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Schemes and Performance Evaluation Criteria of Korean Association of External Quality Assessment (KEQAS) for Improving Laboratory Testing

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External quality assessment (EQA) is important for evaluating clinical laboratories and enhancing their testing quality. EQA schemes are variable; thus, it is crucial that the EQA organizers share their experiences to continuously improve the EQA scheme. The Korean Association of External Quality Assessment Service (KEQAS) has been the leading, authorized EQA institute for the standardization and quality management of laboratory testing in Korean medical institutions since 1976. The EQA scheme underwent a major change in 2016, and the number of EQA programs increased significantly since then. The key changes implemented in EQA scheme include a fully computerized assessment to accelerate feedback and unification of the testing and reporting methods. We provide an overview of the EQA schemes and performance evaluation criteria of the KEQAS and suggest directions for achieving the global harmonization of EQA.

Key Words: Korean Association of External Quality Assessment Service (KEQAS), Performance, Evaluation, Laboratory testing, Schemes, Quality, Harmonization

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External quality assessment (EQA) is a widely accepted method for evaluating clinical laboratories and enhancing their testing quality [1]. EQA helps laboratories recognize and resolve their deficiencies in routine processes while instilling employee confidence [2]. All laboratories should therefore be encouraged to participate in EQA schemes, and such participation should be mandatory wherever possible [3]. Effective participation in EQA schemes in Europe is a mandatory requirement for country-specific accreditation bodies to have access to International Standards Organization (ISO) 15189 accreditation [4, 5]. In the United States, laboratories that conduct moderate or high-complexity tests are subject to reported inspections on a biennial basis and should participate in an EQA scheme authorized by the Center for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendment Law, which applies to all laboratories testing human specimens [6]. In Korea, laboratories with a satisfactory EQA can receive a quality incentive for testing since the notification of the Ministry of Health and Welfare took effect in 2017 [7]. However, EQA participation is not yet mandatory for laboratories in Korea, except for referral laboratories, and even

basic data such as the adequacy of EQA schemes are not available. Since many EQA schemes vary broadly in terms of content, it is crucial that the EQA organizers share their experiences to continuously improve the EQA scheme. We provide an overview of the EQA schemes and performance evaluation criteria of the Korean Association of External Quality Assessment Service (KEQAS) and suggest directions for joining global harmonization movements.

The KEQAS has been the leading authorized EQA institute for the standardization and quality management of clinical laboratories in Korea since 1976. Although the number of KEQAS programs is relatively small compared with other major EQAs, all the most requested routine tests, except special tests performed only at some university hospitals, are covered by the existing programs. The KEQAS obtained ISO 17043 (EQA provider) accreditation in August 2015. Major changes to the EQA schemes were implemented in 2016; the assessment is now fully computerized to accelerate feedback, and the methods of analysis and reporting across schemes are unified [8] (Table 1). Since these changes, the number of programs has increased significantly from 46 in 2016 and 65 in 2019 to 70 in 2020. These programs cover all disciplines of laboratory medicine, including three programs of accuracy-based proficiency tests, two of point-of-care tests, one of liquid biopsy, and three of next-generation sequencing, with a total of 852 test items covered and 1,844 institutions participating in EQA as of February 2020. Approximately 50% of hospitals (including small-to-medium sized hospitals, general hospitals, and tertiary care hospitals) that submit health insurance claims for laboratory tests in Korea participate in the KEQAS EQA [9]. Currently, specimens for 50 programs are prepared in-house, whereas specimens for the remaining programs are purchased from third-party manufacturers. With respect to the transport time after specimen shipments (e.g., the sixth shipment of 2019), 90% of the participating laboratories received the specimens within 32 hours and 99.9% within 48 hours. EQA results may be influenced by the deterioration of specimens during transportation and storage before testing [10]. Many specimens should be transported refrigerated or frozen; therefore, it is advantageous to deliver the specimens as soon as possible.

Accuracy-based EQA, which refers to commutable materials with target values, has substantially contributed to improving the accuracy of clinical laboratory tests [10]. The KEQAS has provided accuracy-based EQA for HbA1c tests since 2009, and for five chemistry tests (cholesterol, HDL cholesterol, LDL cholesterol, triglyceride, and creatinine) since 2011 [11]. The number of participants in accuracy-based EQA for HbA1c and creatinine in 2020 was 597 and 1,758, respectively. In 2011, Miller and colleagues [10] suggested six categories of EQA based on specimen characteristics, including commutability, value assignment method, and replication in the EQA survey. For example, programs in category 1 use commutable specimens with target values established by a reference system, and programs in category 2 are the same as those of category 1, except that specimens are not replicated within the survey cycle. Programs in categories 3 and 4 use commutable specimens, but the target values are not assigned by a reference system. Programs in categories 5 and 6 use non-commutable specimens [10]. Accuracy-based EQA in the KEQAS belongs to category 2, whereas the other KEQAS programs belong to category 6. The KEQAS should not only continue to increase its accuracy-based programs, but should also attempt category 1 EQA, which allows for evaluations of imprecision in laboratories by conducting repeated tests.

