REPORT ON PROFICIENCY TESTING

임상검사와 정도관리

Journal of
LABORATORY MEDICINE / and
QUALITY ASSURANCE

Annual Report of the Korean Association of External Quality Assessment Service on General Chemistry (2018)

Yong-Wha Lee

Department of Laboratory
Medicine and Genetics,
Soonchunhyang University
Bucheon Hospital,
Soonchunhyang University
College of Medicine,
Bucheon, Korea

Corresponding author:

Yong-Wha Lee

Department of Laboratory
Medicine and Genetics,
Soonchunhyang University
Bucheon Hospital,
Soonchunhyang University
College of Medicine, 170 Jomaru-
ro, Wonmi-gu, Bucheon 14584,
Korea

Tel: +82-32-621-5943

Fax: +82-32-621-5944

E-mail: lywmd@schmc.ac.kr

pISSN: 2384-2458

eISSN: 2288-7261

In 2018, the general chemistry proficiency testing program of the Korean Association of External Quality Assessment Service consisted of the routine chemistry and urine chemistry programs including 32 and 13 test items, respectively. The test method classification system was revised in the routine chemistry program, and a qualitative test of human chorionic gonadotropin was added in the urine chemistry program. The routine chemistry program was conducted 4 times a year, while the urine chemistry program was conducted twice a year. Statistical analysis data for the test method and reagent companies were reported based on the information and results of the test items provided by each institution. Statistics included the number of participating institutes, mean, standard deviation, coefficient of variation (CV), median, and minimum and maximum values for each group. Each report included tables, histograms, Levey-Jennings charts, and the standard deviation index showing the statistics of each test item. In the routine chemistry program, more than 1,000 institutions performed the 17 test items, and the number is continuously increasing. CV for each test item showed a tendency to increase with decreasing concentration of the proficiency material but was within 10% in most cases. Alkaline phosphatase and lactate dehydrogenase were found to have relatively high CVs because of the differences in results among test methods. In the urine chemistry program, albumin and protein showed high CVs, and the distribution of the test method was different from that of the routine chemistry program.

(J Lab Med Qual Assur 2019;41:51-64)

Key Words: Proficiency testing, General chemistry, Korean Association of External Quality Assessment Service

서론

대한임상검사정도관리협회에서는 2016년부터 새로운 운영방식의 차세대 신빙도조사사업을 시행하고 있다. 2018년에는 6개 대분류하에 64개 프로그램 단위별 운영체제로 확대되어 프로그램별 검사종목도 319항목으로 증가하였다[1-3]. 임상화학 분야는 6개의 대분류 중 하나로서 일반화학검사 등 10개의 중분류 분야로 구성되고 이들은 일반화학검사와 요화학검사 등 24개의 세부 프로그램으로 나뉜다. 일반화학검사 프로그램에는 총 32종의 검사항목이 포함되어 있고, 요화학검사 프로그램에는 요 human chorionic gonadotropin (hCG) 정성검사가 추가되어 총 13종의 검사항목이 포함되었다. 일반화

학검사 프로그램에 대해서는 검사항목별로 새로운 검사방법 분류체계를 적용하여 각각의 시약들에 대해 새로운 검사방법 명칭을 부여하였다.

저자들은 2018년 대한임상검사정도관리협회의 신빙도조사사업으로 실시되었던 일반화학검사와 요화학검사에 대한 신빙도조사사업 결과를 분석하여 보고하고자 한다.

재료 및 방법

1. 대상

일반화학검사 프로그램은 연 4회에 걸쳐 회차별로 3개의 정도관리물질이 이용되어 시행되었다. 물질은 냉장상태가 유지

될 수 있도록 아이스팩이 내장된 특수 제작박스에 넣어 참여 등록기관을 대상으로 각 회차별로 2월, 4월, 8월과 10월에 발송되었다. 요화학검사 프로그램은 연 2회에 걸쳐, 회차 별로 3개의 정도관리 물질이 이용되었고 1회차와 2회차를 각각 3월과 9월에 발송하였다.

2. 정도관리물질과 검사항목

일반화학검사의 정도관리물질은 사람 혈청을 기질로 한 분말제품인 Randox사(Randox Testing Services, London, UK)와 Bio-Rad사(Bio-Rad Laboratories, Hercules, CA, USA)의 사람 혈청을 기질로 한 분말제품을 사용하였다(Table 1). 검사항목은 성인과 소아의 추정 사구체여과율 항목을 포함하여 총 32항목이었다. 요화학검사의 정도관리물질은 Bio-Rad사의 Lyphocheck Quantitative Urine Control (Bio-Rad Laboratories)을 사용하였다(Table 2). 사전에 공지된 일정에 따라 물질을 수령한 참여기관에서는 검사 시행 후 지정된

회신 마감일 이내에 대한임상검사정도관리협회 신빙도조사사업 홈페이지(<http://eqas.keqas.org>)에 결과를 입력하도록 하였다. 기기회사와 시약회사로부터 제공된 검사항목별 검사방법, 기기와 시약에 대해 기초자료를 검토한 바를 토대로 참여기관이 홈페이지상에서 해당 검사항목에 대한 검사정보 선택과 결과 입력이 가능하도록 전산체계를 구축하였다. 결과 입력기간 내에 최종 전송을 했더라도 결과 수정이 가능하도록 하였다.

3. 검사법 신분류체계 적용

일반화학검사 프로그램의 검사항목별 검사방법 분류체계의 현황과 기기시약별 지정된 검사방법과 동료집단 설정상의 개선점을 분석하였고, 일반화학검사 관련 국내·외 주요 관련 자료와 문헌 및 검사기기와 시약업체로부터 제공되는 설명서를 검토함으로써 참가기관에서 제공하는 검사방법에 대한 정보 및 신빙도조사 결과에 대해서 정확한 동료집단 분류 및 통계분

Table 1. Control materials analyzed and released dates from the trials of general chemistry in 2018

Trial	Material no.	Manufacturer	Product name	Lot no.	Released date
1st	CC-18-01	Randox	Human low serum 5 mL	273ULCM	26 February
	CC-18-02	Randox	Human normal serum 5 mL	1250UNCM	
	CC-18-03	Randox	Human elevated serum 5 mL	973UECM	
2nd	CC-18-04	Randox	Human low serum 5 mL	274ULCM	23 April
	CC-18-05	Randox	Human normal serum 5 mL	1251UNCM	
	CC-18-06	Randox	Human elevated serum 5 mL	974UECM	
3rd	CC-18-07	Bio-Rad	Lyphocheck assayed & unassayed chemistry control	26441	20 August
	CC-18-08	Bio-Rad	Lyphocheck assayed & unassayed chemistry control	26442	
	CC-18-09	Bio-Rad	Lyphocheck assayed & unassayed chemistry control	26432	
4th	CC-18-10	Bio-Rad	Lyphocheck assayed & unassayed chemistry control	28831	1 October
	CC-18-11	Bio-Rad	Lyphocheck assayed & unassayed chemistry control	28832	
	CC-18-12	Bio-Rad	Lyphocheck assayed & unassayed chemistry control	26452	

The instruments were from the following companies: Randox Laboratories (London, UK) and Bio-Rad Laboratories (Hercules, CA, USA).

