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Effect of Accreditation on Accuracy of Diagnostic Tests in Medical Laboratories

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Background: Medical laboratories play a central role in health care. Many laboratories are taking a more focused and stringent approach to quality system management. In Korea, laboratory standardization efforts undertaken by the Korean Laboratory Accreditation Program (KLAP) and the Korean External Quality Assessment Scheme (KEQAS) may have facilitated an improvement in laboratory performance, but there are no fundamental studies demonstrating that laboratory standardization is effective. We analyzed the results of the KEQAS to identify significant differences between laboratories with or without KLAP and to determine the impact of laboratory standardization on the accuracy of diagnostic tests.

Methods: We analyzed KEQAS participant data on clinical chemistry tests such as albumin, ALT, AST, and glucose from 2010 to 2013. As a statistical parameter to assess performance bias between laboratories, we compared 4-yr variance index score (VIS) between the two groups with or without KLAP.

Results: Compared with the group without KLAP, the group with KLAP exhibited significantly lower geometric means of 4-yr VIS for all clinical chemistry tests ($P<0.0001$); this difference justified a high level of confidence in standardized services provided by accredited laboratories. Confidence intervals for the mean of each test in the two groups (accredited and non-accredited) did not overlap, suggesting that the means of the groups are significantly different.

Conclusions: These results confirmed that practice standardization is strongly associated with the accuracy of test results. Our study emphasizes the necessity of establishing a system for standardization of diagnostic testing.

Key Words: The Korean Association of External Quality Assessment Service, The Korean External Quality Assessment Scheme, Quality assurance, Quality system management, Standardization, Accuracy

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INTRODUCTION

Medical laboratories play a central role in health care. Laboratory data are an integral part of physicians' decision-making processes; 70% of all critical medical decisions are based on laboratory test results [1]. The purpose of a laboratory is to provide physicians and other health care professionals with information that enables them to: (1) detect a disease or predisposi-

tion to a disease, (2) confirm or reject a diagnosis, (3) establish prognosis, (4) guide patient management, and (5) monitor the efficacy of therapy. To successfully achieve these goals, every laboratory should strive to achieve medical, scientific, and technical expertise, obtain resources such as personnel, laboratory equipment, supplies, and facilities, and, most importantly, have a management set-up that ensures quality laboratory services.

Many laboratories are adopting a more focused and stringent approach to quality system management. The International Organization for Standardization (ISO) is the first quality management system for medical laboratories. It establishes guidelines that reflect the highest level of quality [2]. The ISO 15189 has been adopted by the College of American Pathologists (CAP) in an effort to improve patient care through quality laboratory practices [3]. Similarly, the CLSI has developed 12 Quality System Essentials based on ISO standards. These 12 essentials serve as a starting point in establishing a quality system that covers pre-testing, testing, and post-testing operations [3]. In the United States, laboratory activities are highly regulated by healthcare-related legislation such as the Clinical Laboratory Improvement Amendments (CLIA) of 1988 [4]. Most clinical laboratories in the United States have received CLIA certification to perform testing on human samples, which indicates that they meet personnel, operational, safety, and quality standards based on test complexity.

In Korea, no national regulatory standards have been developed for clinical laboratories. The standardization of laboratory practice depends on a private sector entity, the Korean Laboratory Accreditation Program (KLAP), and the Korean External Quality Assessment Scheme (KEQAS) [5, 6]. The KLAP was developed by the Korean Society of Laboratory Medicine in 1999, and was reorganized as the Laboratory Medicine Foundation in 2010 [6]. A laboratory that meets the requirements of laboratory accreditation schemes can receive KLAP certification, which expresses confidence in the quality of services provided by that laboratory [6]. The KEQAS was set up in 1976, and is currently run by the Korean Association of External Quality Assessment Service. The main objectives of the KEQAS are to compare test results among participating laboratories nationwide by using the same test item. The number of participants in the KEQAS is gradually increasing [5].

The standardization efforts undertaken by the KLAP and KEQAS may have facilitated an improvement in laboratory performance in Korea; however, there are no fundamental studies demonstrating that laboratory standardization is useful. We analyzed the results of the KEQAS to identify significant differences between laboratories with and without KLAP, and to determine the impact of laboratory practice standardization on the accuracy of diagnostic testing.

METHODS

1. Study subjects and parameters

Data from the KEQAS gathered between 2010 and 2013 by the clinical chemistry subcommittee of the Korean Association of External Quality Assessment Service were included in this study. A total of 19 test items related to clinical chemistry were analyzed: albumin, alkaline phosphatase, ALT, AST, blood urea nitrogen, chloride, creatinine, γ-glutamyl transferase, glucose, lactate dehydrogenase, phosphorus, potassium, sodium, total bilirubin, total calcium, total cholesterol, total protein, triglyceride, and uric acid [7]. As a statistical parameter to assess bias in performance between laboratories, we used the variance index score (VIS). The VIS ranges from 0 to 400, and it provides an overall comparison of test results for each test item. The value of the VIS is calculated as follows: $VIS=[(X_{lab}–DV)/DV\times 100]/CCV\times 100$; where X_{lab} is the result from the participating laboratory; DV is the designated value, which is the mean result from the participating laboratories using that method after excluding outliers more than two standard deviations from the mean; and CCV is the chosen coefficient of variation, taken from the National External Quality Assessment Scheme in the United Kingdom (1971) [8].

2. Comparison of 4-yr VIS between laboratories with or without KLAP

KEQAS participants, whose data on clinical chemistry tests were available, were categorized into two subgroups based on their KLAP status, and the VIS of each test item from 2010–2013 was compared. The number of laboratories participating in the KEQAS was 1,333 in 2013 [7]. Among the KEQAS participants with available data, the number of laboratories with or without KLAP, by year, was 233/767 (23% accredited; 77% non-accredited) in 2010, 245/844 (22% accredited; 78% non-accredited) in 2011, 258/908 (22% accredited; 78% non-accredited) in 2012, and 265/1,008 (21% accredited; 79% non-accredited) in 2013.

