.95	1.14	6.7	7	35.45	2.1	5.94
Cobas Integra	5	3.8	0.39	10.36	5	33.08	1.7	5.14	5	15.44	0.65	4.21	5	34.36	2.02	5.88
Toshiba	2	3.6	0.85	23.57	2	33.45	0.78	2.33	2	15.55	0.78	5	2	30.45	4.88	16.02
Cobas 6000	1	3.3	-	-	1	33.2	-	-	1	15.6	-	-	1	34.6	-	-

Table 11. Amitriptyline proficiency testing results of KAQACL in the year of 2009 (unit, ng/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
Abbott TDx	1	261	-	-	1	843	-	-	1	559	-	-	1	902	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 12. Carbamazepine proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	74	2.84	0.22	7.74	74	15.51	1.1	7.08	73	9.12	0.53	5.79	73	15.4	0.86	5.59
Abbott AxSym	27	2.86	0.13	4.38	27	15.63	1.01	6.48	28	9.13	0.59	6.5	28	15.58	0.71	4.55
Abbott TDx	17	2.89	0.13	4.47	17	15.01	0.58	3.86	13	9.05	0.29	3.16	13	15.23	0.75	4.9
Cobas Integra	11	2.95	0.1	3.29	11	16.9	0.61	3.61	12	9.15	0.61	6.65	12	15.88	0.95	5.98
Cobas 6000	4	2.7	0.32	11.71	4	15.4	0.76	4.95	5	9.24	0.31	3.39	5	15.58	0.66	4.24
VIVA-E	4	2.73	0.13	4.62	4	15.15	0.84	5.56	4	9.57	0.3	3.12	4	15.08	0.32	2.12
Hitachi	3	2.83	0.15	5.39	3	15.47	0.32	2.08	4	8.9	0.66	7.4	4	14.8	1.14	7.7
Dimension	2	2.7	0.14	5.24	2	13.65	0.35	2.59	2	9	0.28	3.14	2	15.15	0.78	5.13
Toshiba	2	3.05	0.07	2.32	2	15.2	0.28	1.86	2	9.6	0.28	2.95	2	15.15	0.07	0.47
Centaur	1	2.1	-	-	1	12.3	-	-	1	8.46	-	-	1	13.48	-	-
Immulite 2000	1	3.4	-	-	1	16.6	-	-	-	-	-	-	-	-	-	-
Immulite 1000	1	2.4	-	-	1	15	-	-	-	-	-	-	-	-	-	-
DxC Synchron	1	2.5	-	-	1	14.1	-	-	2	8.5	0.71	8.32	2	13.9	1.41	10.17

-, CV could not be calculated since the number of institution responded was one or zero.