Table 2. Control materials analyzed and released dates from the trials of urine chemistry in 2018

Trial	Material no.	Manufacturer	Product name	Lot no.	Released date
1st	CUC-18-01	Bio-Rad	Lyphocheck quantitative urine control	63381	12 March
	CUC-18-02	Bio-Rad	Lyphocheck quantitative urine control	63382	
	CUC-18-03	Bio-Rad	Lyphocheck quantitative urine control	63383	
2nd	CUC-18-04	Bio-Rad	Lyphocheck quantitative urine control	63421	10 September
	CUC-18-05	Bio-Rad	Lyphocheck quantitative urine control	63422	
	CUC-18-06	Bio-Rad	Lyphocheck quantitative urine control	63411	

The instruments were from the following company: Bio-Rad Laboratories (Hercules, CA, USA).

석의 기초가 될 수 있는 새로운 검사방법 명칭과 분류체계를 정립하여 일반화학검사 프로그램에 적용하였다.

Table 3. Number of laboratories that participated in each test of general chemistry in 2018

Test	Trials			
	1st	2nd	3rd	4th
Alanine aminotransferase	1,568	1,639	1,676	1,660
Albumin	1,443	1,512	1,548	1,534
Alkaline phosphatase	1,385	1,451	1,479	1,467
Amylase	800	825	820	814
Aspartate aminotransferase	1,567	1,638	1,675	1,659
Bilirubin, direct	782	813	813	809
Bilirubin, total	1,456	1,521	1,557	1,543
Calcium	698	724	736	734
Chloride	991	1,034	1,051	1,046
Cholesterol, total	1,557	1,626	1,662	1,646
Creatine kinase	652	667	676	673
Creatinine	1,520	1,595	1,640	1,628
Gamma-glutamyl transpeptidase	1,520	1,588	1,622	1,608
Glucose	1,543	1,614	1,651	1,635
High density lipoprotein cholesterol	1,443	1,501	1,533	1,519
Iron	403	416	421	419
Lactate dehydrogenase	871	899	916	909
Lipase	392	399	408	403
Low density lipoprotein cholesterol	880	911	920	916
Magnesium	280	283	290	290
Osmolality	146	151	151	149
Phosphorus	649	676	693	687
Potassium	1,004	1,048	1,064	1,060
Protein, total	1,429	1,494	1,529	1,516
Sodium	1,004	1,048	1,064	1,060
Total CO ₂	201	209	216	214
Total iron-binding capacity	367	376	382	381
Triglyceride	1,515	1,587	1,617	1,601
Urea nitrogen	1,499	1,570	1,602	1,591
Uric acid	1,185	1,242	1,262	1,254
Estimated glomerular filtration rate, adult	279	287	295	293
Estimated glomerular filtration rate, child	180	184	189	193

4. 결과 판정 및 분석

일반화학검사와 요화학검사 각각에 대해서 각 기관에서 입력한 각 검사항목에 대한 정보와 결과를 기반으로 검사방법, 기기, 시약에 따라 통계분석을 시행하였고 이를 전체 참여기관의 특성을 보여주는 공통보고서와 개별기관의 평가자료를 보여주는 기관별 보고서로 나누어 보고하였다. 공통보고서는 3 단계로 그룹화하여 통계치를 제시하였다. 전체 참여기관에 해당하는 통계, 검사방법을 기준분류로 한 그룹의 통계와 검사방법별로 시약회사를 세 분류한 그룹의 통계를 각각 제시하였다.

제시된 통계에는 각 그룹별 참여기관 수, 평균, 표준편차, 변동계수, 중앙값, 최소값과 최대값이 포함되도록 하였고 참여기관 수, 중앙값, 최소값과 최대값은 이상치를 제거하지 않은 수치를 제시하였고 평균, 표준편차와 변동계수는 각 그룹별로 이상치를 제거한 후 산출된 수치를 사용하였다. 또한 해당 분류에서 이상치를 제거한 후 기관 수가 8개 미만인 경우 평균, 표준편차와 변동계수를 제시하지 않았고 기관 수가 3개 미만인 경우 중앙값도 제시하지 않았다. 이상치는 각 해당 분류에서 75퍼센타일 값(Q3)과 25퍼센타일 값(Q1)의 차(Q3-Q1, interquartile range [IQR])의 1.5배를 초과하여 Q1보다 낮거나 Q3보다 높은 결과값($<Q1-1.5 \times IQR$ 또는 $>Q3+1.5 \times IQR$)으로 설정하였다.

개별보고서는 각 검사항목별로 통계치를 보여주는 표, 히스토그램과 레비-제닝스 차트로 구성되도록 하였다. 통계치를 제시한 표에는 각 기관의 결과값과 각 분류별 통계치를 제

Table 4. Number of laboratories that participated in each test of urine chemistry in 2018

Test	Trials	
	1st	2nd
Albumin	166	172
Calcium	151	155
Chloride	177	183
Creatinine	206	209
Glucose	135	137
Magnesium	109	108
Phosphorus	138	139
Potassium	178	184
Protein	173	177
Sodium	180	186
Urea nitrogen	152	156
Uric acid	145	146
Urine human chorionic gonadotropin (qualitative)	210	215

Table 5. Peer-group coefficients of variation (%) for the tests and trials of general chemistry in 2018

Test	Trials															
	CC-18-01	CC-18-02	CC-18-03	CC-18-04	CC-18-05	CC-18-06	CC-18-07	CC-18-08	CC-18-09	CC-18-10	CC-18-11	CC-18-12				
Alanine transaminase	7.4	9.2	6.1	7.5	9.2	6.5	6.6	5.8	5.8	5.8	7.3	6.0				
Albumin	5.2	4.4	5.2	3.6	4.3	5.1	4.8	5.4	5.4	5.6	4.9	5.5				
Alkaline phosphatase	43.6	40.6	37.1	44.8	41.0	37.4	44.1	36.8	38.2	35.8	44.9	36.0				
Amylase	15.9	15.0	18.3	15.4	14.4	18.7	12.7	18.9	18.8	17.9	12.9	18.6				
Aspartate aminotransferase	6.7	8.5	5.3	6.3	8.1	5.0	5.1	4.1	4.3	4.3	5.0	4.3				
Bilirubin, direct	17.2	14.7	13.9	14.3	18.0	12.2	20.7	17.4	18.7	19.4	18.6	15.8				
Bilirubin, total	12.0	8.9	6.1	10.5	8.2	5.9	9.4	6.0	6.3	6.3	10.1	6.5				
Calcium	3.1	2.7	2.3	3.1	3.0	2.3	3.3	3.0	2.9	2.9	4.4	2.7				
Chloride	3.0	3.0	2.4	3.1	3.3	2.3	2.9	3.0	3.2	3.0	3.3	2.8				
Cholesterol, total	3.0	2.9	3.1	3.4	2.7	3.1	3.0	5.0	5.1	4.8	3.1	4.7				
Creatine kinase	5.2	5.5	5.1	4.9	4.8	4.9	3.6	4.4	4.3	4.5	3.5	4.6				
Creatinine	9.4	8.1	5.5	8.5	7.6	5.4	11.7	7.6	7.7	7.2	13.4	7.3				
Gamma-glutamyl transpeptidase	6.3	6.2	5.8	6.2	5.6	5.4	7.6	7.7	7.5	7.8	7.8	7.4				
Glucose	3.3	3.3	3.2	3.6	3.4	3.0	4.0	3.1	3.0	2.7	4.1	3.0				
High density lipoprotein cholesterol	8.3	11.3	11.2	7.6	10.2	11.8	11.1	12.6	13.8	14.1	12.6	12.8				
Iron	3.5	3.8	3.5	3.4	3.5	3.2	3.4	4.1	3.8	3.6	3.1	3.8				
Lactate dehydrogenase	37.6	38.4	39.1	37.6	38.4	39.2	37.9	39.8	40.1	40.4	37.5	40.6				
Lipase	9.2	12.3	18.0	10.2	13.7	17.9	8.8	13.9	14.0	14.4	10.2	14.1				
Low density lipoprotein cholesterol	15.7	13.2	20.8	14.3	12.7	21.8	7.3	7.8	6.3	10.4	9.0	5.9				
Magnesium	3.5	5.4	2.9	0.0	3.1	2.1	3.8	3.2	3.1	3.9	5.5	3.2				
Osmolality	1.2	1.2	1.2	1.0	1.1	0.9	1.3	1.2	1.2	1.3	1.3	1.3				
Phosphorus	4.9	3.2	3.0	3.3	2.9	2.9	2.4	2.6	2.3	2.5	2.3	2.3				
Potassium	2.9	1.9	2.3	3.0	1.9	2.4	1.9	2.3	2.3	2.3	1.9	2.2				
Protein, total	2.1	2.8	3.6	3.2	2.8	3.9	3.3	3.8	4.0	3.8	3.4	3.7				
Sodium	1.9	1.2	1.4	1.9	1.2	1.3	1.1	1.2	1.3	1.3	1.2	1.4				
Total CO ₂	9.2	7.8	5.2	8.8	8.2	6.8	6.2	6.5	5.7	5.0	5.1	5.7				
Total iron-binding capacity	3.8	4.0	3.3	3.7	3.7	3.2	3.2	2.9	3.4	3.2	3.3	3.5				