The consensus value of a peer group is the basis of a laboratory's evaluation by the KEQAS EQA scheme. A peer group usually consists of laboratories that use the same analyzer from the same manufacturer, as similar matrix-related bias for a given specimen can be assumed. The use of manufacturer-based peer groups is the only acceptable method for comparing the test results of multiple analytes in immunoassay, hematology, and molecular test schemes, which lack standardization and/or harmonization across participating laboratories that use similar principles but slightly different methodologies [12]. The peer groups are further divided into instrument- or reagent-based subgroups. However, for general chemistry, the peer group is based on those using the same methods, not on the same manufacturer, because many laboratories use an open system with regards to the manufacturers of instruments, calibrators, and reagents. The peer groups are further divided into reagent manufacturer-based subgroups. The KEQAS evaluates the participants' results based on the standard deviation index (SDI) among peer groups for quantitative tests, which is calculated as the difference between the individual laboratory test results and the mean result of the peer group divided by the peer group SD. Therefore, the SDI reflects bias as a multiple of the SD. The SDI is evaluated when the peer group size (i.e., the number of participants in each category) is eight or larger after removing outliers. In such cases, the subgroups are also evaluated. SDI>3 is considered unacceptable.

Currently, there are large differences in the analytical performance specifications (APS) used in different EQA schemes [13]. Maximum tolerance limits can be statistically determined (e.g.,

Table 1. Overview of the proficiency test scheme of the Korean Association of External Quality Assessment Service

Discipline	Classification of the Program	Program	Tests	Distribution/yr	Specimen (origin; type; state; preparation)	Shipping conditions (°C)	N participants (2020)
Transfusion medicine	Pretransfusion testing	Blood crossmatching and Blood typing, general	Blood crossmatching; ABO typing; RhD typing	2	Human; WB; Liquid; IH	FRG	923
		Blood typing, special	ABO subtyping; Rh CcEe Ag test; Weak D test	2	Human; WB; Liquid; IH	FRG	253
		Transfusion Ab, general	Unexpected Ab, screening; Direct anti-human globulin test	2	Human; WB and plasma; Liquid; IH	FRG	335
		Transfusion Ab, special	Unexpected Ab, identification; ABO Ab titration	2	Human; Plasma; Liquid; IH	FRG	139
Diagnostic hematology	Hematology and clinical microscopy	CBC and microscopy	CBC	2	Animal; WB; Liquid; P	FRG	1,819
			Blood cell morphology	2	Human; Blood smear; Image; IH		
		Peripheral blood smear (pilot project)	Malaria detection; Parasitemia; Identification	2	Human; Blood smear; Image; IH		277
		ESR (pilot project)	ESR	2	Synthetic material; Latex; Liquid; P	FRG	448
					Human; WB; Liquid; P	FRG	
	Coagulation	Coagulation, general	PT INR; aPTT; Coagulation factor I (fibrinogen); Thrombin time; Antithrombin III activity	2	Human; Plasma; Lyophilized; P	FRG	606
		Coagulation, special	Protein C (functional); Protein S (functional)	2	Human; Plasma; Lyophilized; P	FRG	20
Clinical chemistry	Urinalysis and stool occult blood, etc.	Urinalysis	Urinalysis	3	Animal; Serum, Hb and Enzyme; Liquid; P	FRG	1,726
			Urine sediment	3	Human; Urine; Image; IH		
		Stool occult blood	Stool occult blood (QL); Stool occult blood (QN)	2	Other origins; Hb; Lyophilized; P	FRG	1,014
	Blood gas analysis	Blood gas analysis	pH; pCO_2; pO_2; Lactic acid; Ionized calcium; Ionized magnesium; Sodium; Potassium; Chloride	2	DW; Buffered bicarbonate and electrolyte solution; Liquid; P	FRG	420
		Blood gas analysis, POCT	pH; pCO_2; pO_2	2	DW; Buffered bicarbonate and electrolyte solution; Liquid; P	FRG	177
	General chemistry	Routine chemistry	Sodium; Potassium; Chloride; Calcium; Phosphorus; Magnesium; BUN; Glucose; Cholesterol; HDL-C; LDL-C; TG; ALT; ALP; AST; Bilirubin, total; Bilirubin, direct; Albumin; Protein; GGT; LDH; Amylase; Lipase; CK; Uric acid; Iron; TIBC; Total CO_2; Osmolality	4	Human; Serum; Lyophilized; P	FRG	1,801
		ICG test	ICG concentration; K; R15	2	Human; plasma; Liquid	FRG	40
		Urine chemistry	Urine albumin; Calcium; Chloride; Creatinine; Glucose; Magnesium; Phosphorus; Potassium; Urine protein; Sodium; Urea Nitrogen; Uric acid; hCG	2	Human; Urine; Lyophilized; P	FRG	304
	Special proteins	Special proteins	Ceruloplasmin; Ferritin; Transferrin; Haptoglobin; Prealbumin; Alpha1-antitrypsin; CRP (QL); CRP (QN); ASO (QL); ASO (QN); RF (QL); RF (QN)	2	Human; Serum; Liquid; P	F	620
	Carbohydrates, lipids, proteins, and vitamins	Glucose, POCT	Glucose		Human; Serum and Hb; Liquid; P	FRG	375
		Cardiac markers	CK-MB, mass; CK-MB, activity; Homocysteine; Myoglobin; Troponin I; Troponin T; BNP; Pro-BNP; High sensitivity CRP	2	Human; Serum; Liquid; IH	F	475
	Metabolism testing	Newborn screening	Total galactose; 17-hydroxyprogesterone; TSH; T4, total; Newborn screening for inborn error of metabolism	2	Human; WB; Dried blood spot; IH	F	17