Table 13. Cyclosporine proficiency testing results of KAQACL in the year of 2009 (unit, ng/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	48	78.41	9.38	11.97	48	382.31	35.53	9.29	48	202.49	15.57	7.69	48	378.92	23.92	6.31
Abbott TDx	19	82.61	7.25	8.77	19	379.35	25.86	6.82	15	208.14	13.06	6.27	15	385.35	10.05	2.61
Abbott AxSym	10	66.72	22.69	34.01	10	357.6	49.56	13.86	9	210.04	30.72	14.62	9	386.12	45.07	11.67
Dimension	5	82.16	2.57	3.13	5	409.06	1.87	0.46	5	203	9.7	4.78	5	389.14	8.35	2.15
VIVA-E	4	77.35	5.76	7.44	4	416.28	12.61	3.03	5	199.16	10.39	5.22	5	362.42	11.2	3.09
RIA	2	75.5	16.26	21.54	2	345	110.3	31.97	2	190.5	58.69	30.81	2	360	111.72	31.03
Toshiba	2	74.5	4.95	6.64	2	402.5	38.89	9.66	2	195.5	12.02	6.15	2	385.5	24.75	6.42
Architect	2	87.97	3.36	3.82	2	415.6	13.26	3.2	5	196.6	12.05	6.13	5	381.68	11.83	3.1
Cobas Integra	2	70	4.24	6.06	2	337.5	4.95	1.47	2	203	21.21	10.45	2	373	33.94	9.1
Centaur	1	76.54	-	-	1	340.01	-	-	2	209.24	6	2.87	2	377.5	13.44	3.56
Biosystems	1	78	-	-	1	387	-	-	1	194.4	-	-	1	370.9	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 14. Digoxin proficiency testing results of KAQACL in the year of 2009 (unit, ng/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	85	0.66	0.12	18.41	85	2.9	0.29	9.85	84	1.66	0.15	9.27	84	2.97	0.26	8.9
Abbott AxSym	25	0.65	0.08	12.74	25	2.84	0.2	7.07	25	1.61	0.11	6.55	25	2.87	0.19	6.46
Abbott TDx	17	0.56	0.08	14.06	17	2.63	0.19	7.04	6	1.36	0.37	27.07	6	2.58	0.5	19.28
Cobas Integra	11	0.77	0.11	14.34	11	3.19	0.26	8.25	12	1.79	0.06	3.12	12	3.16	0.17	5.44
VIDAS	7	0.61	0.05	7.86	7	2.78	0.13	4.71	6	1.58	0.09	5.59	6	2.89	0.14	4.98
Cobas 6000	5	0.72	0.04	5.28	5	3.15	0.04	1.32	6	1.8	0.12	6.68	6	3.2	0.2	6.18
Modular E-170	4	0.71	0.09	12.62	4	3.36	0.12	3.46	4	1.73	0.12	6.82	4	3.3	0.11	3.22
VIVA-E	3	0.54	0.05	9.8	3	2.71	0.09	3.33	3	1.37	0.08	6.06	3	2.7	0.13	4.97
Centaur	3	0.63	0.12	18.23	3	2.8	0.1	3.57	5	1.66	0.11	6.55	5	2.81	0.13	4.77
Hitachi	2	0.8	0	0.03	2	3.1	0	0.02	3	1.77	0.06	3.27	3	3.1	0.2	6.45
Toshiba	2	0.77	0.1	12.86	2	3.11	0.01	0.45	2	1.77	0.04	2.4	2	3.07	0.18	5.99
Dimension	2	0.68	0.01	1.05	2	2.93	0.03	0.97	2	1.76	0.06	3.21	2	3.13	0.03	0.9
Beckman Access	1	0.71	-	-	1	2.87	-	-	1	1.5	-	-	1	2.63	-	-
Elecsys	1	0.6	-	-	1	3.04	-	-	1	1.87	-	-	1	3.62	-	-
DxC Synchron	1	0.4	-	-	1	2.6	-	-	2	1.5	0	0	2	2.85	0.07	2.48
Immulite	1	0.85	-	-	1	3.64	-	-	1	2.09	-	-	1	3.63	-	-
Architect i	-	-	-	-	-	-	-	-	4	1.5	0.09	5.98	4	2.74	0.12	4.3
Architect c	-	-	-	-	-	-	-	-	1	1.7	-	-	1	2.8	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 15. Free phenytoin proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	3	0.75	0.16	20.85	3	1.99	0.52	26.42	4	1.4	0.4	28.64	4	1.98	0.55	28.06
Abbott TDx	3	0.75	0.16	20.85	3	1.99	0.52	26.42	4	1.4	0.4	28.64	4	1.98	0.55	28.06

Table 16. Gentamicin proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	8	3.03	0.18	5.79	8	7.02	0.7	9.97	8	5.6	0.43	7.72	8	6.99	0.48	6.89
Abbott TDx	4	3.05	0.24	7.8	4	7.48	0.37	4.93	3	6.0	0.2	3.33	3	7.35	0.22	3.06
Abbott AxSym	2	3.0	0.14	4.71	2	7.05	0.07	1.0	3	5.57	0.21	3.74	3	7.0	0.46	6.55
Cobas Integra	2	3.0	0.14	4.71	2	6.1	0.71	11.59	2	5.05	0.21	4.2	2	6.45	0.35	5.48

-, CV could not be calculated since the number of institution responded was one or zero.