(Continued to the next page)

Table 5. Continued

Test	Trials											
	CC-18-01	CC-18-02	CC-18-03	CC-18-04	CC-18-05	CC-18-06	CC-18-07	CC-18-08	CC-18-09	CC-18-10	CC-18-11	CC-18-12
Triglyceride	33.4	19.4	46.8	33.1	20.3	46.3	4.0	5.7	5.5	5.3	4.0	5.5
Urea nitrogen	4.0	4.0	4.1	5.1	4.0	4.3	4.7	3.9	4.9	4.2	5.2	4.3
Uric acid	6.9	4.0	3.8	5.8	3.7	3.8	3.4	3.6	3.3	3.6	4.2	3.5
Estimated glomerular filtration rate, adult	NA	10.5	5.8	12.3	10.2	NA	10.0	NA	6.5	6.5	NA	0.0
Estimated glomerular filtration rate, child	42.6	NA	NA	NA	NA	38.4	NA	56.1	NA	NA	44.7	NA

Abbreviation: NA, not applicable.

시하고 기준분류와 세분류에서는 표준편차지수(standard deviation index, SDI)를 함께 제시하였다. 전체 결과에 대해서는 SDI를 제시하지 않았고 각 그룹에서 이상치 제거 후 기관 수가 8개 미만일 경우 SDI를 제시하지 않았다. 표준편차가 0이지만 기관의 결과값이 평균과 다를 경우에도 SDI를 제시하지 않았다.

히스토그램에서는 전체 기관의 분포와 기준 분류별 분포를 제시하였고 각 기관의 위치를 표시하였다. 레비-제닝스 차트는 기준 분류별 SDI를 이용하여 작성하였다.

결과 및 고찰

2018년 일반화학검사 프로그램의 특징으로 검사항목별로 새로운 검사방법 명칭과 분류체계를 적용하여 이를 기반으로 통계분석 및 결과를 보고한 점과 요화학검사 프로그램에 요 hCG 정성검사를 추가한 점을 들 수 있다. 기존 검사방법 분류 체계로서는 수용 안 되는 시약이 증가함에 따라 검사방법을 기타 방법으로 선택하는 사례가 증가하였고, 일부 검사항목에 대해서 현재에는 사용되지 않는 과거의 검사방법이 그대로 적용되거나 제조사 명칭이 검사방법 명칭으로 사용된 사례가 있었다. 검사방법 명칭과 관련된 국내·외 관련 자료를 수집하고 분석하여 검사항목별 신 분류안을 적용함으로써 정확한 동료 집단 설정과 데이터 오분류 및 누락 방지를 통해 신뢰할 수 있는 신빙도조사 결과를 제공할 수 있게 되었다.

일반화학검사 프로그램에서는 1,000개 이상의 기관이 참여

Table 6. Peer-group coefficients of variation (%) for the tests and trials of urine chemistry in 2018

Test	Trials					
	CUC-18-01	CUC-18-02	CUC-18-03	CUC-18-04	CUC-18-05	CUC-18-06
Albumin	30.0	19.0	19.4	14.2	20.3	32.5
Calcium	4.0	2.7	2.3	4.3	2.6	3.4
Chloride	8.8	2.5	2.5	9.0	2.4	8.7
Creatinine	5.5	4.9	4.8	5.2	4.9	5.1
Glucose	2.2	2.2	2.2	3.3	2.6	1.3
Magnesium	3.0	2.8	3.5	3.3	3.6	3.6
Phosphorus	2.5	2.6	2.9	2.6	2.8	2.8
Potassium	2.1	3.1	3.4	1.8	3.6	1.9
Protein	11.0	9.0	8.6	9.9	9.0	10.5
Sodium	2.8	1.2	1.1	2.2	1.1	2.3
Urea nitrogen	2.9	2.8	2.3	3.3	3.1	3.2
Uric acid	4.3	3.5	3.6	4.6	3.7	4.5

Table 7. Distribution of analytical methods (principle) and coefficients of variation (%) for the principles of general chemistry in 2018