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Table 1. Continued

Discipline	Classification of the Program	Program	Tests	Distribution/yr	Specimen (origin; type; state; preparation)	Shipping conditions (°C)	N participants (2020)
		Organic acid profile	Organic acid profile	2	Human; Urine; Liquid; IH	F	5
		Amino acid profile	Amino acid profile	2	Human; Plasma; Liquid; IH	F	7
		Special metabolites	Methylmanonic acid; Vanillylmandelic acid; Epinephrine, urine; Norepinephrine, urine; Dopamine, urine; Metanephrine, urine; Normetanephrine, urine; Epinephrine, plasma; Norepinephrine, plasma; Dopamine, plasma; Metanephrine, plasma; Normetanephrine, plasma	2	Human; Urine and plasma; Liquid; IH	F	10
	Endocrinology	Hormones I	TSH; T4, total; T4, free; T3, total; Thyroglobulin; hCG, total (serum); Testosterone; Estradiol; Progesterone; Prolactin; Insulin; Folate; Human growth hormone; Vitamin B_{12}; Cortisol	2	Human; Serum; Liquid; P	F	661
		Hormones II	PTH; Erythropoietin; Vitamin D; Procalcitonin	2	Human; Serum; Lyophilized; P	FRG	315
		Hormones III (pilot project)	Anti-Müllerian hormone	2	Human; Serum; Liquid	F	31
	Tumor markers	Tumor markers I	AFP (QN); CEA; PSA; PIVKA-II	2	Human; Serum; Liquid; IH	F	723
		Tumor markers II	CA 125; CA 19-9; CA 15-3; CA 72-4; Beta2-microglobulin; Human epididymis protein 4	2	Human; Serum; Lyophilized; P	FRG	446
	Therapeutic drug monitoring and toxicology	Therapeutic drug monitoring, general	Acetaminophen; Amikacin; Amitriptyline; Carbamazepine; Carbamazepine,free; Chloramphenicol; Desipramine; Disopyramide; Digoxin; Ethosuximide; Lidocaine; Gentamicin; Lithium; Methotrexate; Nortriptyline; Phenobarbital; Phenytoin; Phenytoin, free; Primidone; Procainamide; Propranolol; Quinidine; Salicylate; Theophylline; Tobramycin; Valproic acid; Valproic acid, free; Vancomycin	2	Human; Serum; Lyophilized; P	FRG	106
		Immunosuppressants therapeutic drug monitoring	Cyclosporine; Tacrolimus (FK506); Sirolimus; Everolimus	2	Human; WB; Liquid; P	FRG	13
		Therapeutic drug monitoring, special	MPA; Voriconazole; Posaconazole; Itraconazole	2	Human; Serum; Liquid; IH	FRG	77
		Drug of abuse (QL)	Amphetamine; Methamphetamine; MDMA; Morphine, Free; Phencyclidine; 3,4-Secobarbital; 9-COOH-11-nor-Δ9-THC; Benzoylecgonine; Ethanol; LSD; Methadone; Methaqualone; Nordiazepam; Nortriptyline; Oxazepam; Propoxyphene	2	Human; Urine; Liquid; P	FRG	141
	Accuracy-based chemistry	Accuracy-based lipids	Cholesterol, total; HDL-C; LDL-C; TG; Apolipoprotein A1; Apolipoprotein B; Lipoprotein(a)	2	Human; Serum; Liquid; IH	F	275
		Accuracy-based creatinine	Creatinine; estimated GFR	2	Human; Plasma; Liquid; IH	F	1,758
		Accuracy-cased HbA1c	HbA1c	2	Human; WB; Liquid; IH	FRG	597
Diagnostic immunology	Complements and immunoglobulins	Complements and immunoglobulins	C3; C4; IgG; IgA; IgM; IgE; FLC, kappa; FLC, lambda	2	Human; Serum; Liquid; P	F	164
	Serology	Syphilis tests	Non-treponemal test; Treponemal test	2	Human; Plasma; Liquid; IH	F	595