3. Comparison of 4-yr VIS between laboratories categorized by institution type

All participants in the KEQAS were categorized into four laboratory subgroups based on the institutional type; these subgroups were general hospitals with 100 or more beds, hospitals with 30–99 beds, clinics with less than 30 beds, and entrusted labora-

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Table 1. Comparison of variance index scores between laboratories with or without KLAP from 2010 to 2013

Test item	Year	Accredited laboratory		Non-accredited laboratory		$P^{\ddagger}$
		N*	VIS† (95% CI)	N*	VIS† (95% CI)	
Albumin	2010	232	40.9 (38.7–43.2)	722	47.6 (45.7–49.6)	<0.0001
	2011	244	36.4 (34.3–38.7)	789	44.3 (42.7–46.0)	<0.0001
	2012	257	36.3 (34.3–38.5)	845	45.2 (43.5–46.8)	<0.0001
	2013	264	38.3 (36.3–40.4)	937	48.3 (46.7–50.0)	<0.0001
ALP	2010	228	39.8 (36.5–43.3)	696	50.0 (47.0–53.2)	<0.0001
	2011	240	40.6 (37.4–44.1)	764	53.3 (50.5–56.2)	<0.0001
	2012	254	40.5 (37.2–44.1)	815	50.2 (47.5–53.1)	<0.0001
	2013	261	43.8 (40.1–47.8)	892	57.4 (54.4–60.6)	<0.0001
ALT	2010	233	33.2 (31.2–35.4)	767	38.4 (36.7–40.2)	0.0002
	2011	245	28.8 (27.0–30.8)	844	37.1 (35.6–38.7)	<0.0001
	2012	258	32.7 (30.8–34.7)	908	41.3 (39.8–42.8)	<0.0001
	2013	265	33.6 (31.5–35.9)	1,008	43.3 (41.8–44.9)	<0.0001
AST	2010	233	30.1 (28.2–32.2)	766	37.1 (35.5–38.7)	<0.0001
	2011	245	27.3 (25.6–29.1)	845	33.1 (31.9–34.4)	<0.0001
	2012	257	27.8 (25.9–29.7)	908	36.0 (34.6–37.3)	<0.0001
	2013	264	28.1 (26.3–30.1)	1,007	36.5 (35.1–38.0)	<0.0001
BUN	2010	233	47.0 (44.0–50.2)	735	63.9 (61.0–67.0)	<0.0001
	2011	245	41.8 (39.3–44.4)	806	63.3 (60.7–66.1)	<0.0001
	2012	257	41.8 (39.4–44.3)	859	62.5 (60.0–65.1)	<0.0001
	2013	264	42.4 (39.9–45.0)	959	68.4 (65.7–71.2)	<0.0001
Chloride	2010	224	76.1 (71.5–81.0)	424	107.7 (102.4–113.3)	<0.0001
	2011	236	75.3 (71.9–78.8)	471	101.9 (97.5–106.4)	<0.0001
	2012	248	78.3 (74.6–82.2)	507	102.3 (97.9–106.9)	<0.0001
	2013	256	85.0 (81.0–89.2)	561	99.0 (94.9–103.3)	<0.0001
Creatinine	2010	228	45.8 (42.8–48.9)	754	66.9 (64.1–69.9)	<0.0001
	2011	240	45.7 (43.1–48.3)	829	61.4 (58.9–64.1)	<0.0001
	2012	254	45.6 (43.2–48.2)	892	63.7 (61.1–66.3)	<0.0001
	2013	261	46.1 (43.6–48.8)	993	68.2 (65.6–70.8)	<0.0001
γ-glutamyl transferase	2010	229	27.6 (25.6–29.6)	749	36.8 (35.1–38.5)	<0.0001
	2011	241	27.9 (26.0–30.0)	824	34.5 (33.1–36.0)	<0.0001
	2012	254	27.8 (26.0–29.8)	886	33.8 (32.4–35.3)	<0.0001
	2013	261	27.3 (25.6–29.2)	983	36.2 (34.8–37.6)	<0.0001
Glucose	2010	229	23.4 (21.9–24.9)	744	35.9 (34.3–37.6)	<0.0001
	2011	241	23.4 (22.1–24.9)	820	34.2 (32.8–35.7)	<0.0001
	2012	254	24.3 (22.8–26.0)	839	33.8 (32.5–35.3)	<0.0001
	2013	261	22.5 (21.1–24.1)	981	34.8 (33.4–36.2)	<0.0001
LDH	2010	226	16.0 (14.3–18.0)	520	22.8 (20.9–24.8)	<0.0001
	2011	238	13.9 (12.6–15.2)	540	20.2 (18.7–21.8)	<0.0001
	2012	250	14.3 (13.2–15.5)	562	20.3 (18.9–21.7)	<0.0001
	2013	256	17.2 (15.9–18.5)	604	23.5 (22.0–25.2)	<0.0001
Phosphorus	2010	219	33.4 (31.1–35.9)	283	45.8 (42.5–49.4)	<0.0001
	2011	231	29.2 (27.3–31.2)	307	43.8 (40.7–47.2)	<0.0001
	2012	245	29.7 (27.7–31.9)	326	40.3 (37.3–43.4)	<0.0001
	2013	251	28.9 (27.0–30.9)	338	40.1 (37.2–43.2)	<0.0001

(continued to the next page)