Test/method	Trials															
	1st				2nd				3rd				4th			
	Lab*	CC- 18-01	CC- 18-02	CC- 18-03	Lab	CC- 18-04	CC- 18-05	CC- 18-06	Lab	CC- 18-07	CC- 18-08	CC- 18-09	Lab	CC- 18-10	CC- 18-11	CC- 18-12
Alanine aminotransferase	1,568	7.4	9.2	6.1	1,639	7.5	9.2	6.5	1,676	6.6	5.8	5.8	1,660	5.8	7.3	6.0
Dry chemistry	11	11.1	16.6	3.4	12	12.8	15.0	2.2	10	3.6	3.2	3.2	10	3.4	28.8	2.4
LDH with P5P	13	16.6	16.6	3.3	14	13.7	12.3	1.5	15	7.0	2.8	2.0	14	0.5	13.6	3.6
LDH without P5P	1,461	7.4	9.0	6.0	1,557	6.9	9.2	6.3	1,616	6.6	5.7	5.7	1,601	5.7	7.2	5.9
Other method	83	7.6	11.3	8.2	56	8.0	7.8	8.3	35	8.0	7.6	8.3	35	7.9	7.4	7.7
Albumin	1,443	5.2	4.4	5.2	1,512	3.6	4.3	5.1	1,548	4.8	5.4	5.4	1,534	5.6	4.9	5.5
Dye binding-BCG	1,380	5.1	4.3	5.1	1,463	3.6	4.3	5.1	1,514	4.8	5.4	5.3	1,499	5.6	4.9	5.5
Dye binding-BCP	7	4.8	4.2	6.0	7	5.8	4.7	5.9	8	4.4	2.9	5.5	8	5.6	4.2	6.2
Other method	56	6.4	4.8	5.8	42	5.2	4.1	3.0	26	5.0	2.5	2.9	27	4.7	5.1	5.8
Alkaline phosphatase	1,385	43.6	40.6	37.1	1,451	44.8	41.0	37.4	1,479	44.1	36.8	38.2	1,467	35.8	44.9	36.0
Other method	73	37.0	35.9	32.5	48	39.6	37.2	33.3	26	45.0	36.9	37.5	26	19.4	41.4	19.1
PNPP, AMP buffer	780	13.2	14.7	16.2	830	13.2	14.5	16.0	856	13.7	16.3	16.8	847	15.8	12.6	15.9
PNPP, DEA buffer	147	14.9	15.5	12.9	154	11.5	11.8	11.5	164	10.3	9.7	9.8	160	11.5	12.7	11.0
PNPP, EAE buffer	385	4.0	3.9	3.5	419	4.5	3.9	3.6	433	5.7	4.7	5.2	434	4.3	5.3	4.8
Amylase	800	15.9	15.0	18.3	825	15.4	14.4	18.7	820	12.7	18.9	18.8	814	17.9	12.9	18.6
Dry chemistry	8	5.0	4.1	2.2	8	11.9	4.4	5.3	7	3.4	2.6	1.2	7	3.3	8.5	3.3
Hydrolysis of 2-chloro-4-nitrophenyl-azido-deoxy-maltopentaoside	6	2.8	1.5	2.1	4	16.9	18.5	16.9	5	0.6	0.2	1.0	4	1.2	8.3	2.1
Hydrolysis of 2-chloro-4-nitrophenyl-galactopyranosylmaltoside	94	1.6	2.0	1.4	101	1.9	1.8	1.7	106	2.3	1.4	1.3	103	1.8	2.1	1.6
Hydrolysis of 2-chloro-4-nitrophenyl-α-D-maltotriose	198	3.2	3.4	2.9	205	5.1	3.0	2.4	212	2.8	2.3	1.9	215	2.9	3.2	3.1
Hydrolysis of 4,6-ethylidene-4-nitrophenyl-maltoheptaose	318	3.6	4.6	4.1	342	4.1	4.7	3.7	345	4.3	3.6	3.8	342	3.9	4.3	3.6
Hydrolysis of 4-nitrophenylbenzyl-α-maltopentaose	130	15.7	15.4	17.0	131	15.9	14.8	18.6	134	12.8	18.4	18.2	131	18.4	13.1	18.4
Other method	46	15.7	16.2	17.5	34	16.2	13.8	19.9	11	15.2	19.2	19.2	12	19.8	13.1	20.5
(Continued to the next page)																

(Continued to the next page)

Table 7. Continued

Test/method	Trials															
	1st				2nd				3rd				4th			
	Lab*	CC-18-01	CC-18-02	CC-18-03	Lab	CC-18-04	CC-18-05	CC-18-06	Lab	CC-18-07	CC-18-08	CC-18-09	Lab	CC-18-10	CC-18-11	CC-18-12
Aspartate aminotransferase	1,567	6.7	8.5	5.3	1,638	6.3	8.1	5.0	1,675	5.1	4.1	4.3	1,659	4.3	5.0	4.3
Dry chemistry	11	12.8	13.1	3.8	12	9.7	5.3	5.6	10	0.0	0.6	1.3	10	2.0	1.7	2.2
MDH with P5P	13	22.5	27.7	9.6	14	23.6	25.9	10.2	15	4.1	3.8	5.7	14	7.4	5.4	4.9
MDH without P5P	1,464	6.6	8.5	5.1	1,561	6.3	8.0	4.9	1,618	5.1	4.1	4.1	1,603	4.2	4.9	4.3
Other method	79	8.0	9.2	8.2	51	7.7	9.5	6.4	32	5.9	7.0	6.5	32	7.4	7.2	6.5
Bilirubin, direct	782	17.2	14.7	13.9	813	14.3	18.0	12.2	813	20.7	17.4	18.7	809	19.4	18.6	15.8
Copper ion oxidation	38	15.9	11.5	9.6	45	9.8	14.5	13.1	48	2.2	6.4	9.6	47	10.6	1.2	8.6
Diazonium salt with blank	296	8.7	6.2	12.4	314	6.7	8.0	11.5	325	22.6	5.2	5.3	325	5.7	18.8	5.4
Diazo-sulfanilic acid with blank	30	43.9	43.4	28.9	46	35.6	28.0	27.9	48	35.0	34.1	34.1	47	27.6	32.7	26.8
Diazo-sulfanilic acid without blank	15	36.9	53.4	30.1	16	38.1	41.9	23.4	14	38.6	25.0	27.0	15	29.0	34.8	27.1
Enzymatic oxidation	5	9.5	7.8	3.7	5	9.1	5.6	8.3	6	22.1	5.1	5.4	6	22.0	22.3	21.0
Other method	74	30.0	20.8	25.1	46	21.3	22.4	21.6	22	28.7	17.4	15.1	22	21.0	21.6	29.1
Vanadate oxidation	324	3.9	9.7	6.3	341	11.0	9.2	9.0	350	14.2	12.1	12.0	347	9.7	11.9	13.7
Bilirubin, total	1,456	12.0	8.9	6.1	1,521	10.5	8.2	5.9	1,557	9.4	6.0	6.3	1,543	6.3	10.1	6.5
Copper ion oxidation	66	7.7	4.9	4.1	73	4.6	5.0	4.7	85	6.4	4.4	4.1	86	5.1	6.0	5.3
Diazo-caffeine, sodium benzoate with blank	7	16.8	15.4	9.2	7	17.0	18.8	10.5	8	7.9	10.3	10.4	8	7.2	7.5	12.0
Diazo-dimethyl sulfoxide with blank	125	14.0	13.0	6.6	135	14.0	13.5	7.2	128	8.8	6.2	7.0	123	6.5	6.7	6.7
Diazo-dimethyl sulfoxide without blank	85	17.0	16.2	9.3	97	13.9	16.8	6.7	107	13.1	5.5	5.7	108	5.8	14.7	5.9
Diazo-diphenylamine with blank	12	18.4	13.3	4.6	12	14.2	9.3	5.9	10	14.5	5.9	4.5	10	8.8	7.4	2.8
Diazonium salt-surfactant with blank	452	13.6	10.0	5.6	476	12.0	9.7	5.1	489	11.4	6.1	5.7	485	6.3	10.6	6.7
Diazonium salt-surfactant without blank	37	9.2	5.7	11.6	38	7.8	10.1	9.7	40	17.4	12.3	12.3	39	10.9	12.8	10.7
Enzymatic oxidation	24	6.3	5.6	4.1	27	4.4	4.3	5.1	24	6.7	7.3	7.4	24	6.1	7.7	5.5
Other method	72	15.5	12.5	8.6	54	11.6	12.3	7.6	39	9.7	4.6	5.5	39	6.5	10.6	6.2
Vanadate oxidation	576	3.1	5.2	4.6	602	2.7	5.3	4.3	626	2.8	4.3	4.3	620	4.5	6.1	4.2
Calcium	698	3.1	2.7	2.3	724	3.1	3.0	2.3	736	3.3	3.0	2.9	734	2.9	4.4	2.7
Colorimetry arsenazo III	132	4.0	2.8	3.6	144	4.3	3.6	3.9	152	3.7	3.1	3.3	155	3.7	2.7	3.5
Colorimetry_methylxlenol blue	20	3.0	2.4	3.6	23	2.6	2.6	2.7	23	1.5	1.3	1.1	22	1.6	1.6	1.9
Colorimetry_OPC	408	2.9	2.5	1.8	422	3.0	2.1	2.2	427	3.0	2.9	2.6	422	2.6	3.6	2.8
NM-BAPTA	121	2.0	2.1	1.6	126	1.8	1.7	1.3	130	1.6	1.5	1.6	131	1.4	1.7	1.6
Other method	16	3.9	3.9	3.3	8	4.3	3.2	2.2	4	5.6	3.9	2.6	4	2.6	4.0	2.2

