Letter to the Editor
Diagnostic Hematology

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Effect of Accreditation on the Accuracy of Diagnostic Hematologic Tests: Standard Deviation Index Analysis

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Dear Editor,

Thorough quality management is paramount because diagnostic tests play an important role in medical decisions and can involve a complex, multistep process, from sampling to reporting the test results. In general, the reliability of a diagnostic test is based on two factors: diagnostic product standardization and practice standardization. While diagnostic product standardization is established on a legal basis with administrative assistance, practice standardization is less well established and can, to a large extent, depend on the private sector. In Korea, this private sector involvement is mediated through the Korean Laboratory Accreditation Program (KLAP).

KLAP was established in 1999 and instituted by Korean Society for Laboratory Medicine (KSLM) [1]. KLAP conducts document screening and on-site inspections to assess test results and compliance with practice standardization.

The Korean external quality assessment scheme (KEQAS) is a proficiency testing program run by the Korean Association of Quality Assurance for Clinical Laboratory [2]. KEQAS distributes the same material to all participating laboratories and statistically analyzes the results of the measurements. This permits the analytical accuracy of the test results of individual laboratories to be monitored and objectively measured.

Laboratories that participate only in the KEQAS are designated as basically-standardized laboratories (BSL). A highly-standardized laboratory (HSL) is a laboratory that participates simultaneously in KEQAS and KLAP and obtains a certificate of accreditation.

Recently, we reported the results of an accreditation analysis of clinical chemistry tests in clinical laboratories [3]. We concluded that practice standardization is strongly associated with the accuracy of clinical chemistry test results. Here, we extended the findings by analyzing the impact of standardization on diagnostic hematology test results.

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Table 1. Comparison of standard deviation index between accredited and non-accredited laboratories

	Year	Non-accredited laboratories			Accredited laboratories			$P^{\ddagger}$
		N*	SDI†	95% CI	N	SDI	95% CI	
Hb	2005	290	0.73	[0.68 0.78]	172	0.52	[0.47 0.57]	<0.01
	2006	381	0.85	[0.79 0.92]	180	0.68	[0.62 0.74]	<0.01
	2007	372	0.66	[0.61 0.72]	189	0.55	[0.50 0.60]	<0.01
	2008	450	0.71	[0.66 0.75]	201	0.58	[0.54 0.62]	<0.01
	2009	652	0.85	[0.81 0.89]	215	0.62	[0.58 0.65]	<0.01
	2010	778	0.71	[0.67 0.74]	230	0.49	[0.45 0.52]	<0.01
	2011	850	0.93	[0.89 0.97]	242	0.62	[0.58 0.66]	<0.01
	2012	911	0.66	[0.63 0.69]	255	0.47	[0.43 0.50]	<0.01
	2013	1025	0.82	[0.78 0.85]	261	0.56	[0.52 0.60]	<0.01
Hct	2006	381	0.77	[0.72 0.82]	180	0.77	[0.71 0.84]	0.91
	2007	372	0.70	[0.66 0.75]	189	0.74	[0.68 0.80]	0.38
	2008	450	0.74	[0.70 0.79]	201	0.66	[0.61 0.71]	<0.01
	2009	652	0.71	[0.67 0.74]	215	0.79	[0.73 0.86]	0.02
	2010	778	0.66	[0.63 0.69]	230	0.71	[0.65 0.77]	0.20
	2011	850	0.71	[0.67 0.74]	242	0.94	[0.87 1.02]	<0.01
	2012	911	0.69	[0.66 0.72]	255	0.84	[0.79 0.89]	<0.01
	2013	1025	0.74	[0.71 0.77]	261	0.79	[0.73 0.86]	0.19
RBC	2005	290	0.72	[0.67 0.78]	172	0.52	[0.48 0.57]	<0.01
	2006	381	0.80	[0.74 0.86]	180	0.73	[0.68 0.79]	0.12
	2007	372	0.69	[0.64 0.74]	189	0.63	[0.59 0.68]	0.13
	2008	450	0.68	[0.64 0.73]	201	0.67	[0.63 0.72]	0.78
	2009	652	0.78	[0.74 0.83]	215	0.64	[0.59 0.69]	<0.01
	2010	778	0.68	[0.64 0.71]	230	0.53	[0.49 0.58]	<0.01
	2011	850	0.78	[0.74 0.82]	242	0.68	[0.62 0.74]	<0.01
	2012	911	0.20	[0.19 0.22]	255	0.16	[0.15 0.18]	<0.01
	2013	1025	0.82	[0.79 0.86]	261	0.60	[0.57 0.64]	<0.00
WBC	2005	290	0.65	[0.60 0.71]	172	0.59	[0.54 0.65]	0.13
	2006	381	0.86	[0.79 0.94]	180	0.77	[0.69 0.85]	0.09
	2007	372	0.67	[0.62 0.73]	189	0.65	[0.59 0.72]	0.67
	2008	450	0.67	[0.62 0.72]	201	0.60	[0.56 0.65]	0.05
	2009	652	0.89	[0.84 0.95]	215	0.81	[0.74 0.88]	0.07
	2010	778	0.68	[0.64 0.71]	230	0.60	[0.56 0.65]	0.01
	2011	850	0.84	[0.80 0.88]	242	0.73	[0.67 0.78]	<0.01
	2012	911	0.43	[0.41 0.45]	255	0.37	[0.35 0.39]	<0.01
	2013	1025	0.80	[0.77 0.84]	261	0.74	[0.70 0.79]	0.04
Platelet	2005	290	0.68	[0.63 0.73]	172	0.71	[0.66 0.76]	0.44
	2006	381	0.76	[0.71 0.81]	180	0.84	[0.77 0.91]	0.08
	2007	372	0.68	[0.64 0.73]	189	0.75	[0.69 0.81]	0.07
	2008	450	0.67	[0.63 0.71]	201	0.77	[0.73 0.82]	<0.01
	2009	652	0.73	[0.69 0.76]	215	0.73	[0.68 0.79]	0.86
	2010	778	0.67	[0.64 0.71]	230	0.86	[0.80 0.92]	<0.01
	2011	850	0.72	[0.68 0.75]	242	0.78	[0.72 0.85]	0.07
	2012	911	0.68	[0.65 0.71]	255	0.72	[0.67 0.76]	0.25
	2013	1025	0.75	[0.72 0.78]	261	0.70	[0.65 0.75]	0.09