Table 1. Continued

Test item	Year	Accredited laboratory		Non-accredited laboratory		$P^{‡}$
		N*	VIS† (95% CI)	N*	VIS† (95% CI)	
Potassium	2010	225	48.9 (45.8–52.3)	438	73.6 (69.6–77.8)	<0.0001
	2011	237	45.5 (42.7–48.6)	484	74.7 (71.1–78.5)	<0.0001
	2012	248	44.6 (42.2–47.2)	519	66.1 (63.0–69.3)	<0.0001
	2013	255	43.4 (40.5–46.5)	574	68.5 (65.3–71.8)	<0.0001
Sodium	2010	225	61.1 (57.0–65.5)	437	83.6 (79.3–88.2)	<0.0001
	2011	237	61.5 (57.9–65.4)	484	87.7 (83.5–92.1)	<0.0001
	2012	249	59.6 (56.4–63.0)	519	88.4 (84.5–92.6)	<0.0001
	2013	256	56.4 (53.1–59.9)	574	84.1 (80.4–87.9)	<0.0001
Total bilirubin	2010	228	25.7 (23.8–27.8)	720	36.9 (34.9–38.9)	<0.0001
	2011	240	28.1 (26.1–30.2)	790	37.1 (35.4–38.9)	<0.0001
	2012	254	26.9 (25.0–29.0)	845	33.7 (32.1–35.4)	<0.0001
	2013	261	26.5 (24.7–28.5)	942	36.1 (34.6–37.7)	<0.0001
Total calcium	2010	220	53.9 (50.3–57.8)	321	77.8 (72.9–83.0)	<0.0001
	2011	233	52.7 (49.6–56.0)	348	79.5 (75.1–84.1)	<0.0001
	2012	246	52.8 (49.5–56.4)	362	76.2 (72.1–80.6)	<0.0001
	2013	251	49.8 (46.7–53.1)	383	73.2 (68.8–77.9)	<0.0001
Total cholesterol	2010	233	28.3 (26.5–30.2)	754	37.4 (35.7–39.1)	<0.0001
	2011	245	26.7 (25.0–28.4)	829	35.4 (34.1–36.8)	<0.0001
	2012	257	26.7 (25.1–28.3)	820	34.7 (33.3–36.2)	<0.0001
	2013	264	26.8 (25.2–28.4)	993	37.5 (36.1–39.0)	<0.0001
Total protein	2010	233	57.0 (53.2–60.9)	715	75.4 (71.8–79.2)	<0.0001
	2011	245	53.1 (50.5–55.9)	780	74.9 (71.9–78.1)	<0.0001
	2012	258	51.2 (48.4–54.2)	834	71.9 (69.0–74.9)	<0.0001
	2013	265	50.2 (47.4–53.1)	855	75.5 (72.4–78.8)	<0.0001
Triglyceride	2010	229	32.0 (29.3–34.9)	738	45.1 (42.7–47.5)	<0.0001
	2011	241	35.4 (32.8–38.3)	811	48.0 (45.5–50.6)	<0.0001
	2012	246	33.1 (30.7–35.8)	645	45.6 (43.1–48.3)	<0.0001
	2013	261	30.3 (28.3–32.4)	975	45.5 (43.5–47.7)	<0.0001
Uric acid	2010	228	32.5 (30.4–34.7)	649	44.1 (41.9–46.5)	<0.0001
	2011	239	30.2 (28.3–32.2)	701	42.2 (40.3–44.3)	<0.0001
	2012	254	28.3 (26.7–30.1)	740	41.0 (39.2–43.0)	<0.0001
	2013	261	28.2 (26.6–29.9)	805	44.1 (42.0–46.2)	<0.0001

*Number of laboratories; †Geometric mean of VIS; ‡*P* value by Student's t-test using the log-transformed values.
Abbreviations: BUN, blood urea nitrogen; CI, confidence interval; KLAP, Korean Laboratory Accreditation Program; LDH, lactate dehydrogenase; VIS, variance index score.

tory agencies. During 2010–2013, the number of laboratories in general hospitals varied between 321 and 356; the number of laboratories in hospitals varied between 314 and 453; the number of laboratories in clinics varied between 272 and 351; and the number laboratories in entrusted laboratory agencies varied between 11 and 15. We analyzed the VIS difference in each test by institutional type. Furthermore, we analyzed the difference in VIS between laboratories in general hospitals based on their KLAP status to rule out confounding factors such as personnel, laboratory equipment, supplies, and facilities. These factors are likely to affect the value of the VIS, because the hospital and clinic institutional types had a very small number of KLAP-accredited laboratories. Therefore, only data from the general hospital group, which had a sufficient number of laboratories with or without KLAP spanning, were included in further analysis.

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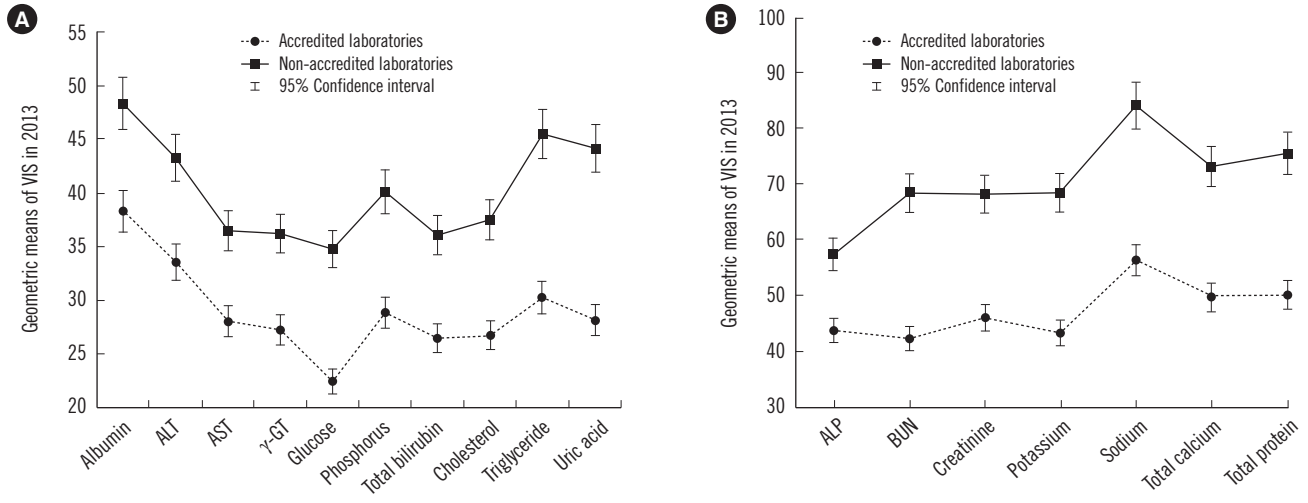

Fig. 1. Comparison of geometric means of the variance index score (VIS) for clinical chemistry tests between laboratories with or without KLAP in 2013. The 95% confidence intervals for the mean of each test in the two groups did not overlap. (A) VIS<50 and (B) VIS: 50–100. The graph shows the clinical chemistry tests on the X-axis and the geometric means of the VIS on the Y-axis.
Abbreviations: BUN, blood urea nitrogen; KLAP, Korean Laboratory Accreditation Program; γ -GT, γ-glutamyl transferase; VIS, variance index score.