(Continued to the next page)

Table 7. Continued

Test/method	Trials															
	1st			2nd			3rd			4th						
	Lab*	CC- 18-01	CC- 18-02	CC- 18-03	Lab	CC- 18-04	CC- 18-05	CC- 18-06	Lab	CC- 18-07	CC- 18-08	CC- 18-09	Lab	CC- 18-10	CC- 18-11	CC- 18-12
Chloride	991	3.0	3.0	2.4	1,034	3.1	3.3	2.3	1,051	2.9	3.0	3.2	1,046	3.0	3.3	2.8
ISE, diluted	539	3.0	2.4	1.8	557	2.9	2.6	1.6	567	2.3	2.1	2.0	569	2.5	3.6	2.5
ISE, undiluted	413	2.0	2.2	2.1	442	2.5	1.9	1.9	452	2.4	2.6	3.2	448	2.6	3.1	2.8
Other method	39	3.4	2.2	1.9	35	2.1	2.6	2.7	32	3.3	5.0	5.3	29	2.8	1.5	2.8
Cholesterol, total	1,557	3.0	2.9	3.1	1,626	3.4	2.7	3.1	1,662	3.0	5.0	5.1	1,646	4.8	3.1	4.7
Cholesterol esterase	1,481	3.0	2.9	3.1	1,574	3.3	2.7	3.1	1,629	3.0	5.0	5.1	1,614	4.8	3.1	4.7
Other method	76	3.3	3.3	2.9	52	3.3	3.0	3.4	33	4.0	4.5	5.8	32	5.9	3.4	4.1
Creatine kinase	652	5.2	5.5	5.1	667	4.9	4.8	4.9	676	3.6	4.4	4.3	673	4.5	3.5	4.6
Creatine phosphate to creatine	201	3.8	4.5	2.9	211	3.7	3.3	3.0	217	3.5	2.4	2.8	214	2.5	3.0	2.8
Creatine phosphate to creatine with activator	411	5.5	5.7	5.6	428	5.2	5.0	5.5	437	3.5	5.1	4.8	439	5.1	3.6	5.1
Dry chemistry	6	1.7	6.3	4.0	6	6.4	6.5	5.4	6	8.2	9.1	8.9	6	4.5	7.7	8.1
Other method	34	7.0	6.3	5.1	22	6.0	6.4	6.7	16	4.0	3.9	4.4	14	3.6	6.5	4.2
Creatinine	1,520	9.4	8.1	5.5	1,595	8.5	7.6	5.4	1,640	11.7	7.6	7.7	1,628	7.2	13.4	7.3
Enzymatic method	66	4.1	5.5	5.6	74	6.9	6.2	3.8	78	13.1	3.6	4.5	76	4.7	31.7	5.7
Kinetic Jaffe with compensation	333	10.8	6.6	3.8	357	10.6	6.2	3.8	371	10.8	6.8	7.5	368	6.0	11.9	6.5
Kinetic Jaffe without compensation	812	7.6	6.9	7.0	867	6.6	6.6	6.6	905	7.3	7.0	7.3	895	6.5	11.4	6.0
Other method	65	13.2	13.8	12.1	47	13.5	12.3	11.0	28	11.2	10.3	10.6	31	12.3	9.0	10.3
Rate blanked compensated kinetic Jaffe method	244	4.2	4.1	3.4	250	4.1	4.2	2.8	258	4.5	3.4	3.5	258	3.1	6.1	3.2
Gamma-glutamyl transpeptidase	1,520	6.3	6.2	5.8	1,588	6.2	5.6	5.4	1,622	7.6	7.7	7.5	1,608	7.8	7.8	7.4
Gamma-glutamyl-carboxy-nitroanilide	1,418	6.3	6.1	5.7	1,511	6.2	5.6	5.4	1,563	7.6	7.7	7.8	1,549	7.7	7.6	7.4
Gamma-glutamyl-p-nitroanilide	14	9.1	8.5	8.8	17	10.1	7.5	9.8	16	12.0	11.8	12.6	16	8.9	9.4	10.4
G-glutamyl-p-nitroanilide (dry chemistry)	12	2.4	21.6	6.5	12	21.4	3.6	11.7	10	4.3	1.7	1.6	10	2.4	6.8	2.3
Other method	76	6.7	7.3	6.7	48	7.0	6.0	4.7	33	8.5	7.0	6.6	33	9.5	11.3	9.0
Glucose	1,543	3.3	3.3	3.2	1,614	3.6	3.4	3.0	1,651	4.0	3.1	3.0	1,635	2.7	4.1	3.0
Glucose oxidase	384	5.4	5.0	4.1	416	5.1	5.0	4.2	441	4.4	4.0	4.2	431	3.7	4.3	4.0
Hexokinase	1,084	3.0	2.8	2.7	1,147	2.8	2.7	2.6	1,179	3.6	2.6	2.7	1,173	2.4	3.5	2.4
Other method	75	5.2	4.7	4.1	51	4.8	4.1	3.0	31	6.3	5.6	4.9	31	5.2	5.5	5.5

(Continued to the next page)