Table 17. Lithium proficiency testing results of KAQACL in the year of 2009 (unit, mmol/L)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	33	0.51	0.1	18.89	33	2.19	0.35	16.18	34	1.46	0.21	14.11	34	2.26	0.37	16.26
Vitros	5	0.66	0.04	6.66	5	2.4	0.06	2.62	5	1.6	0.07	4.35	5	2.39	0.06	2.6
Nova CRT	4	0.49	0.04	8.35	4	2.58	0.27	10.44	9	1.64	0.2	12.34	9	2.67	0.4	15.03
Cobas Integra	4	0.48	0.01	2.06	4	2.0	0.14	6.83	6	1.34	0.05	3.98	6	2.03	0.09	4.24
AVL Scientific	4	0.45	0.05	10.22	4	1.97	0.28	14.5	5	1.37	0.18	13.24	5	2.21	0.2	9.24
Nova	3	0.56	0.06	10.98	3	2.68	0.43	16.17	-	-	-	-	-	-	-	-
Dimension	3	0.33	0.04	10.54	3	1.78	0.06	3.2	2	1.17	0.05	4.25	2	1.79	0.06	3.57
Abbott AxSym	2	0.5	0.01	1.4	2	2.44	0.33	13.65	-	-	-	-	-	-	-	-
Cobas 6000	2	0.54	0.06	11.68	2	1.96	0.05	2.52	2	1.34	0.06	4.22	2	1.99	0.01	0.71
Vitros DT60 II	1	0.6	-	-	1	2.1	-	-	1	1.5	-	-	1	2.2	-	-
Medica EasyLyte	1	0.52	-	-	1	2.2	-	-	1	1.42	-	-	1	2.22	-	-
DxC Synchron	1	0.4	-	-	1	1.9	-	-	1	1.2	-	-	1	1.9	-	-
Roche 9100	1	0.45	-	-	1	2.06	-	-	-	-	-	-	-	-	-	-
Perkin Elmer	1	0.47	-	-	1	1.84	-	-	1	1.28	-	-	1	1.87	-	-
Varian	1	0.58	-	-	1	1.82	-	-	1	1.3	-	-	1	1.9	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 18. Methotrexate proficiency testing results of KAQACL in the year of 2009 (unit, μmol/L)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	19	0.4	0.04	9.32	19	9.54	1.05	11.03	19	1.28	0.11	8.25	19	9.34	0.63	6.71
Abbott TDx	17	0.41	0.03	8.23	17	9.7	0.97	9.96	15	1.28	0.1	8.14	15	9.3	0.46	4.9
Cobas Integra	1	0.4	-	-	1	8.89	-	-	2	1.17	0.01	1.21	2	8.78	0.16	1.77
VIVA-E	1	0.32	-	-	1	7.5	-	-	1	1.38	-	-	1	11.1	-	-
Hitachi	-	-	-	-	-	-	-	-	1	1.4	-	-	1	3.4	-	-

-, CV could not be calculated since number of institution responded was one or zero.