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Table 1. Continued

Discipline	Classification of the Program	Program	Tests	Distribution/yr	Specimen (origin; type; state; preparation)	Shipping conditions (°C)	N participants (2020)
		Hepatitis serology	HBsAg; HBsAb; HCV Ab; HBcAb, total; HBc Ab, IgM; HBeAg; HBeAb; HAV Ab, total; HAV Ab, IgG; HAV Ab, IgM	2	Human; Plasma; Liquid; IH	F	1,103
		Virus serology I	HIV Ag/Ab; HTLV Ab; CMV Ab, IgG; CMV Ab, IgM	2	Human and Animal; Serum; Liquid; IH	F	591
		Virus serology II	Rubella IgG; Rubella IgM; EBV Viral Capsid Ag, IgG; EBV Viral Capsid Ag, IgM; EBV Nucleic Acid Ag, IgG	2	Human and Animal; Serum; Liquid; IH	F	93
	Histocompatibility testing	HLA typing	HLA Typing	2	Human; WB; Liquid; IH	FRG	69
		HLA typing, special	HLA B27 Typing; HLA B51 Typing	2	Human; WB; Liquid; IH	FRG	62
		HLA crossmatching	HLA crossmatching, CDC; HLA crossmatching, flow cytometry	2	Human; Serum and PBMC; Liquid; IH	RT (PBMC) and FRG (serum)	48
		HLA Ab tests	HLA Ab screening; HLA Ab identification	2	Human; Serum; Liquid; IH	FRG	26
	Cellular immunity, flow cytometry	Lymphocyte subset assay	Lymphocyte subset assay	2	Human; WB; Liquid; IH	RT	56
		Stem/progenitor cell assay	CD34+Stem/Progenitor cell assay	2	Human; WB; Liquid; IH	RT	42
		Hematologic malignancy immunophenotyping	Hematologic malignancy immunophenotyping	2	Human; WB and BM aspirate; Liquid; IH	RT	44
	Autoimmunity	Autoimmune Assay I	ANA; Anti-mitochondrial Ab; Anti-smooth muscle Ab	2	Human; Serum; Liquid; IH	F	82
		Autoimmune Assay II	Anti-thyroglobulin Ab; Anti-thyroperoxidase Ab; Anti-dsDNA Ab	2	Human; Serum; Liquid; IH	F	111
	Allergy test	Allergy test	Allergen-specific IgE (QN), Multi-allergen screen (Semi-QN)	2	Human; Serum; Liquid; IH	F	121
	Infection-induced immune responses	Tuberculosis Ag response	IGRA	2	Animal; Serum and Interferon-gamma power; Lyophilized; IH	FRG	76
Clinical microbiology	Microbiology	Mycobacteriology, general	Acid-fast stain microscopy	3	Human; MTB; Slide; IH	FRG	255
			Acid fast bacilli culture; Acid fast bacilli identification	3	Human; Sputum; Liquid; IH	FRG	
		Mycobacteriology, drug sensitivity	Acid-fast bacilli antibiotic sensitivity	3	Human; MTB; Liquid; IH	FRG	7
		Bacteriology	Bacteria stain microscopy; Bacteria culture; Bacteria identification; Antibiotics sensitivity test	3	Human; Bacteria; Liquid medium; IH	FRG	282
		Mycology	Fungus stain microscopy; Fungus culture; Fungus identification	2	Human; Fungus; Liquid medium; IH	FRG	135
		Parasitology	Parasite eggs image	3	Human and Animal; Parasite egg; Image; IH	FRG	217
			Parasite eggs slide	3	Human and Animal; Parasite egg; Slide; IH	FRG	
Molecular diagnostics	Molecular microbiology	Molecular microbiology, mycobacteria	MTB DNA; MTB DNA, isoniazid resistance mutation; MTB DNA, rifampicin resistance mutation	3	Human; MTB and NTM; Liquid; IH	FRG	132
		Molecular microbiology, hepatitis viruses	HBV (QL); HBV (QN); HCV (QL); HCV (QN); HBV DNA drug resistance mutation	2	Human; Plasma; Liquid; IH	F	121