Table 7. Continued

Test/method	Trials															
	1st				2nd				3rd				4th			
	Lab*	CC-18-01	CC-18-02	CC-18-03	Lab	CC-18-04	CC-18-05	CC-18-06	Lab	CC-18-07	CC-18-08	CC-18-09	Lab	CC-18-10	CC-18-11	CC-18-12
High density lipoprotein cholesterol	1,443	8.3	11.3	11.2	1,501	7.6	10.2	11.8	1,533	11.1	12.6	13.8	1,519	14.1	12.6	12.8
	519	4.7	6.3	6.0	552	4.0	5.8	6.6	578	8.7	10.0	9.9	578	8.7	8.8	8.5
Enzymatic with detergent																
Enzymatic with immunoinhibition	204	3.8	4.0	4.8	218	4.4	4.5	6.6	221	3.6	3.4	3.5	222	3.5	4.0	3.3
Enzymatic with others	189	9.3	9.9	15.2	197	8.8	9.1	15.5	210	11.3	13.3	13.1	203	13.5	11.4	12.5
Enzymatic with polyanion precipitation	167	15.9	14.4	19.0	181	17.3	15.6	19.0	185	17.1	9.5	9.3	179	10.8	13.2	9.3
Enzymatic with polyethylene glycol	289	6.2	5.3	9.5	299	9.1	7.4	9.8	310	5.1	5.5	6.5	307	9.8	7.4	6.2
Other method	74	10.8	12.6	13.5	53	11.0	12.2	11.0	28	9.2	13.9	13.3	29	9.2	15.1	12.3
Iron	403	3.5	3.8	3.5	416	3.4	3.5	3.2	421	3.4	4.1	3.8	419	3.6	3.1	3.8
Bathophenanthroline without deproteinization	137	1.9	2.0	1.6	142	2.1	2.2	1.6	145	1.4	2.5	2.3	143	2.1	1.4	2.3
Ferene with deproteinization	3	6.7	7.1	6.5	3	10.0	10.2	0.0	3	2.5	8.1	3.8	3	2.1	0.4	0.8
Ferrozine without deproteinization	137	2.3	2.2	2.1	142	2.3	3.1	2.4	146	2.0	3.6	2.4	146	2.7	1.8	3.0
Nitroso-PSAP without deproteinization	34	1.9	1.9	1.8	42	2.5	1.9	1.4	43	1.7	3.1	2.7	43	2.9	1.7	3.2
Pyridyl AZO dye ascorbate without deproteinization	2	19.0	13.5	9.3	3	17.6	11.5	10.9	2	8.7	28.3	2.5	2	5.0	0.8	0.0
Tripyridyltriazine without deproteinization	77	2.1	1.6	1.6	80	2.3	1.9	1.4	81	1.4	2.8	2.6	80	2.1	0.9	2.3
Lactate dehydrogenase	871	37.6	38.4	39.1	899	37.6	38.4	39.2	916	37.9	39.8	40.1	909	40.4	37.5	40.6
Lactate to pyruvate	443	4.7	4.7	4.4	460	4.6	4.5	4.1	485	4.9	5.2	5.1	480	4.9	4.8	4.8
Other method	39	34.0	34.0	35.2	27	37.3	35.9	34.3	11	32.3	31.9	32.1	12	34.0	31.1	33.2
Pyruvate to lactate	382	7.5	7.8	9.3	406	7.6	8.2	9.5	414	7.1	7.2	7.4	411	7.2	7.1	7.3
Pyruvate to lactate (dry chemistry)	7	53.4	53.2	53.1	6	9.0	9.1	9.2	6	1.5	3.0	1.9	6	4.5	2.5	5.1
Lipase	392	9.2	12.3	18.0	399	10.2	13.7	17.9	408	8.8	13.9	14.0	403	14.4	10.2	14.1
Hydrolysis of 1,2-diglyceride with quinone dye	100	7.7	9.3	13.3	104	7.5	10.8	8.4	103	4.2	5.0	6.1	82	2.8	3.8	2.3
Hydrolysis of 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin) ester	259	5.4	4.9	6.9	273	6.3	5.9	7.3	285	8.8	13.2	13.4	302	14.9	8.4	14.7
Hydrolysis of 1-oleoyl-2,3-diacetyl glycerol	9	2.1	4.1	5.9	9	4.0	4.2	5.9	8	2.7	2.4	2.8	8	2.6	4.3	2.0
Other method	24	21.3	21.0	20.5	13	22.0	15.4	15.6	12	8.7	12.0	12.6	11	5.1	14.1	9.8

(Continued to the next page)

Table 7. Continued

Test/method	Trials															
	1st				2nd				3rd				4th			
	Lab*	CC- 18-01	CC- 18-02	CC- 18-03	Lab	CC- 18-04	CC- 18-05	CC- 18-06	Lab	CC- 18-07	CC- 18-08	CC- 18-09	Lab	CC- 18-10	CC- 18-11	CC- 18-12
Low-density lipoprotein cholesterol	880	15.7	13.2	20.8	911	14.3	12.7	21.8	920	7.3	7.8	6.3	916	10.4	9.0	5.9
Enzymatic with detergent	587	16.1	12.5	22.4	618	14.9	12.4	23.9	642	7.4	7.3	6.4	640	10.9	9.8	5.8
Enzymatic with others	229	13.2	11.0	15.3	233	11.7	10.8	15.9	230	7.3	7.2	6.9	229	7.1	6.0	7.5
Enzymatic with polyethylene glycol	32	9.7	9.7	21.2	34	7.4	4.1	19.1	34	6.4	8.2	9.9	33	7.7	5.6	5.5
Other method	32	14.3	13.6	21.2	26	14.4	15.0	21.4	14	6.3	8.5	7.5	14	12.4	8.4	9.8
Magnesium	280	3.5	5.4	2.9	283	0.0	3.1	2.1	290	3.8	3.2	3.1	290	3.9	5.5	3.2
Colorimetry_Xylydyl blue	268	3.4	5.3	2.9	274	0.0	3.1	2.2	286	3.8	3.2	3.1	286	3.9	5.4	3.2
Dry chemistry	4	6.1	5.4	5.3	3	2.9	4.4	1.3	2	8.3	1.7	1.6	2	3.2	11.5	3.1
Osmolality	146	1.2	1.2	1.2	151	1.0	1.1	0.9	151	1.3	1.2	1.2	149	1.3	1.3	1.3
Freezing point depression osmometer	128	1.3	1.1	1.3	134	1.1	1.2	0.9	138	1.2	1.0	1.2	138	1.4	1.3	1.3
Other method	18	1.2	1.4	1.2	17	0.8	0.6	1.8	13	1.3	1.0	1.1	11	1.6	1.8	2.0
Phosphorus	649	4.9	3.2	3.0	676	3.3	2.9	2.9	693	2.4	2.6	2.3	687	2.5	2.3	2.3
Enzymatic	5	2.7	2.2	2.2	4	11.6	10.7	9.7	7	2.2	1.9	1.7	7	3.4	1.8	2.7
Molybden blue colorimetry	139	3.3	1.8	2.3	147	0.0	1.9	2.2	157	2.4	2.2	1.9	155	2.0	2.3	2.1
Other method	18	4.4	7.5	7.9	11	11.3	9.3	7.6	3	2.6	3.3	3.2	4	4.4	6.9	7.4
Phosphomolybdate	487	3.4	3.1	2.5	514	3.3	1.9	2.2	526	2.4	2.2	2.3	521	2.2	2.3	2.2
Potassium	1,004	2.9	1.9	2.3	1,048	3.0	1.9	2.4	1,064	1.9	2.3	2.3	1,060	2.3	1.9	2.2
ISE, diluted	541	2.5	1.8	1.3	559	2.4	1.7	1.2	569	1.8	1.4	1.6	571	1.5	1.8	1.4
ISE, undiluted	424	3.0	2.8	2.6	454	3.0	2.1	2.8	463	2.1	1.6	2.5	460	1.5	2.1	1.5
Other method	39	5.7	3.5	3.8	35	3.1	2.4	3.4	32	2.5	4.2	3.9	29	2.6	2.1	3.5
Protein, total	1,429	2.1	2.8	3.6	1,494	3.2	2.8	3.9	1,529	3.3	3.8	4.0	1,516	3.8	3.4	3.7
Biuret method	1,370	2.1	2.8	3.5	1,451	3.2	2.8	3.9	1,502	3.3	3.8	4.0	1,487	3.8	3.3	3.7
Other method	59	5.5	5.2	6.3	43	3.7	3.8	4.7	27	4.5	5.8	4.7	29	5.1	4.6	5.2
Sodium	1,004	1.9	1.2	1.4	1,048	1.9	1.2	1.3	1,064	1.1	1.2	1.3	1,060	1.3	1.2	1.4
ISE, diluted	504	1.2	1.1	1.0	526	1.2	1.0	0.9	537	0.7	1.1	1.1	539	1.2	1.1	1.2
ISE, undiluted	461	1.8	1.6	1.4	487	1.8	1.6	1.5	494	1.2	1.4	1.6	491	1.5	1.4	1.7
Other method	39	1.9	1.4	2.2	35	1.9	1.4	1.9	33	1.9	2.1	1.8	30	1.8	1.5	2.0
Total CO ₂	201	9.2	7.8	5.2	209	8.8	8.2	6.8	216	6.2	6.5	5.7	214	5.0	5.1	5.7
Other method	10	8.6	5.3	9.5	7	5.4	5.9	7.7	6	12.1	10.2	4.3	5	5.0	7.1	4.7
Phosphoenolpyruvate carboxylase	191	9.2	7.6	5.7	202	9.2	8.4	6.6	210	6.2	6.4	5.6	209	4.9	4.6	5.7