Table 19. Phenobarbital proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	56	9.96	1.0	10.02	56	50.19	3.84	7.65	54	25.24	2.03	8.05	54	49.63	3.79	7.64
Abbott TDx	19	10.6	0.98	9.32	19	51.39	5.74	11.17	13	26.3	1.75	6.64	13	50.42	3.59	7.11
Abbott AxSym	17	10.4	0.97	9.32	17	50.26	3.96	7.89	18	24.96	2.34	9.37	18	49.15	4.06	8.26
Cobas Integra	8	9.21	0.66	7.16	8	48.4	2.43	5.02	7	24.6	0.7	2.86	7	48.27	1.8	3.74
Cobas 6000	4	8.82	0.22	2.51	4	50.15	1.49	2.97	5	24.42	0.92	3.77	5	49.6	3.01	6.06
VIVA-E	3	9.9	0.7	7.07	3	53.5	3.65	6.82	3	28.13	0.67	2.37	3	55.23	1.76	3.19
Toshiba	2	8.35	0.21	2.54	2	50.1	0.14	0.28	2	24.8	0.85	3.42	2	49.75	0.07	0.14
Centaur	1	8.8	-	-	1	53.2	-	-	1	26.95	-	-	1	56.01	-	-
DxC Synchron	1	9.5	-	-	1	45.0	-	-	2	24.2	1.56	6.43	2	48.3	3.96	8.2
Hitachi	1	9.1	-	-	1	48.8	-	-	2	24.5	0.71	2.89	2	48.25	0.07	0.14
Architect	-	-	-	-	-	-	-	-	1	20.29	-	-	1	40.57	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 20. Phenytoin proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	72	6.74	0.49	7.3	72	22.98	1.23	5.34	70	13.7	0.63	4.59	70	22.9	1.28	5.57
Abbott AxSym	22	6.99	0.24	3.44	22	22.97	0.9	3.9	23	14.05	0.43	3.04	23	23.12	0.91	3.93
Abbott TDx	20	6.98	0.44	6.26	20	22.88	0.89	3.88	14	13.69	0.46	3.37	14	22.65	0.63	2.77
Cobas Integra	12	6.19	0.28	4.59	12	22.6	1.23	5.44	13	13.2	0.47	3.59	13	22.16	1.12	5.04
Cobas 6000	4	6.13	0.3	4.88	4	22.75	0.79	3.49	5	12.94	0.57	4.39	5	21.54	0.99	4.58
VIVA-E	4	6.38	0.39	6.06	4	25.78	2.53	9.83	4	13.58	0.39	2.85	4	24.17	1.77	7.34
Hitachi	3	6.43	0.15	2.37	3	22.87	0.81	3.56	4	13.22	0.46	3.51	4	22.35	0.87	3.87
Dimension	2	7.4	0.28	3.82	2	26.05	0.92	3.53	2	15.55	0.49	3.18	2	25.95	0.35	1.36
Toshiba	2	7.05	0.21	3.01	2	23.2	0.42	1.83	2	14.65	0.35	2.41	2	23.35	0.07	0.3
DxC Synchron	1	6.2	-	-	1	22.9	-	-	2	14.05	0.07	0.5	2	23.65	0.21	0.9
Centaur	1	7.2	-	-	1	24.3	-	-	1	14.52	-	-	1	26.39	-	-
Immulite	1	6.0	-	-	1	22.1	-	-	-	-	-	-	-	-	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 21. Primidone proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	1	2.9	-	-	1	11.0	-	-	1	5.7		-	1	11.8	-	-
HPLC	1	2.9	-	-	1	11.0	-	-	1	5.7		-	1	11.8	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 22. Salicylate proficiency testing results of KAQACL in the year of 2009 (unit, mg/dL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	5	6.03	0.32	5.31	5	45.0	1.15	2.6	5	17.05	0.65	3.8	5	44.74	1.02	2.29
Cobas Integra	4	5.9	0.06	1.0	4	44.4	0.47	1.06	4	16.91	0.66	3.9	4	44.7	1.18	2.63
Cobas 6000	1	6.5	-	-	1	46.6	-	-	1	17.6	-	-	1	44.9	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 23. Tacrolimus (FK-506) proficiency testing results of KAQACL in the year of 2009 (unit, ng/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	41	3.02	0.83	27.45	41	18.03	1.76	9.73	43	9.5	0.74	7.77	43	18.19	1.56	8.57
Abbott IMx	16	3.62	0.47	13.04	16	18.98	1.58	8.3	13	9.64	0.8	8.28	13	18.89	1.92	10.18
Dimension	7	1.65	0.44	26.48	7	15.66	0.96	6.11	7	8.93	0.64	7.19	7	18.01	0.72	4.0
Architect i	7	2.73	0.14	5.06	7	18.64	1.01	5.39	10	9.79	1.16	11.81	10	18.76	2.67	14.26
VIVA-E	6	3.58	0.34	9.41	6	17.92	1.21	6.78	7	9.9	0.57	5.71	7	18.23	0.75	4.1
Waters	3	2.87	0.21	7.26	3	18.27	1.46	8.01	3	8.07	1.33	16.51	3	16.1	2.79	17.31
Architect c	2	2.5	0.28	11.31	2	16.6	1.41	8.52	3	9.77	0.25	2.58	3	18.13	1.1	6.05

-, CV could not be calculated since the number of institution responded was one or zero Abbott AxSym.