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Table 1. Continued

Discipline	Classification of the Program	Program	Tests	Distribution/yr	Specimen (origin; type; state; preparation)	Shipping conditions (°C)	N participants (2020)
		Molecular microbiology, viruses	CMV (QL); CMV (QN); EBV (QL); EBV (QN); HPV (QL); HIV (QL); HIV (QN); Adenovirus (QL); Influenzavirus A,B (QL); Parainfluenza 1,2,3 virus (QL); RSV (QL), BK virus (QL)	2	Human; Serum (Plasma); Liquid; IH	F	124
				2	Human; Virus; Liquid; IH	F	
	Human genetics	Cytogenetics	Chromosomal analysis	3	Human; WB; Image; IH	-	40
		FISH	Fluorescence in situ hybridization	3	Human; WB; Slide; IH	F	32
		Molecular, hematologic malignancy	Leukemia gene rearrangement; *JAK2* gene V617F mutation; *FLT3* gene internal tandem duplication; *FLT3* gene tyrosine kinase domain mutation; *NPM1* gene mutation, *CALR* gene mutation	2	Human; WB; Liquid (DNA); IH	FRG	48
		Molecular, solid tumors	*KRAS* gene mutation; *EGFR* gene mutation; *BRAF* gene mutation; *KIT* (*C-Kit*) gene mutation	2	Human; DNA; Liquid; IH	FRG	28
		Molecular, genetic disorders	*BRCA1*; *BRCA2*; *TP53*; *ATP7B*; *MT-TL1*; *MT-TK*; *GJB2*; *LHON* major mutation; *RET*; Spinocerebellar ataxia; *APOE* genotyping; *FGFR3* major mutation; *MTHFR* genotyping; Prader-Willi/Angelman syndrome; *DMD*, Del/Dup; *HD* gene trinucleotide repeat expansion; *FMR1* gene trinucleotide repeat expansion; *TGFBI* major mutation; *SBMA; SMN1*, Del/Dup	2	Human; DNA; Liquid; IH	FRG	56
		Pharmacogenetics, Molecular, pharmacogenetics	*CYP2C19* genotyping; *CYP2C9* genotyping; *VKORC1* genotyping; *CYP2D6* genotyping; *TPMT* genotyping	2	Human; DNA; Liquid; IH	FRG	21
		Human genetics, others Molecular, others	*ABO* genotyping	2	Human; DNA; Liquid; IH	FRG	16
		Liquid biopsy	*EGFR* gene	2	Human; Plasma; Liquid; IH	F	30
		NGS, somatic	NGS - somatic	2	Human; DNA; Liquid and FASTQ file; IH	F	23
		NGS, germline	NGS - germline	2	Human; DNA; Liquid and FASTQ file; IH	F	24
		NGS, liquid biopsy (pilot project)	NGS - liquid biopsy	2	Human; DNA; Liquid	F	5

Abbreviations: Ab, antibody; AFP, alpha-fetoprotein; Ag, antigen; ALP, alkaline phosphatase; ALT, alanine transferase; ANA, anti-nuclear Ab; aPTT, activated partial thromboplastin time; ASO, anti-streptolysin O; AST, aspartate aminotransferase; BNP, brain natriuretic peptide; BUN, blood urea nitrogen; C, complement component; CA, cancer antigen; CBC, complete blood cell count; CDC, complement-dependent cytotoxicity; CEA, carcinoembryonic Ag; CK, creatine kinase; CK-MB, creatine kinase-MB; CMV, cytomegalovirus; CRP, C-reactive protein; EBV, Epstein–Barr virus; estimated GFR, estimated glomerular filtration rate; F, frozen; FISH, fluorescence *in situ* hybridization; FLC, free light chain; FRG, refrigerated; GGT, gamma-glutamyl transferase; HAV, hepatitis A virus; Hb, hemoglobin; HbA1c, hemoglobin A1c; HBcAb, hepatitis B virus core Ab; HBeAb hepatitis B virus envelope Ab; HBeAg, hepatitis B virus envelope Ag; HBsAb, hepatitis B virus surface Ab; HBsAg, hepatitis B virus surface Ag; hCG, human chorionic gonadotropin; HCV, hepatitis C virus; HDL-C, high-density lipoprotein cholesterol; HIV, human immunodeficiency virus; HLA, human leukocyte antigen; HPV, human papillomavirus; HTLV, human T-lymphotropic virus; ICG, indocyanine green; Ig, immunoglobulin; IGRA, interferon-gamma release assay; IH, in-house prepared quality material; LDH, lactate dehydrogenase; LDL-C, low-density lipoprotein cholesterol; LSD, lysergic acid diethylamide; MDMA, methylene dioxy methamphetamine; MPA, methiopropamine; NGS, next-generation sequencing; P, purchased quality material; PBMC, peripheral blood mononuclear cell; PIVKA-II, protein induced by vitamin K absence or antagonist-II; POCT, point-of-care testing; PSA, prostate-specific antigen; PT, prothrombin time; PTH, parathyroid hormone; QL, qualitative; QN, quantitative; RF, rheumatoid factor; RSV, respiratory syncytial virus; RT, room temperature; T3, triiodothyronine; T4, thyroxine; TG, triglyceride; TIBC, total iron-binding capacity; TSH, thyroid-stimulating hormone; WB, whole blood.