(Continued to the next page)

Table 7. Continued

Test/method	Trials															
	1st			2nd			3rd			4th						
	Lab*	CC- 18-01	CC- 18-02	CC- 18-03	Lab	CC- 18-04	CC- 18-05	CC- 18-06	Lab	CC- 18-07	CC- 18-08	CC- 18-09	Lab	CC- 18-10	CC- 18-11	CC- 18-12
Total iron-binding capacity	367	3.8	4.0	3.3	376	3.7	3.7	3.2	382	3.2	2.9	3.4	381	3.2	3.3	3.5
Bathophenanthroline	123	3.3	2.7	2.3	131	2.4	2.2	2.1	136	1.6	2.5	2.5	134	2.1	2.0	2.9
Chromazural B	18	2.3	2.0	4.5	19	3.2	2.8	3.2	17	3.6	2.8	2.9	17	3.4	4.3	3.0
Ferrozine	105	3.5	3.5	3.9	108	4.4	3.5	3.1	112	2.4	3.0	3.4	114	3.3	2.8	3.2
Nitroso-PSAP	97	2.3	2.2	2.1	104	3.1	2.3	2.2	110	2.5	2.4	2.7	108	2.2	2.9	2.1
Other method	24	4.2	6.8	5.6	14	2.4	2.1	7.3	7	8.5	11.0	10.0	8	12.1	4.7	12.0
Triglyceride	1,515	33.4	19.4	46.8	1,587	33.1	20.3	46.3	1,617	4.0	5.7	5.5	1,601	5.3	4.0	5.5
Enzymatic with free glycerol elimination	488	5.7	5.3	7.1	518	5.5	6.0	7.0	526	2.8	3.3	3.2	527	3.1	2.8	2.6
Enzymatic without free glycerol elimination	952	4.7	4.5	4.3	1,019	4.7	4.1	4.0	1,061	4.8	6.7	6.6	1,045	6.4	4.5	6.3
Other method	75	35.7	19.7	46.1	50	33.2	20.3	44.1	30	6.0	6.2	6.5	29	5.7	4.4	3.3
Urea nitrogen	1,499	4.0	4.0	4.1	1,570	5.1	4.0	4.3	1,602	4.7	3.9	4.9	1,591	4.2	5.2	4.3
Other method	69	7.7	5.0	3.6	48	5.3	6.1	6.1	29	6.8	9.4	7.2	29	10.0	8.9	7.9
Urease with colorimetry	18	7.9	4.4	5.6	19	9.6	7.7	6.9	18	6.0	8.9	9.1	17	9.5	6.1	8.7
Urease with GLDH	1,411	4.0	3.8	4.1	1,502	5.0	4.0	4.2	1,554	4.7	3.8	4.9	1,544	4.2	5.1	4.3
Uric acid	1,185	6.9	4.0	3.8	1,242	5.8	3.7	3.8	1,262	3.4	3.6	3.3	1,254	3.6	4.2	3.5
Other method	48	7.2	6.2	5.2	33	6.1	5.1	4.5	20	8.6	5.9	7.0	20	5.1	7.8	4.5
Uricase	1,131	6.9	4.0	3.8	1,203	5.9	3.6	3.8	1,236	3.3	3.6	3.3	1,228	3.4	4.2	3.5
Uricase (dry chemistry)	6	1.7	1.7	1.9	6	3.4	1.8	1.7	6	1.1	1.3	1.2	6	0.6	2.5	2.0
Estimated glomerular filtration rate, adult	279	10.5	5.8	5.8	287	12.3	10.2	10.2	295	10.0	6.5	6.5	293	6.5	0.0	0.0
Others	19	15.1	0.0	0.0	17	10.6	15.7	15.7	18	16.6	21.3	21.3	17	17.2	28.2	28.2
CKD-EPI	48	8.7	5.1	5.1	51	8.3	10.4	10.4	53	8.9	6.5	6.5	53	5.8	0.0	0.0
Cockcroft-Gault	10	8.9	7.0	7.0	11	8.1	11.9	11.9	8	11.3	25.1	25.1	9	8.8	8.5	8.5
MDRD 4 variable (IDMS-traceable)	132	9.2	5.4	5.4	135	11.6	10.3	10.3	142	9.9	6.0	6.0	141	0.0	0.0	0.0
MDRD 4 variable (non IDMS-traceable)	69	8.9	5.2	5.2	72	10.2	8.5	8.5	71	11.5	7.3	7.3	71	9.7	8.9	8.9
MDRD 6 variable	1				1				3	18.5	4.9	4.9	2	0.0	0.0	0.0
(Continued to the next page)																

(Continued to the next page)

Table 7. Continued

Test/method	Trials															
	1st				2nd				3rd				4th			
	Lab*	CC-18-01	CC-18-02	CC-18-03	Lab	CC-18-04	CC-18-05	CC-18-06	Lab	CC-18-07	CC-18-08	CC-18-09	Lab	CC-18-10	CC-18-11	CC-18-12
Estimated glomerular filtration rate, child	45	42.6			45			38.4	43		56.1		44		44.7	
Others	18	70.3			16			53.0	16		63.9		15		61.9	
Cockcroft-Gault	5	12.8			5			0.0	4		134.4		4		8.9	
Schwartz	16	15.5			16			17.0	15		19.1		17		20.4	
Updated bedside Schwartz	6	1.3			8			4.6	8		7.2		8		8.0	

Abbreviations: LDH, lactate dehydrogenase; P5P, pyridoxal-5-phosphate; BCG, bromocresol green; PNPP, para nitrophenylphosphate; AMP, 2-amino-2-methyl-1-propanol; DEA, diethanolamine; EAE, 2-ethylaminoethanol; MDH, malate dehydrogenase; OCP, o-cresolphthalein complexone; NM-BAPTA, 5-nitro-5'-methyl-BAPTA; ISE, ion-selective electrodes; Nitroso-PSAP, 2-nitroso-5-(N-propyl-N-sulfo-propylamino)-phenol; GLDH, glutamate dehydrogenase; CKD-EPI, chronic kidney disease epidemiology collaboration; MDRD, modification of diet in renal disease; IDMS, isotope-dilution mass spectrometry.

*Number of laboratories that participated in the Korean External Quality Assessment Service 2018.

하는 검사항목은 alanine aminotransferase (ALT), albumin, alkaline phosphatase, aspartate aminotransferase (AST), total bilirubin, chloride, total cholesterol, creatinine, gamma-glutamyl transferase, glucose, high-density lipoprotein (HDL) cholesterol, potassium, total protein, sodium, triglyceride, urea nitrogen과 uric acid 등이었고 1 회차와 2회차에 비해 3회차와 4회차의 참가기관 수가 증가하였다(Table 3). 요화학검사 프로그램에서는 새로 추가된 검사항목인 요 hCG 정성검사에 참여하는 기관이 가장 많았고 creatinine검사가 뒤를 이었다(Table 4).