4. Statistical analysis

VIS differences between laboratories with or without KLAP were compared by Student's t-test. One-way ANOVA followed by Tukey's multiple comparison test was used to evaluate the statistical significance of the differences among the institutional types. Logarithmic transformation of VIS was performed because of its right skewed distribution. The values of VIS were reported as the geometric mean with 95% confidence intervals. *P* values were based on two-sided comparisons, and *P* values<0.05 were considered statistically significant.

RESULTS

1. Differences in the VIS between laboratories with or without KLAP

Statistical data on VIS, by test, are listed in Table 1. Most of the VIS data received scores of less than 100, except for a chloride test result from laboratories without KLAP (107.7 in 2010, 101.9 in 2011, and 102.3 in 2012). Relative to the group of laboratories without KLAP, the group of laboratories with KLAP exhibited significantly lower geometric means of 4-yr VIS in all tests (*P*< 0.0001). Confidence intervals for the mean of each test item in the two groups (accredited and non-accredited) did not overlap; this gap suggested that the means of the two groups were significantly different (Table 1). The geometric means of VIS in 2013 are shown in Fig. 1.

2. Differences in the VIS between laboratories categorized by institution type

Laboratories in general hospitals and entrusted laboratory agencies exhibited significantly lower geometric means of 4-yr VIS for all test items compared with that of laboratories in hospitals and clinics (*P*<0.0001) (Table 2). The laboratories in general hospitals were further classified into two subgroups based on their KLAP status; the numbers in the accredited and non-accredited groups were 205 (64%) and 116 (36%) in 2010, 212 (65%) and 116 (35%) in 2011, 219 (66%) and 113 (34%) in 2012, and 221 (62%) and 135 (38%) in 2013, respectively. Among the laboratories in general hospitals, the means of 4-yr VIS in laboratories with KLAP were significantly lower than those in laboratories without KLAP for blood urea nitrogen, chloride, creatinine, glucose, lactate dehydrogenase, phosphorus, potassium, sodium, total calcium, total cholesterol, triglyceride, and uric acid (Table 3).

DISCUSSION

The major finding of this study is that the 4-yr VIS was significantly different between laboratories with or without KLAP. The VIS scores in KLAP-accredited laboratories were significantly lower than those in laboratories without KLAP for all clinical chemistry tests; this difference justifies a high level of confidence in standardized services provided by accredited laboratories. The present study is the first to demonstrate a strong impact of practice standardiza-

Table 2. Comparison of variance index scores between laboratories categorized by institution type between 2010 and 2013