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using ±3 SDIs or Z-scores) or established as fixed percentages or amounts (e.g., ±15% of the target value or ±10 mg/dL) [14]. As the SDI is a standardized value, it can be compared among all analytes [15]. However, the limitation of the statistical method is that when applying the SDI as a tolerance limit, the acceptable range for peer groups with larger SDs is larger than that for

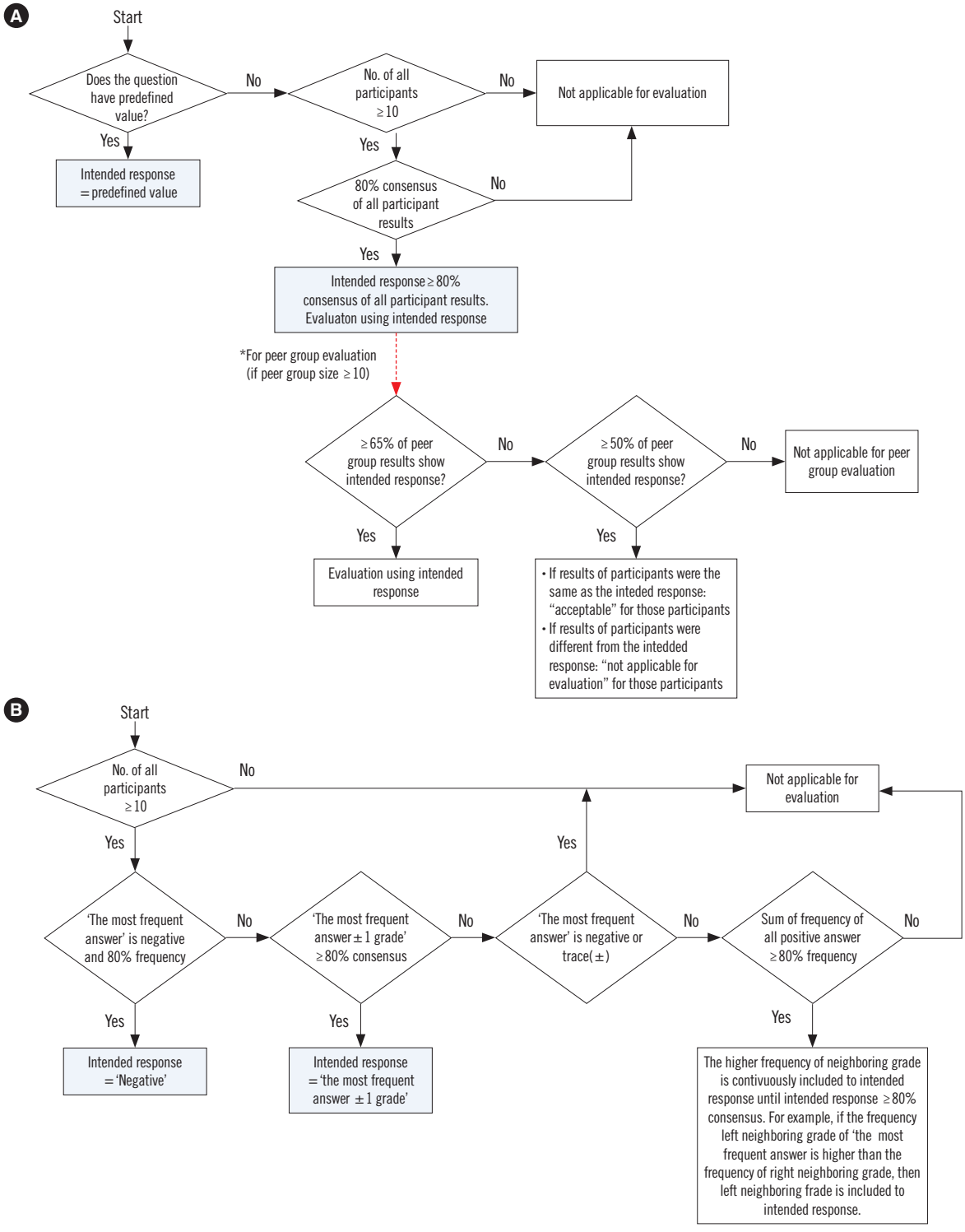

Fig. 1. Flow diagram of performance evaluation for (A) qualitative and (B) semi-quantitative tests in the KEQAS EQA scheme.
Abbreviations: KEQAS, Korean Association of External Quality Assessment Service; EQA, external quality assessment.