Table 24. Theophylline proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	70	4.99	0.32	6.41	70	29.12	1.11	3.81	69	14.7	0.6	4.09	69	29.33	1.55	5.3
Abbott AxSym	21	5.02	0.23	4.51	21	29.54	1.03	3.47	22	14.74	0.64	4.31	22	29.59	1.6	5.39
Abbott TDx	20	4.77	0.37	7.69	20	28.56	1.15	4.03	13	14.55	0.38	2.61	13	28.64	0.63	2.18
Cobas Integra	9	5.14	0.36	7.02	9	29.52	0.53	1.79	11	14.92	0.54	3.61	11	29.08	1.2	4.13
Cobas 6000	4	4.88	0.17	3.5	4	29.18	1.01	3.47	4	14.53	0.76	5.22	4	29.25	0.67	2.28
VIVA-E	4	4.95	0.13	2.61	4	28.47	0.67	2.34	4	15.52	1.39	8.96	4	31.92	1.59	4.99
Hitachi	2	5.2	0	0.03	2	29.4	1.56	5.29	3	14.63	0.72	4.94	3	30.37	0.85	2.8
Toshiba	2	4.6	0.57	12.3	2	29.7	0.71	2.38	2	13.46	0.79	5.88	2	26.2	1.98	7.56
Dimension	2	5.2	0.28	5.44	2	29.65	0.92	3.1	2	14.8	0.14	0.96	2	29.65	0.21	0.72
Immulite 2000	1	5.9	-	-	1	38.1	-	-	1	13.7	-	-	1	27.4	-	-
Immulite 1000	1	5.1	-	-	1	36.1	-	-	1	17.5	-	-	1	35.8	-	-
DxC Synchron	1	5.3	-	-	1	28.8	-	-	2	15.35	0.07	0.46	2	30.75	1.06	3.45
Architect	1	4.64	-	-	1	26.16	-	-	2	14.95	0.07	0.47	2	27.8	0.28	1.02
Vitros	1	5.5	-	-	1	39.6	-	-	1	17.5	-	-	1	35.9	-	-
Centaur	1	5.4	-	-	1	30.3	-	-	1	15.1	-	-	1	29.9	-	-

-, CV could not be calculated since number of institution responded was one or zero.

Table 25. Tobramycin proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	7	0.83	0.15	18.26	7	7.64	1.26	16.48	6	3.55	0.56	15.91	6	7.83	1.37	17.5
Abbott TDx	3	0.77	0.06	7.53	3	7.43	0.15	2.05	2	3.5	0	0	2	7.4	0.28	3.82
Abbott AxSym	3	0.97	0.06	6.27	3	8.66	0.36	4.18	3	3.93	0.15	3.88	3	8.8	1.0	11.36
Cobas Integra	1	0.6	-	-	1	5.2	-	-	1	2.5	-	-	1	5.8	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 26. Valproic acid proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	92	35.24	2.36	6.7	92	120.0	8.43	7.03	89	75.13	4.13	5.5	89	121.2	6.52	5.38
Abbott AxSym	31	35.46	1.71	4.82	31	120.3	6.07	5.05	33	74.79	2.83	3.78	33	120.8	3.21	2.66
Abbott TDx	25	33.92	2.18	6.44	25	117.8	4.27	3.62	16	73.54	2.46	3.35	16	120.6	3.94	3.27
Cobas Integra	12	34.04	1.86	5.48	12	117.5	8.46	7.2	14	74.38	1.98	2.66	14	119.9	4.91	4.1
Hitachi	4	32.48	2.96	9.12	4	111.1	11.6	10.47	4	73.17	4.84	6.62	4	120.4	6.21	5.15
Cobas 6000	4	37.35	2.11	5.66	4	131.4	13.0	9.91	5	76.92	4.02	5.23	5	123.6	7.88	6.37
VIVA-E	4	39.5	1.23	3.11	4	133.8	1.14	0.86	4	86.27	4.34	5.03	4	138.3	2.54	1.83
Centaur	3	37.0	1.73	4.68	3	119.3	5.51	4.62	4	75.47	2.73	3.61	4	115.8	2.52	2.17
Toshiba	2	39.05	0.07	0.18	2	131.7	0.42	0.32	2	86.0	2.83	3.29	2	133.3	2.47	1.86
Dimension	2	37.15	1.91	5.14	2	120.2	4.74	3.94	2	77.9	0.71	0.91	2	120.0	2.83	2.36
Architect	1	34.2	-	-	1	114.7	-	-	1	75.0	-	-	1	112.0	-	-
DxC Synchron	1	30.0	-	-	1	104.0	-	-	2	69.25	8.84	12.76	2	107.9	6.86	6.36
Immulite 1000	1	38.0	-	-	1	131.0	-	-	-	-	-	-	-	-	-	-
Immulite 2000	1	39.5	-	-	1	136.0	-	-	1	66.9	-	-	1	108.0	-	-
Other	1	34.0	-	-	1	101.0	-	-	1	82.3	-	-	1	131.6	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 27. Vancomycin proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)	No. Lab	Mean	SD	CV(%)
All methods	41	13.22	0.99	7.48	41	70.7	7.71	10.91	41	37.21	2.78	7.46	41	71.05	5.43	7.64
Abbott TDx	14	14.17	1.51	10.65	14	71.01	10.3	14.52	9	36.47	2.33	6.38	9	67.13	3.49	5.2
Abbott AxSym	11	12.69	0.68	5.38	11	68.83	4.4	6.43	12	35.66	1.16	3.26	12	68.83	3.93	5.71
Cobas Integra	10	13.32	0.5	3.78	10	79.02	12.2	15.37	11	40.04	1.42	3.55	11	75.08	3.49	4.65
Cobas 6000	2	11.75	0.92	7.82	2	70.45	7.42	10.54	3	39.67	3.61	9.1	3	71.7	9.4	13.1
VIVA-E	1	11.7	-	-	1	73.4	-	-	1	34.0	-	-	1	72.2	-	-
Architect	1	12.63	-	-	1	63.16	-	-	2	35.42	3.14	8.86	2	74.71	11.6	15.53
Toshiba	1	14.8	-	-	1	70.0	-	-	1	36.0	-	-	1	77.7	-	-
Centaur	1	8.5	-	-	1	52.0	-	-	1	26.31	-	-	1	50.96	-	-
DxC Synchron	-	-	-	-	-	-	-	-	1	31.9	-	-	1	71.4	-	-