Test item	Year	General hospital		Hospital		Clinic		Entrusted laboratory		$P^{\ddagger}$
		N*	VIS† (95% CI)	N*	VIS† (95% CI)	N*	VIS† (95% CI)	N*	VIS† (95% CI)	
Albumin	2010	313	43.0 (40.9–45.3)	312	46.3 (43.7–49.2)	253	48.2 (44.7–51.9)	11	36.4 (29.6–44.6)	0.0302
	2011	320	37.5§,‖ (35.5–39.6)	350	44.9§ (42.6–47.4)	282	44.5‖ (41.6–47.6)	12	35.5 (26.4–47.7)	<0.0001
	2012	324	37.1§,‖ (35.2–39.1)	394	46.5§,¶ (44.1–48.9)	302	45.1‖,** (42.3–48.1)	13	30.6¶,** (22.2–45.1)	<0.0001
	2013	345	39.7§,‖ (37.7–41.9)	447	49.9§ (47.5–52.5)	321	47.3‖ (44.6–50.1)	15	41.9 (33.6–52.1)	<0.0001
ALP	2010	312	41.3§ (38.1–44.9)	308	47.5 (43.5–51.9)	229	52.6§ (46.9–59.1)	11	43.9 (26.2–73.4)	0.0058
	2011	319	43.1§,‖ (40.0–46.5)	346	52.8§ (48.9–57.0)	259	53.5‖ (48.5–59.1)	12	42.7 (28.8–63.4)	0.0007
	2012	323	40.9§,‖ (37.7–44.2)	390	52.1§ (48.2–56.3)	274	49.5‖ (44.7–54.8)	13	47.5 (29.7–75.9)	0.0005
	2013	340	46.6§ (43.0–50.5)	436	59.8§ (55.3–64.6)	289	52.7 (47.9–58.0)	15	51.2 (31.6–82.7)	0.0004
ALT	2010	321	34.3§ (32.3–36.4)	314	38.5 (36.0–41.3)	272	40.6§ (37.6–43.8)	11	31.8 (25.8–39.2)	0.0042
	2011	328	31.8§,‖ (30.0–33.8)	353	36.0§ (34.0–38.2)	309	38.3‖ (35.5–41.4)	12	32.0 (23.7–43.1)	0.0010
	2012	332	35.4§,‖ (33.5–37.3)	397	40.0§ (38.0–42.2)	335	42.6‖,¶ (40.0–45.3)	13	27.5¶ (21.6–35.0)	<0.0001
	2013	356	36.0§,‖ (34.0–38.2)	453	42.9§ (40.7–45.2)	351	44.5‖ (41.8–47.5)	15	38.1 (31.1–46.6)	<0.0001
AST	2010	321	31.2§,‖ (29.4–33.0)	314	36.9§ (34.5–39.4)	271	38.9‖ (36.1–41.9)	11	27.4 (21.0–35.6)	<0.0001
	2011	328	28.2§,‖ (26.6–29.9)	353	32.3§ (30.4–34.2)	309	35.3‖ (33.2–37.5)	12	29.9 (21.9–40.8)	<0.0001
	2012	332	28.7§,‖ (27.1–30.5)	397	35.7§ (33.8–37.7)	334	36.8‖ (34.4–39.3)	13	24.9 (18.9–32.8)	<0.0001
	2013	355	29.6§,‖ (27.8–31.6)	453	35.3§ (33.3–37.4)	350	37.8‖ (35.3–40.5)	15	32.4 (24.6–42.8)	<0.0001
BUN	2010	314	51.2§,‖ (48.2–54.3)	313	63.1§ (59.0–67.5)	255	64.6‖ (59.1–70.6)	11	43.7 (34.0–56.2)	<0.0001
	2011	321	46.4§,‖ (43.8–49.1)	352	62.8§ (59.2–66.7)	286	63.7‖ (58.7–69.0)	12	46.4 (32.7–65.9)	<0.0001
	2012	325	45.0§,‖ (42.7–47.5)	395	63.3§,¶ (59.9–67.0)	303	64.5‖,** (59.8–69.5)	13	38.5¶,** (28.3–52.4)	<0.0001
	2013	351	48.1§,‖ (45.3–51.1)	448	69.0§,¶ (65.2–73.1)	323	69.1‖,** (64.2–74.4)	15	39.2¶,** (29.9–51.5)	<0.0001
Chloride	2010	306	84.4§ (79.8–89.3)	273	108.3§ (101.6–115.3)	45	98.0 (81.2–118.3)	10	83.0 (63.5–108.4)	<0.0001
	2011	313	80.4§,‖ (77.0–84.0)	311	104.6§ (99.0–110.5)	53	96.0‖ (83.3–110.5)	11	90.1 (71.5–113.6)	<0.0001
	2012	316	85.1§ (81.1–89.2)	341	103.9§ (98.4–109.7)	65	90.3 (79.3–102.8)	12	76.0 (59.2–97.5)	<0.0001
	2013	323	88.3§ (84.4–92.4)	386	98.1§ (93.0–103.4)	71	99.6 (89.6–110.6)	15	89.2 (68.5–116.2)	0.0213
Creatinine	2010	313	48.8§,‖ (46.1–51.6)	314	67.0§,¶ (62.9–71.5)	271	69.2‖,** (64.1–74.9)	11	38.2¶,** (23.1–63.0)	<0.0001
	2011	320	47.4§,‖ (44.9–50.0)	353	61.4§ (57.8–65.3)	306	64.2‖ (59.5–69.3)	12	44.8 (35.9–55.9)	<0.0001
	2012	324	48.6§,‖ (46.0–51.3)	397	62.9§ (59.3–66.8)	333	66.9‖,¶ (62.4–71.8)	13	41.9¶ (35.4–49.7)	<0.0001
	2013	350	51.0§,‖ (48.1–54.0)	453	68.3§,¶ (64.8–72.0)	349	71.3‖,** (66.7–76.1)	15	38.5¶,** (30.0–49.3)	<0.0001
γ-glutamyl transferase	2010	313	30.5§,‖ (28.6–32.5)	311	36.5§ (34.0–39.2)	271	36.2‖ (33.2–39.5)	11	24.8 (18.0–34.1)	0.0005
	2011	320	28.2§,‖ (26.5–30.1)	348	35.6§ (33.4–37.9)	307	34.4‖ (31.9–37.1)	12	25.6 (20.6–31.9)	<0.0001
	2012	324	29.4§,‖ (27.6–31.2)	391	33.8§,¶ (31.8–35.9)	332	34.2‖,** (31.6–37.0)	13	19.6¶,** (14.5–26.3)	0.0002
	2013	350	30.5§,‖,¶ (28.7–32.4)	443	35.1§,** (33.2–37.1)	348	37.0‖,†† (34.5–39.6)	15	19.1¶,**,†† (13.9–26.4)	<0.0001
Glucose	2010	313	26.6§,‖ (25.0–28.4)	314	36.2§ (33.9–38.7)	270	33.9‖ (31.2–36.9)	11	28.2 (21.8–36.3)	<0.0001
	2011	320	25.4§,‖ (24.0–26.9)	353	34.4§ (32.4–36.6)	306	34.5‖ (32.1–37.2)	12	26.9 (22.0–32.9)	<0.0001
	2012	324	26.0§,‖ (24.5–27.6)	397	34.1§,¶ (32.1–36.1)	330	34.6‖,** (32.2–37.1)	13	21.2¶,** (15.6–28.9)	<0.0001
	2013	350	26.1§,‖ (24.4–28.0)	452	35.5§ (33.5–37.6)	346	33.2‖ (30.8–35.7)	15	23.6 (17.1–32.5)	<0.0001
LDH	2010	307	17.2§ (15.5–19.1)	239	24.1§ (21.3–27.3)	148	20.2 (17.2–23.8)	11	21.7 (10.8–43.9)	0.0007
	2011	312	15.0§ (13.7–16.4)	256	21.3§ (19.0–23.8)	157	18.3 (15.9–21.1)	12	16.8 (11.0–25.7)	<0.0001
	2012	315	15.2§,‖ (14.1–16.4)	284	20.3§ (18.6–22.1)	159	20.0‖ (17.3–23.2)	13	13.9 (8.0–24.3)	<0.0001
	2013	327	19.3§ (17.8–20.8)	308	23.3§ (21.2–25.6)	165	22.2 (19.5–25.4)	14	13.7 (9.7–19.3)	0.0032
Phosphorus	2010	287	35.8§ (33.6–38.3)	142	46.8§ (42.0–52.1)	53	45.0 (37.3–54.3)	10	41.2 (28.2–60.4)	0.0001
	2011	293	32.1§,‖ (30.1–34.3)	159	42.9§ (38.9–47.4)	64	45.6‖ (37.8–54.9)	11	27.3 (19.7–37.8)	<0.0001
	2012	298	31.6§,‖ (29.5–33.9)	182	39.0§ (35.3–43.2)	68	42.6‖ (36.2–50.1)	12	27.5 (18.8–40.3)	0.0001
	2013	303	31.0§,‖ (29.1–33.1)	189	40.3§,¶ (36.5–44.4)	72	39.1‖,** (32.7–46.6)	14	23.9¶,** (17.1–33.5)	<0.0001