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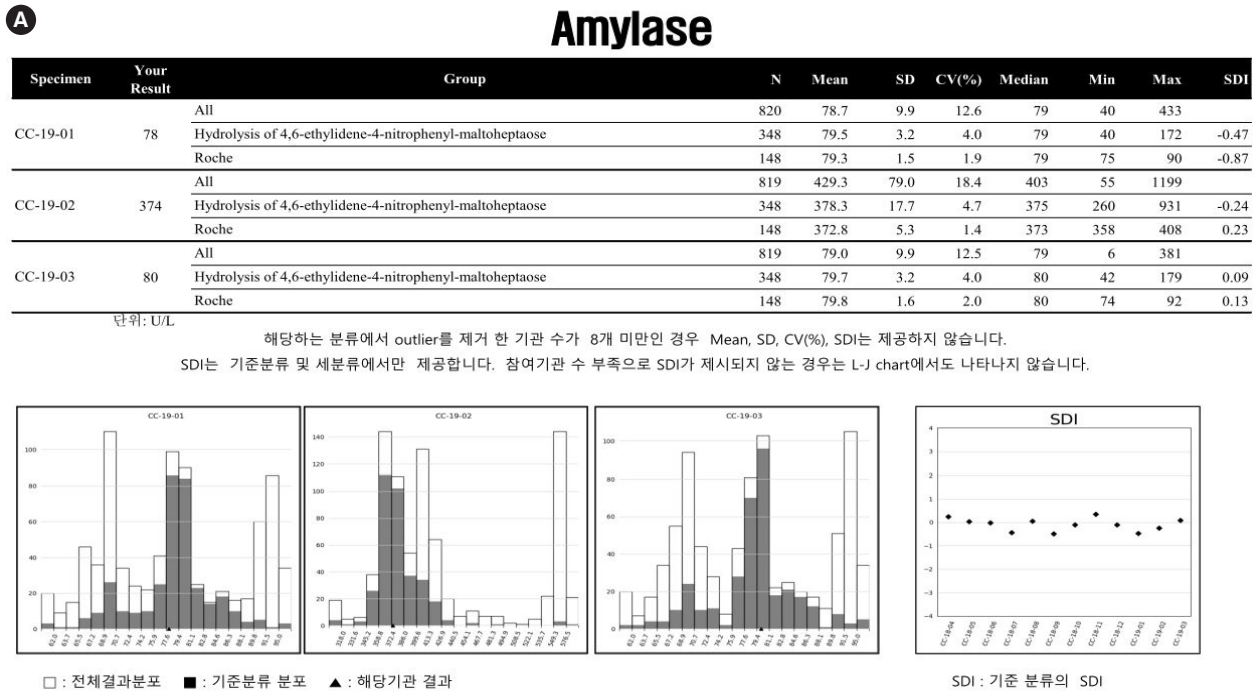
peer groups with smaller SDs. Quantitative responses of the US College of American Pathologists (CAP) EQA scheme are evaluated based on a fixed range, mean percentage, SD, or variable range according to the test items. Switzerland's Suisse de Contrôle de Qualité uses government regulations and a combination of limits established by scientific societies and Z-scores to deter-



A

Amylase

Specimen	Your Result	Group	N	Mean	SD	CV(%)	Median	Min	Max	SDI
CC-19-01	78	All	820	78.7	9.9	12.6	79	40	433	
		Hydrolysis of 4,6-ethylidene-4-nitrophenyl-maltoheptaose	348	79.5	3.2	4.0	79	40	172	-0.47
		Roche	148	79.3	1.5	1.9	79	75	90	-0.87
CC-19-02	374	All	819	429.3	79.0	18.4	403	55	1199	
		Hydrolysis of 4,6-ethylidene-4-nitrophenyl-maltoheptaose	348	378.3	17.7	4.7	375	260	931	-0.24
		Roche	148	372.8	5.3	1.4	373	358	408	0.23
CC-19-03	80	All	819	79.0	9.9	12.5	79	6	381	
		Hydrolysis of 4,6-ethylidene-4-nitrophenyl-maltoheptaose	348	79.7	3.2	4.0	80	42	179	0.09
		Roche	148	79.8	1.6	2.0	80	74	92	0.13

단위: U/L

해당하는 분류에서 outlier를 제거 한 기관 수가 8개 미만인 경우 Mean, SD, CV(%), SDI는 제공하지 않습니다.
SDI는 기준분류 및 세분류에서만 제공합니다. 참여기관 수 부족으로 SDI가 제시되지 않는 경우는 L-J chart에서도 나타나지 않습니다.