-, CV could not be calculated since the number of institution responded was one or zero.

Table 28. Ethosuximide proficiency testing results of KAQACL in the year of 2009 (unit, μg/mL)

Method	09-01				09-02				09-03				09-04			
	No.Lab	Mean	SD	CV(%)	No.Lab	Mean	SD	CV(%)	No.Lab	Mean	SD	CV(%)	No.Lab	Mean	SD	CV(%)
HPLC	1	29.9	-	-	1	110.1	-	-	1	74.4	-	-	1	111.7	-	-

-, CV could not be calculated since number of institution responded was one or zero.

Table 29. The participating laboratories for drug of abuse in the proficiency testing of KAQACL in the year of 2009

The kinds of laboratories	2007-1st	2007-2nd	2008-1st	2008-2nd	2009-1st	2009-2nd
University hospital laboratory	6	9	8	7	10	12
Independent Medical laboratory	4	4	4	4	4	4
Community hospital laboratory	3	4	5	4	3	3
Total	13	17	17	15	17	19

*Average numbers of drug of abuse items were 3.2 for 1st trial and 4.8 for 2nd trial.

Table 30. The items of drug of abuse and the number of participating laboratories with percent of correct answer in the proficiency tesing of KAQACL in the year of 2009

No.	Name of drug of abuse test	N (% of correct answer) of participating laboratories in 2009	
		1st	2nd
1	d-Methamphetamine	12 (100%)	14 (100%)
2	d-Amphetamine	11 (100%)	11 (100%)
3	Morphine, Free	8 (100%)	10 (100%)
4	9-COOH-11-nor-Δ9-THC	8 (100%)	9 (100%)
5	Benzoylecgonine	8 (100%)	9 (100%)
6	Phencyclidine (PCP)	6 (100%)	8 (100%)
7	3,4-Methylenedioxymethamphetamine	3 (100%)	2 (100%)
8	Oxazepam	2 (100%)	3 (100%)
9	Nordiazepam	2 (100%)	3 (100%)
10	Nortriptyline	1 (100%)	3 (100%)
11	Secobarbital	2 (100%)	3 (100%)
12	Ethanol	1 (100%)	1 (100%)
13	Methadone	1 (100%)	3 (100%)
Total		65	79