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Table 2. Continued

Test item	Year	General hospital		Hospital		Clinic		Entrusted laboratory		$P^{\ddagger}$
		N*	VIS† (95% CI)	N*	VIS† (95% CI)	N*	VIS† (95% CI)	N*	VIS† (95% CI)	
Potassium	2010	306	52.9§,‖ (49.8–56.1)	283	77.3§,¶ (72.2–82.9)	49	76.3‖ (63.9–91.1)	11	48.2¶ (36.9–63.0)	<0.0001
	2011	313	49.9§,‖ (46.9–53.0)	319	78.2§ (73.6–83.0)	57	73.9‖ (63.4–86.0)	12	54.8 (44.7–67.2)	<0.0001
	2012	315	48.6§,‖ (46.0–51.4)	349	68.2§,¶ (64.6–72.1)	69	60.2‖ (51.5–70.4)	13	43.4¶ (33.9–55.7)	<0.0001
	2013	322	46.3§,‖ (43.4–49.3)	395	71.2§ (67.4–75.3)	74	63.9‖ (55.5–73.6)	15	49.1 (35.1–68.7)	<0.0001
Sodium	2010	306	63.9§,‖ (60.1–68.0)	283	85.1§ (79.9–90.8)	48	100.4‖ (84.7–119.1)	11	67.8 (47.5–96.7)	<0.0001
	2011	313	65.3§,‖ (61.6–69.2)	319	88.6§ (83.6–93.8)	57	92.6‖ (79.4–108.0)	12	80.1 (57.4–111.8)	<0.0001
	2012	316	62.8§,‖ (59.5–66.3)	349	91.4§ (86.6–96.4)	69	87.5‖ (76.8–99.6)	13	69.4 (52.8–91.3)	<0.0001
	2013	323	59.8§,‖ (56.6–63.2)	395	86.1§,¶ (81.7–90.8)	74	81.5‖,** (71.9–92.4)	15	55.0¶,** (41.1–73.6)	<0.0001
Total bilirubin	2010	312	26.6§,‖ (24.9–28.5)	310	36.8§,¶ (33.8–40.0)	248	40.1‖,** (36.4–44.3)	11	20.2¶,** (15.4–26.6)	<0.0001
	2011	319	28.7§,‖ (26.9–30.7)	350	37.8§ (35.8–40.5)	278	38.0‖ (34.8–41.4)	12	29.2 (22.1–38.6)	<0.0001
	2012	323	27.0§,‖ (25.2–29.0)	394	33.9§ (31.7–36.2)	299	34.4‖ (31.4–37.6)	13	24.2 (19.2–30.5)	<0.0001
	2013	348	28.3§,‖ (26.4–30.4)	446	35.1§ (33.0–37.3)	319	37.7‖ (35.0–40.7)	15	26.5 (19.2–36.7)	<0.0001
Total calcium	2010	295	57.8§,‖ (54.4–61.5)	164	81.9§ (74.9–89.5)	60	74.9‖ (62.7–89.4)	10	65.2 (48.5–87.6)	<0.0001
	2011	302	57.6§,‖ (54.4–60.9)	185	82.9§,¶ (76.9–89.2)	71	75.4‖ (64.9–87.5)	11	54.6¶ (42.6–69.9)	<0.0001
	2012	305	57.6§,‖ (54.3–60.9)	205	79.4§ (73.4–85.9)	74	67.6 (58.8–77.6)	12	46.5‖ (31.5–68.5)	<0.0001
	2013	312	52.1§,‖ (49.1–55.3)	217	77.5§ (71.3–84.2)	76	71.8‖ (62.5–82.5)	14	54.8 (44.3–67.8)	<0.0001
Total cholesterol	2010	315	29.2§,‖ (27.6–30.9)	314	37.7§ (35.2–40.3)	272	37.4‖ (34.6–40.5)	11	26.5 (18.1–39.0)	<0.0001
	2011	322	28.4§,‖ (26.9–30.0)	351	36.6§ (34.6–38.7)	308	33.8‖ (31.5–36.3)	12	27.0 (19.4–37.6)	<0.0001
	2012	324	27.5§,‖ (26.0–29.1)	389	36.0§ (34.0–38.1)	331	34.5‖ (32.1–37.1)	13	29.8 (24.3–36.5)	<0.0001
	2013	352	30.1§,‖ (28.3–31.9)	450	37.7§ (35.7–39.9)	349	36.1‖ (33.8–38.6)	15	26.0 (20.5–32.9)	<0.0001
Total protein	2010	314	59.1§,‖ (55.6–62.8)	312	78.4§ (73.3–83.9)	248	73.8‖ (67.0–81.2)	11	61.5 (48.6–77.7)	<0.0001
	2011	321	58.8§,‖ (55.9–61.8)	350	74.3§ (70.1–78.7)	275	75.1‖ (69.5–81.0)	12	52.9 (40.5–69.0)	<0.0001
	2012	325	55.2§,‖ (52.4–58.1)	394	73.0§ (69.0–77.3)	293	70.3‖ (65.3–75.8)	13	53.6 (39.3–73.0)	<0.0001
	2013	340	56.9§,‖ (53.7–60.3)	433	77.4§ (73.1–82.0)	311	71.5‖ (66.4–77.0)	15	53.2 (40.4–70.1)	<0.0001
Triglyceride	2010	312	37.1§,‖ (34.2–40.2)	304	45.0§ (41.3–49.0)	269	45.0‖ (41.4–48.9)	11	35.8 (21.5–59.8)	0.0023
	2011	318	39.8§,‖ (36.8–43.0)	341	47.2§ (43.4–51.3)	305	48.1‖ (44.4–52.2)	12	35.3 (19.4–64.2)	0.0029
	2012	310	36.4§,‖ (33.8–39.3)	301	45.0§ (41.3–49.1)	259	44.6‖ (41.1–48.5)	11	34.0 (21.0–55.0)	0.0005
	2013	349	35.3§,‖ (32.8–38.0)	439	45.7§,¶ (42.6–49.0)	347	44.4‖,** (41.4–47.5)	15	26.1¶,** (21.5–31.8)	<0.0001
Uric acid	2010	311	34.4§,‖ (32.4–36.6)	281	45.5§ (42.2–49.1)	207	43.5‖ (39.3–48.2)	11	33.3 (25.7–43.3)	<0.0001
	2011	318	31.8§,‖ (30.1–33.6)	315	43.0§ (40.2–46.0)	225	42.7‖ (38.7–47.1)	11	35.5 (24.2–52.0)	<0.0001
	2012	322	30.1§,‖ (28.4–31.8)	352	43.7§,¶ (41.0–46.6)	236	39.3‖ (35.7–43.2)	13	26.3¶ (20.4–33.9)	<0.0001
	2013	346	33.0§,‖ (31.0–35.2)	386	45.7§,¶ (42.8–48.8)	245	40.8‖,** (37.2–44.7)	15	24.6¶,** (19.4–31.1)	<0.0001