□ : 전체결과분포 ■ : 기준분류 분포 ▲ : 해당기관 결과

SDI : 기준 분류의 SDI

B

Testosterone

CH1-18-01

	N	Mean	SD	CV(%)	Median	Min	Max
All	96	3.8449	0.4823	12.5444	4	0.188	15.19
Abbott	19	3.9214	0.2675	6.8222	3.88	3.44	4.5
ARCHITECT i1000	3				4.05	3.65	4.386
ARCHITECT i2000	16	3.8614	0.2133	5.5235	3.88	3.44	4.5
Beckman Coulter Inc.	12	3.5055	0.1508	4.3025	3.54	3.31	4.26
Access2	1				3.85		
UniCel DxI800	11	3.471	0.1038	2.9893	3.53	3.31	4.26
Biomerieux	4				3.14	2.77	3.49
Mini vidas	1				3.49		
Vidas	3				3.05	2.77	3.23
DiaSorin	1				0.188		
LIAISON	1				0.188		
Roche	46	4.1971	0.155	3.6925	4.195	0.883	15.19
cobas e801	6				4.325	4.17	4.4
cobas4000 e411	3				4.26	4.17	4.4
cobas6000 e601	11	4.164	0.0759	1.8217	4.2	4.02	4.48
cobas8000 e602	19	4.1069	0.1234	3.0043	4.13	0.908	15.19
Modular E170	7				4.14	0.883	4.43
Siemens Healthcare Diagnostics, Inc	14	3.0581	0.1866	6.1004	3.042	2.794	3.4
ADVIA Centaur® XP Immunoassay System	7				3.068	2.87	3.4
ADVIA Centaur® XPT Immunoassay System	7				2.97	2.794	3.385

Fig. 2. Examples of the EQA reports of the KEQAS. (A) Participant evaluation report and (B) participants' summary.
Abbreviations: KEQAS, Korean Association of External Quality Assessment Service; EQA, external quality assessment.

mine the acceptable range. The Netherlands' Dutch Foundation for Quality Assessment in Medical Laboratorie (SKML) and the UK Welsh EQA provider (WEQAS) use a combination of biological variation and state-of-the-art methods [13]. Although the KEQAS has been using the SDI as a tolerance limit for evaluation, APS should be considered as an alternative based on the clinical requirement for each test.

Peer groups of qualitative tests are formed in the same manner, that is, according to the same instrument manufacturer and the same reagent manufacturer with respect to the characteristics of the tests. Flow diagrams of performance evaluation for qualitative and semi-quantitative tests are shown in Fig. 1A and B, respectively.

The performance evaluation for qualitative and semi-quantitative tests has not yet been standardized [13]. For qualitative tests, 80% consensus of referees or participants is the standard used for evaluation in the US CAP EQA scheme; for example, in urinalysis dipstick tests, 80% participant consensus can be determined by grouping the mode with the next one or the two most frequent responses. In the EQA scheme of the UK WEQAS, the spiked values are used to determine the target value; if these values are not available, interpretation is based on the majority percentage of responses from participants. In the EQA scheme of SKML, performance is scored using a point system based on expert findings or consensus results. However, detailed information on the evaluation criteria of these EQA schemes are not available. The KEQAS's new suggestions for performance criteria for qualitative and semi-quantitative tests based on experience will be useful for achieving global EQA harmonization.

Two reports (the participant evaluation report and participants' summary) are electronically generated simultaneously within five working days after each participant submit its results for each round of the scheme (Fig. 2). The mean turnaround time from result submission to report release was 33 days (range 6–104 days) in 2019 because of the review by the program manager. One of the drawbacks of EQAs is that laboratories cannot obtain feedback in a timely manner [6]. Therefore, KEQAS should consider ways to shorten the time for the review. For example, the evaluation criteria should be well established, there should be measures in place to cope with exceptions, and the assessment should be fully automated.

Approximately 60%–70% of the laboratory tests errors are due to the pre-analytical process [16]. Therefore, identifying appropriate quality metrics is crucial in determining the quality of laboratory services [17]. According to the model of quality indicators developed by the Working Group of the International Federation of Clinical Chemistry and Laboratory Medicine [17], proficiency testing and EQA schemes have allowed clinical laboratories to measure, monitor, and improve their analytical performance over time [18-20]. It may be helpful to introduce extra-analytical quality indicators in the KEQAS EQA scheme to monitor and improve the overall quality of more laboratories.

In conclusion, the KEQAS has been providing the EQA scheme for 45 years to improve the quality of clinical laboratories in Korea. Our summary of the EQA scheme, performance evaluation criteria of the KEQAS, and suggestions for improvement would help achieve global harmonization of EQA.

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AUTHOR CONTRIBUTIONS

SC and WKM designed the study; SK and KL collected data and wrote manuscript; and HDP and WHL edited the manuscript. All authors have read and approved the final manuscript.

CONFLICTS OF INTEREST

None declared.

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