일반화학검사 프로그램에서 변동계수는 각 검사항목별 회차별로 상대적으로 정도관리물질의 농도가 낮을수록 높은 경향을 보였다(Table 5). 대부분 10% 이내의 변동계수를 보였지만 alkaline phosphatase, amylase, direct bilirubin, lactate dehydrogenase (LDH), lipase, HDL cholesterol, low-density lipoprotein cholesterol과 triglyceride 등의 일부 방법에서 10% 이상의 높은 변동계수를 보였다. 물론 동일한 검사법을 사용하는 그룹 내에서는 비교적 작은 변동계수를 보였으나 alkaline phosphatase와 LDH는 검사법 간에 결과의 차이가 유의하게 큼으로써 변동계수도 상대적으로 큰 것으로 관찰되었다(Table 5). 요화학검사 프로그램에서 각 검사항목별 변동계수는 대부분 10% 이내의 값을 보였으나 albumin과 protein은 상대적으로 높은 변동계수를 보였다(Table 6). 변동계수는 각각 기관의 상대적 위치를 나타내는 SDI와도 관련되므로 변동계수가 큰 경우 SDI는 상대적으로 작아질 수 있으므로 결과해석 시 고려되어야 한다.

일반화학검사에 있어서 한 가지 검사방법이 전체의 80%를 넘는 검사로는 albumin의 dye binding bromocresol green법, ALT의 LDH without pyridoxal-5-phosphate (P5P)법, AST의 malate dehydrogenase without P5P법, total cholesterol의 cholesterol esterase법, gamma-glutamyl transpeptidase의 gamma-glutamyl-carboxy-nitroanilide법, magnesium의 colorimetry-xylidyl blue법, osmolality의 freezing point depression osmometer법, total protein의 biuret법, total CO₂의 phosphoenolpyruvate carboxylase법, urea nitrogen의 urease with glutamate dehydrogenase (GLDH)법과 uric acid의 uricase법이 있었다(Table 7).

요화학검사항목 중 albumin과 protein은 측정법의 분포가 일반화학검사와 차이가 있었다. Albumin의 측정법으로는 immunoturbidimetry법이 주로 이용되었고 protein의 측정법으로 dye binding using pyrogallol red법과 turbidimetry using benzethonium chloride법이 이용되었다(Table 8).

Table 8. Distribution of analytical methods (principle) and coefficients of variation (%) for the principles of urine chemistry in 2018

Test/method	Trials							
	1st				2nd			
	Lab*	CUC-18-01	CUC-18-02	CUC-18-03	Lab*	CUC-18-04	CUC-18-05	CUC-18-06
Albumin	166	30.0	19.0	19.4	172	14.2	20.3	32.5
Dye binding-BCG	2	15.7	12.7	13.2	2	33.9	26.3	44.7
Immunoturbidimetry	155	29.7	17.7	18.0	160	13.9	18.6	30.0
Calcium	151	4.0	2.7	2.3	155	4.3	2.6	3.4
Arsenazo III dye	19	4.1	3.0	2.7	22	2.3	4.0	3.4
Cresolphthalein complexone	79	3.8	3.0	2.7	77	3.9	2.4	3.3
MXB method (methylxlenol blue)	4	2.0	1.1	1.8	5	7.3	0.9	5.4
NM-BAPTA	47	2.1	1.7	1.8	49	2.8	1.9	2.8
Chloride	177	8.8	2.5	2.5	183	9.0	2.4	8.7
ISE, diluted (indirect)	170	8.5	2.5	2.5	176	8.6	2.4	8.5
ISE, undiluted (direct)	4	8.5	11.6	12.1	4	15.4	15.7	15.2
Creatinine	206	5.5	4.9	4.8	209	5.2	4.9	5.1
Compensated kinetic Jaffe method	50	2.0	2.7	2.5	50	1.8	2.3	2.3
Enzymatic method	10	2.4	3.1	3.5	10	2.3	3.1	3.3
kinetic Jaffe method	56	5.1	5.2	4.5	57	4.2	4.6	4.1
Rate blanked compensated kinetic Jaffe method	89	3.7	3.7	3.4	91	3.8	3.5	3.6
Glucose	135	2.2	2.2	2.2	137	3.3	2.6	1.3
Hexokinase	134	2.2	2.2	2.2	136	3.3	2.7	2.6
Magnesium	109	3.0	2.8	3.5	108	3.3	3.6	3.6
Chlorophosphonazo III	2	13.0	1.2	0.8				
Colorimetric test-Xylidyl blue	11	3.5	1.1	1.7	11	4.3	3.7	5.8
Colorimetric (Dye-Xylidyl blue/magon)	95	3.0	2.9	3.6	96	3.1	3.6	3.5
Phosphorus	138	2.5	2.6	2.9	139	2.6	2.8	2.8
Phosphomolybdate with any reduction method	3	2.2	0.9	1.8	4	0.4	2.5	1.2
Phosphomolybdate, UV	135	2.5	2.6	2.8	135	2.6	2.8	2.9
Potassium	178	2.1	3.1	3.4	184	1.8	3.6	1.9
ISE, diluted (indirect)	171	2.1	3.1	3.5	177	1.8	3.7	1.9
ISE, undiluted (direct)	4	4.2	11.9	12.5	4	5.5	21.0	4.7
Protein	173	11.0	9.0	8.6	177	9.9	9.0	10.5
Biuret method	5	14.3	12.1	9.3	4	5.6	7.3	9.2
dye binding using pyrogallol red	97	13.3	10.3	9.2	102	12.5	10.0	15.0
turbidimetry using benzethonium chloride	69	5.3	3.6	3.8	70	5.3	3.5	5.1
Sodium	180	2.8	1.2	1.1	186	2.2	1.1	2.3
ISE, diluted (indirect)	172	2.8	1.2	1.0	178	2.2	1.1	2.3
ISE, undiluted (direct)	5	3.7	3.3	4.1	5	4.3	2.6	0.0
Urea nitrogen	152	2.9	2.8	2.3	156	3.3	3.1	3.2
Enzymatic UV test (urease-GLDH)	9	5.5	1.8	3.7	9	5.4	5.7	2.8
Urease with GLDH (coupled enzymes)	143	2.8	2.5	2.3	147	3.0	3.2	3.1

(Continued to the next page)

Table 8. Continued

Test/method	Trials							
	1st				2nd			
	Lab*	CUC-18-01	CUC-18-02	CUC-18-03	Lab*	CUC-18-04	CUC-18-05	CUC-18-06
Uric acid	145	4.3	3.5	3.6	146	4.6	3.7	4.5
Uricase	143	4.4	3.5	3.6	144	4.6	3.7	4.5

Abbreviations: BCG, bromocresol green; NM-BAPTA, 5-nitro-5'-methyl-BAPTA; ISE, ion-selective electrodes; UV, ultra violet; GLDH, glutamate dehydrogenase.

*Number of Laboratories participated in Korean External Quality Assessment Service 2018.

2018년 일반화학검사 프로그램과 요화학검사 프로그램의 신빙도조사 결과에 대해 보다 자세한 통계분석 결과는 대한임상검사정도관리협회 신빙도조사사업 홈페이지(<http://eqas.keqas.org>)에서 조회가 가능하다.

REFERENCES

1. Lee YW. Annual report on the external quality assessment scheme for general chemistry in Korea (2017). J Lab Med Qual Assur 2018;40:113-27.
2. Lee YW, Jeon BR, Kim JG, Jun SH, Yun YM, Chun S, et al. Annual report on the external quality assessment scheme for routine clinical chemistry in Korea (2016). J Lab Med Qual Assur 2017;39:61-75.
3. Jun SH, Song J, Song WH; Clinical Chemistry Subcommittee, Korean Association of External Quality Assessment Service. Annual report on the external quality assessment scheme for clinical chemistry in Korea (2015). J Lab Med Qual Assur 2016;38:111-9.