*Number of laboratories; †Geometric mean of the VIS; ‡*P* value represents overall differences across groups as determined by ANOVA using log-transformed values; §, ‖, ¶, **, ††Matching letters indicate statistical significance based on Tukey's multiple comparison.
Abbreviations: see Table 1.

tion on the accuracy of test results.

Implementation of laboratory standards is verified through the process of accreditation. In many countries, accreditation of medical laboratories has been established for several decades [9-12]. Accredited medical laboratories should have a well-functioning quality management system, demonstrate technical competence, and provide timely and customer-focused services that contribute to patient care. Our observation of a lower VIS in KLAP-accredited laboratories suggests that the KLAP assesses laboratories in accordance with the accepted standards. This finding provides external validation that KLAP-accredited laboratory services are accurate, traceable, and reproducible.

Clinical laboratories must provide high-quality services by producing accurate, precise, relevant, and comprehensive data, which have a direct impact on the medical management of patients [1]. Enhancement of the quality of laboratory services in-

Table 3. Comparison of variance index scores between laboratories in the general hospital group between 2010 and 2013

Test item	Year	Accredited laboratory		Non-accredited laboratory		$P^{\ddagger}$
		N*	VIS† (95% CI)	N*	VIS† (95% CI)	
Albumin	2010	205	40.8 (38.5–43.4)	108	47.5 (43.5–52.0)	0.0045
	2011	212	36.4 (34.1–38.9)	108	39.6 (36.0–43.6)	0.1534
	2012	219	36.5 (34.3–38.9)	105	38.3 (34.9–42.1)	0.3865
	2013	221	37.6 (35.4–39.9)	124	43.9 (39.8–48.6)	0.0080
ALP	2010	203	39.3 (36.0–43.0)	109	45.4 (38.5–53.6)	0.1310
	2011	210	40.3 (37.0–44.0)	109	49.1 (42.5–56.6)	0.0209
	2012	217	39.9 (36.5–43.6)	106	42.9 (36.5–50.4)	0.4376
	2013	219	43.4 (39.6–47.5)	121	53.1 (45.5–61.9)	0.0262
ALT	2010	205	33.9 (31.7–36.3)	116	35.0 (31.2–39.2)	0.6480
	2011	212	29.1 (27.2–31.3)	116	37.4 (33.8–41.4)	<0.0001
	2012	219	33.4 (31.3–35.6)	113	39.6 (36.0–43.5)	0.0028
	2013	221	34.0 (31.6–36.5)	135	39.6 (35.8–43.9)	0.0130
AST	2010	205	30.0 (27.9–32.2)	116	33.4 (30.3–36.8)	0.0794
	2011	212	27.3 (25.5–29.3)	116	29.8 (26.7–33.2)	0.1722
	2012	219	27.7 (25.7–29.8)	113	30.8 (27.9–34.0)	0.0914
	2013	221	28.0 (26.0–30.1)	134	32.6 (29.2–36.4)	0.0199
BUN	2010	205	46.9 (43.8–50.3)	109	60.2 (54.3–66.8)	<0.0001
	2011	212	41.2 (38.7–43.9)	109	58.4 (52.6–64.8)	<0.0001
	2012	219	42.2 (39.7–45.0)	106	51.4 (46.9–56.3)	0.0005
	2013	221	42.3 (39.7–45.1)	130	59.7 (53.3–66.8)	<0.0001
Chloride	2010	203	76.0 (71.2–81.1)	103	103.9 (94.2–114.5)	<0.0001
	2011	210	74.7 (71.2–78.5)	103	93.4 (86.3–101.2)	<0.0001
	2012	217	77.5 (73.6–81.7)	99	104.2 (95.5–113.7)	<0.0001
	2013	219	83.1 (79.0–87.4)	104	100.2 (91.7–109.5)	0.0004
Creatinine	2010	203	44.8 (41.9–47.9)	110	57.1 (51.8–62.9)	<0.0001
	2011	210	45.2 (42.4–48.1)	110	51.9 (46.8–57.5)	0.0257
	2012	217	45.1 (42.5–47.9)	107	56.5 (50.6–63.1)	0.0005
	2013	219	45.6 (43.0–48.3)	131	61.5 (54.8–69.0)	<0.0001
γ-glutamyl transferase	2010	203	27.7 (25.6–29.9)	110	36.5 (32.8–40.6)	<0.0001
	2011	210	27.8 (25.7–30.0)	110	29.1 (26.0–32.6)	0.5024
	2012	217	28.5 (26.5–30.6)	107	31.2 (27.9–34.8)	0.1758
	2013	219	27.9 (26.0–29.9)	131	35.3 (31.6–39.4)	0.0004
Glucose	2010	203	23.2 (21.7–24.9)	110	34.3 (30.7–38.3)	<0.0001
	2011	210	23.2 (21.8–24.7)	110	30.3 (27.4–33.6)	<0.0001
	2012	217	23.8 (22.2–25.4)	107	31.3 (28.0–35.1)	<0.0001
	2013	219	22.1 (20.6–23.8)	131	34.5 (30.6–38.9)	<0.0001
LDH	2010	201	15.2 (13.5–17.1)	106	21.7 (17.9–26.4)	0.0021
	2011	208	13.2 (12.0–14.6)	104	19.2 (16.1–23.0)	0.0004
	2012	214	14.0 (12.9–15.2)	101	18.1 (15.4–21.4)	0.0064
	2013	216	17.1 (15.8–18.5)	111	24.3 (20.6–28.7)	0.0002