고 찰

대한임상정도관리협회 TDM분과위원회의 '09년도 신빙도 조사사업은 전년도와 같이 2회 실시하였으며, 참가 기관이 최근 3년간 유사한 수준으로 더 이상 늘고 있지는 않다는 것을 알 수 있었다 (Table 1, Fig. 1)[1]. 회신율은 평균 97.3%로 높은 수준을 유지하였다(Table 1). 가장 많은 기관에서 회신한 약물 농도 검사 종목은 valproic acid,

digoxin, carbamazepine, phenytoin 및, theophylline 등 5 종목으로서 63.8% 이상의 기관에서 응답하였다 (Table 3). 다음으로 phenobarbital, cyclosporine, vancomycin, tacrolimus, vancomycin, lithium, methotrexate, amikacin 순이었고, 10% 미만의 회신을 보인 종목은 gentamicin, acetaminophen, tobramycin, salicylate, free phenytoin, amitriptyline, ethosuximide, primidone 순으로 예년과 유사한 수준이었는데 cyclosporine, tacrolimus 및 vancomycin 의 응답률은 꾸준히 증가하였다(Table 3). 또한 각 기관 당 검사 종목 수는 평균 6.2종목으로 최근 5개년 간(2003년~2007년)의 평균 종목 수 6.5종목에 비해 0.3 종목 감소하여 사용이 많지 않은 검사 종목은 중단하는 경향이 있음을 알 수 있었다(Table 2 및 Table 3). 사용 기종은 최근 단종되는 것으로 알려진 TDx/TDxFLx의 사용률이 급격히 줄었고, 반면에 AxSym, Cobas Integra 의 비율은 유사하였으며, 대신에 Viva-E, cobas c501, Dimension, Abbott Architect 등의 사용률이 조금씩 증가하며 다변화하는 것을 알 수 있었다(Table 4). 이번에도 각 기관별 평가를 위해서 검사 기종의 차이를 고려하지 않은 종목별 SDI값과 검사 기종별 SDI값을 별도로 보고하였다. 연도별 검사 기관간 변이 계수를 정도관리 물질 농도별로 비교하여 보았을 때, 예년에 비해 큰 변화가 있지는 않았다(Table 7, 8, 9). 약물별 신빙도 조사결과는 대체로 예년과 유사하였으나 검사 기종이 다변화되는 것을 알 수 있었다.(Table 9-28). 약물남용검사 신빙도조사 참여 기관은 예년보다 약간씩 증가하였다(Table 29-30).

요 약

1. TDM신빙도조사에 참여한 기관은 1차에서 110기관, 2차에서 108기관으로 최근 3년간 유사한 수준이었다.

2. 제1회 차 및 제2회 차 모두에서 두 가지 농도의 정도관리 물질을 동시에 평가하여 연 총 4가지 정도관리 물질을 평가하였고, 약물검사 신빙도 조사에 대한 참여기관의 회신율은 1회 차 및 2회 차 평균 97.8%의 회신율을 보였다.

3. 가장 많은 기관에서 검사를 하고있는 약물검사로는 valproic acid, digoxin, carbamazepine, phenytoin, theophylline 등 5종으로서 전체참여기관 110 기관 중 63.8% 이상에서 응답하였다. 그 다음으로 phenobarbital, cyclosporine, tacrolimus, vancomycin, lithium, methotrexate, amikacin, gentamicin, acetaminophen, tobramycin, salicylate, free phenytoin, amitryptyline, ethosuximide, primidone 순이었다.

4. 기관당 약물농도 검사 종목 수는 평균 6.2 종목으로 최근 5개년 간의 평균 종목 수 6.5 종목에 비해 0.3 종목 감소하여 이용도가 많지 않은 종목은 시행을 하지 않는 경향이 있음을 알 수 있었다

5. 연도별 검사 기관간 변이 계수를 정도관리 물질 농도별로 비교하여 보았을 때, 예년과 유사한 수준이었다.

6. 검사장비의 이용률은 Abbott AxSym (26.9%), Abbott TDx/TDxFLx (24.8%), Roche Cobas Integra (15.1%) 순이었고, Siemens Diagnostics Viva-E (5.5%), Roche Cobas c501 (5.1%), Siemens Diagnostics Dimension RXL 5.5%) 등 비롯한 다양한 장비가 활용되고 있음을 알 수 있었다.

7. 약물남용검사 신빙도 조사 참여기관은 19개 기관으로 약간 늘었고, 기관별로 평균 3.2~4.8종의 약물에 대해 회신이 왔으며 모두 정답을 회신하였다.

결론적으로 2009년도 TDM분과위원회의 신빙도 조사 결과는 최근 3년간 유사한 성과를 보였다.

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