*Number of laboratories; †Values represent the geometric mean; ‡*P*-value by Student's t-test using the log-transformed values.
Abbreviations: SDI, standard deviation index; RBC, red blood cell; WBC, white blood cell; CI, confidence interval; Hb, hemoglobin; Hct, hematocrit.

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Table 2. Comparison of hemoglobin standard deviation index between accredited and non-accredited laboratories by institutional type

Year	General Hospital				*P*‡	Hospital				*P*	Clinic				*P*
	Non-accredited laboratories		Accredited laboratories			Non-accredited laboratories		Accredited laboratories			Non-accredited laboratories		Accredited laboratories		
	N*	SDI†	N	SDI		N	SDI	N	SDI		N	SDI	N	SDI	
2005	112	0.68	156	0.53	0.00	78	0.80	5	0.62	0.48	56	0.67	11	0.40	<0.01
2006	121	0.77	163	0.67	0.08	109	1.00	5	1.15	0.76	102	0.74	12	0.56	0.24
2007	113	0.60	171	0.55	0.31	108	0.75	6	0.78	0.94	102	0.60	12	0.46	0.27
2008	115	0.68	183	0.58	0.02	142	0.77	6	0.81	0.85	135	0.63	12	0.50	0.03
2009	125	0.80	194	0.63	0.00	241	0.87	8	0.53	0.09	207	0.85	13	0.52	0.01
2010	123	0.63	203	0.49	0.00	306	0.73	11	0.47	0.02	267	0.72	15	0.42	<0.01
2011	124	0.77	210	0.61	0.00	341	0.99	14	0.95	0.87	296	0.93	17	0.55	<0.01
2012	120	0.54	217	0.46	0.04	380	0.71	17	0.59	0.23	322	0.67	20	0.41	<0.01
2013	151	0.74	219	0.55	0.00	433	0.85	20	0.70	0.11	343	0.84	21	0.51	<0.01

*Number of laboratories; †Values representthe geometric mean; ‡*P*-value by Student's t-test using the log-transformed values.
Abbreviation: see Table 1.

Five items, Hb, Hct, red blood cell (RBC), white blood cell (WBC), and platelet count, were analyzed. The analyses involved results obtained from 30,616 samples over a 9-year period (2005–2013). The Hct data were from an 8-year period (2006–2013). The standard deviation index (SDI), defined as: (measured value of the institution - average of the participating institutions)/standard deviation of the participating institutions, was used for evaluation. The higher the absolute SDI value, the more inferior the results, as they are less similar to the average of the participating institutions.

First, we compared the SDI of all five items according to whether laboratories were KLAP-certified using diagnostic blood test result data from the 9-year KEQAS. SDI mean values were compared using the Student's t-test; significance was assigned at $P<0.05$. Compared with non-KLAP accredited laboratories, accredited laboratories showed significantly lower geometric means for all 9-year SDI in Hb, 3-year SDI in Hct and WBCs, 5-year SDI in RBCs, and 2-year SDI in platelets (all $P<0.05$; Table 1).

Second, the SDI of Hb test results was analyzed statistically in KEQAS according to KLAP certification status and institutional type. Participating institutes were categorized as general hospitals with >100 beds, hospitals with 30-99 beds, and clinics with <30 beds. For the 9-year Hb test data, laboratories with KLAP accreditation showed significantly lower geometric means of 8-year SDI in general hospitals, 1-year SDI in hospitals, and 7-year SDI in clinics compared with laboratories without KLAP accreditation (all $P<0.05$; Table 2).

Clinical chemistry results were reported to be more accurate and reliable in KLAP-accredited laboratories [3]. However, the present diagnostic hematology results show that practice standardization did not significantly affect test results, except for the Hb test item. There are several differences between diagnostic hematology and clinical chemistry tests [4-7]. Most diagnostic hematology instruments use flow cytometry cell counting, but use spectrophotometry to measure Hb values. Spectrophotometry is widely used in clinical chemistry, while flow cytometry exhibits high precision with low uncertainty. In other words, product standardization, conducted prior to practice standardization, is already excellent; thus, practice standardization will have little effect on the results. It can be assumed that only Hb values are meaningful for all the analysis years, while the other test items exhibit varying significance depending on year. In conclusion, diagnostic test practice standardization is useful for obtaining more reliable and accurate test results; however, the degree of improvement will depend on the particular test measurement principles in diagnostic hematology.

Authors' Disclosures of Potential Conflicts of Interest

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

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