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Table 3. Continued

Test item	Year	Accredited laboratory		Non-accredited laboratory		$P^{\ddagger}$
		N*	VIS† (95% CI)	N*	VIS† (95% CI)	
Phosphorus	2010	198	32.9 (30.6–35.4)	89	43.4 (38.0–49.4)	0.0001
	2011	205	29.2 (27.2–31.4)	88	40.1 (35.1–45.8)	<0.0001
	2012	214	29.4 (27.4–31.7)	84	37.9 (32.6–44.1)	0.0033
	2013	217	29.0 (27.0–31.2)	86	36.7 (32.1–42.0)	0.0011
Potassium	2010	203	48.4 (45.1–51.9)	103	63.0 (56.5–70.2)	<0.0001
	2011	210	44.4 (41.4–47.6)	103	63.1 (56.6–70.3)	<0.0001
	2012	216	44.0 (41.5–46.7)	99	60.4 (53.9–67.7)	<0.0001
	2013	218	41.9 (39.0–45.1)	104	56.8 (50.9–63.4)	<0.0001
Sodium	2010	203	59.5 (55.3–64.0)	103	73.7 (66.0–82.3)	0.0011
	2011	210	59.7 (56.0–63.6)	103	78.5 (70.0–88.0)	<0.0001
	2012	217	57.2 (54.0–60.6)	99	76.9 (68.9–85.9)	<0.0001
	2013	219	54.4 (51.1–58.0)	104	72.9 (65.9–80.7)	<0.0001
Total bilirubin	2010	203	25.6 (23.6–27.8)	109	28.6 (25.2–32.4)	0.1378
	2011	210	27.6 (25.5–29.9)	109	31.0 (27.7–34.7)	0.0926
	2012	217	26.8 (24.7–29.1)	106	27.5 (24.3–31.2)	0.7206
	2013	219	26.0 (24.0–28.2)	129	32.6 (28.7–37.2)	0.0036
Total calcium	2010	200	52.9 (49.2–57.0)	95	69.7 (62.7–77.5)	<0.0001
	2011	208	51.8 (48.5–55.3)	94	72.8 (66.0–80.3)	<0.0001
	2012	216	53.3 (49.8–57.1)	89	69.2 (62.9–76.1)	<0.0001
	2013	217	48.7 (45.7–52.1)	95	60.5 (53.6–68.4)	0.0024
Total cholesterol	2010	205	27.8 (25.9–29.7)	110	32.1 (28.9–35.6)	0.0188
	2011	212	26.0 (24.3–27.9)	110	33.7 (30.8–36.8)	<0.0001
	2012	219	25.7 (24.1–27.5)	105	31.6 (28.4–35.3)	0.0007
	2013	221	26.4 (24.8–28.0)	131	37.5 (33.3–42.1)	<0.0001
Total protein	2010	205	57.1 (53.1–61.4)	109	62.9 (56.3–70.4)	0.1389
	2011	212	53.4 (50.6–56.4)	109	70.9 (64.4–78.1)	<0.0001
	2012	219	50.9 (47.9–54.0)	106	65.1 (59.2–71.7)	<0.0001
	2013	221	50.5 (47.5–53.7)	119	71.0 (63.5–79.3)	<0.0001
Triglyceride	2010	203	32.2 (29.3–35.3)	109	48.5 (42.0–55.9)	<0.0001
	2011	210	35.3 (32.5–38.3)	108	50.3 (43.1–58.7)	<0.0001
	2012	212	32.7 (30.0–35.5)	98	46.2 (39.8–53.6)	<0.0001
	2013	219	29.4 (27.3–31.7)	130	47.9 (41.7–54.9)	<0.0001
Uric acid	2010	203	32.4 (30.2–34.7)	108	38.6 (34.4–43.2)	0.0100
	2011	210	29.7 (27.7–31.7)	108	36.5 (33.3–40.0)	0.0005
	2012	217	28.0 (26.2–29.9)	105	34.9 (31.6–38.5)	0.0003
	2013	219	28.0 (26.3–29.9)	127	43.7 (38.8–49.3)	<0.0001

*Number of laboratories; †Geometric mean of the VIS; ‡*P* value by Student's t-test using log-transformed values.
Abbreviations: see Table 1.

volves laboratory quality management plans, including pre-analytic, analytic, and post-analytic plans, and standardization of activities and practices. A lack of standardization makes it impossible to guarantee the reliability or accuracy of laboratory test

results, which increases the error rate and endangers patient safety [13]. Laboratory standards critical to patient safety include proficiency testing, laboratory accreditation, continuing education, safety goals, health information technology use, and electronic records. Therefore, accreditation bodies, consisting of independent entities as well as government authorities, should work to improve the quality of laboratory practices and patient safety.

We used the VIS statistical parameter, obtained from the KEQAS, to assess the standardized performance of different laboratories. One could argue that the parameter accurately reflects laboratory standardization, because the KEQAS is run by a voluntary organization, and not government authorities. However, the KEQAS has great value in quality assessment, allowing a laboratory to confirm that its results are consistent with those of other laboratories using the same or similar methods, and thus to confirm that it is correctly following the methods [14]. It is also important for maintaining long-term accuracy of analytical methods, and thus, it was chosen as a parameter to assess the effect of standardization.

In conclusion, our investigation of the KEQAS data confirmed that practice standardization is strongly associated with the accuracy of test results. Our analysis emphasizes the necessity of establishing a system for providing standardized diagnostic testing.

Authors' Disclosures of Potential Conflicts of Interest

No potential conflicts of interest relevant to this article were reported.

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