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Portable Blood Gas and Electrolyte Analyzer Evaluated in a Multiinstitutional Study

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A recently introduced blood gas/electrolyte analyzer (SenDx 100®, renamed ABL70) intended for point-of-care, near-patient, or stat laboratory use was evaluated simultaneously in four different institutions and compared with three different laboratory bench analyzers with respect to imprecision, inaccuracy (assessed by tonometry), and patient-sample analyses. The analyzer is equipped with a sensor cassette and a reagent cartridge for 50, 100, or 200 analyses and 100 or more traditional quality-control measurements. One analysis requires 170 μL of whole blood and takes <90 s. Statistically, the instrument performed somewhat better (lower CVs) for P_{O_2} and potassium and somewhat worse for pH, P_{CO_2}, and ionized calcium than the respective comparison analyzers. However, the overall performance (in terms of CV and accuracy) was satisfactory in terms of clinical (e.g., CLIA '88) goals in all institutions. The mean difference and the CV of that difference in some 400 patient-sample comparisons were as follows: 0.010 (± 0.002%) for pH, −0.65 mmHg (± 4%) for P_{CO_2}, −0.49 mmHg (± 6%) for P_{O_2}, 0.44 mmol/L (± 1.2%) for sodium, −0.013 mmol/L (± 2.9%) for potassium, −0.016 mmol/L (± 2.6%) for ionized calcium, and −0.016 L/L (± 7.1%) for the hematocrit. Its acceptable analytical performance and ease of operation make the SenDx 100 suitable for the analysis of blood gases and electrolytes.

Changes in the practice of clinical chemistry and clinical medicine have paved the way for the introduction of small- and medium-sized devices *(1–5)* for the measurement of vital clinical chemistry indicators near the patient, at the bedside or, as commonly called today, at the point of care. This development has been fostered by advances in sensor technology that have obviated the need for preanalytical separation of blood cells and plasma. An important advantage of these devices is the reduction of preanalytical errors associated with centralized testing, e.g., ongoing metabolism and electrolyte movements in the blood cells during transport of the sample and gas exchange through the (mostly plastic) wall of the syringe *(6)*.

One of the latest newcomers in this field of decentralized point-of-care testing by use of sensor technology is the SenDx 100® blood gas/electrolyte analyzer (SenDx Medical, Inc., Carlsbad, CA).[6] This portable tabletop instrument contains a sample introduction stylus, a disposable sensor cassette, a printer, a liquid crystal display touch color screen, and a disposable calibration cartridge. Each combination of calibration cartridge and sensor cassette allows the measurement of 50, 100, or 200 patient samples and at least 100 control samples within a period of 2 weeks. The cartridge contains sensors for pH, P_{CO_2}, P_{O_2}, sodium, potassium, ionized calcium, and conductivity (as a measure for hematocrit).

The SenDx 100 retains the features of a traditional laboratory bench analyzer but is portable and is intended for use in a near-patient setting. The SenDx 100 permits traditional quality-control procedures, which cover the entire analytical phase of the measurement, including the sensors. Specific lock-out procedures in the resident software preclude use of an improperly functioning sensor cassette or use by unauthorized personnel.

In the present study, four instruments were evaluated at four different clinical institutions with respect to im-

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[6] Since the completion of this study, SenDx Medical, Inc. has been acquired by Radiometer A/S, Copenhagen, Denmark. As a consequence, the SenDx 100 blood gas/electrolyte analyzer has been renamed ABL70.

precision, inaccuracy, and comparability of patient-sample results with three different routinely used laboratory blood gas/electrolyte analyzers.

Materials and Methods

SenDx 100 portable blood gas/electrolyte analysis system

Each of the participating hospital laboratories (identified as A, B, C, and D) was equipped with a SenDx 100 analyzer and a sufficient number of two lots of calibration cartridges and sensor cassettes to complete the study, all made available by the manufacturer. The analyzers were operated according to the manufacturer's standard operating procedures and without special adjustments by the manufacturer.

The analyzer measures 13 × 8 × 9 inches and weighs 14 pounds. The sensors are incorporated into a visible sample measurement cassette that uses ~170 μL of blood sample, which is introduced by aspiration. The temperature of the measuring chamber is monitored continuously and regulated at 37.0 °C during calibration and analysis. A self-contained disposable cartridge contains the calibrator/wash reagents and a waste container. In this study, the instrument was ready for analysis continuously and did not need preanalysis calibration. An automatic two-point calibration was scheduled every 4 h. The built-in battery is charged continuously when the analyzer is plugged into an electrical outlet, which allows the instrument to operate on battery power for ~30 analyses or 1 h. Patient data and quality-control results can be downloaded and stored on disk. The built-in printer provides a hard copy of patient results and calibration and quality-control data.

thin-film tonometer

Each testing site was equipped with an IL 237 tonometer (Instrumentation Laboratory Co.) and supplied with appropriate, certified gas mixtures.

comparison analyzers

Laboratories A and C used the ABL 505 from Radiometer; laboratory B used Chiron 288 and 270 (Chiron Diagnostics) as comparison instruments. Laboratory D used an Instrumentation Laboratory type 1312 blood gas analyzer for blood gases and the Beckman CX3 analyzer (Beckman Instruments) for electrolytes (on plasma samples). Hematocrit comparisons were conducted against routinely used automated hematology analyzers, which were themselves calibrated against the centrifuged hematocrit.

materials

For imprecision studies, the "three-level" Euro-Trol Gas-ISE Protein, lot nos. AD1–541C, AD2–543C, and AD3–544C, respectively (Euro-Trol bv) were used in all participating laboratories. Comparison instruments were used with the manufacturers' reagents and calibrators. For tonometry, each laboratory applied two different gas mixtures, which were analyzed with a relative inaccuracy of <2% for O_2 and CO_2 (in practice between 0.1 and 0.2 volume percent absolute) and certified.

whole blood samples

Each testing site analyzed 80–100 anaerobically handled, heparin-treated (3-mL syringe with 7 units/mL dry lithium heparin) patient samples, selected without conscious bias from those received routinely in the laboratory. For tonometry, heparin-treated (15 units/mL) whole blood was collected from healthy human volunteers.

protocol

Within-day imprecision. On each of 3 days, sequential samples of each Euro-Trol control were analyzed 10 times with one cartridge on the SenDx 100 and the comparison analyzer in each laboratory. This procedure was repeated with another calibration cartridge and sensor cassette of a different lot number. In the four institutions, three different cartridge/cassette combinations in total were used. Laboratory B accidentally omitted the comparison analyzer data from the within-day imprecision study; laboratory D did not provide comparison analyzer data for electrolyte because they could not use the control material in their comparison analyzer.

Between-day imprecision. For 10 days, a Euro-Trol control was analyzed in duplicate with both the SenDx 100 and the comparison analyzer in random order.

Tonometry. Tonometry using fresh, heparin-treated human whole blood was performed, according to IFCC recommendations on tonometry of blood *(7)*, on 3 days on both the SenDx 100 and the corresponding comparison analyzer in each laboratory. For each gas mixture, the exact partial pressures were calculated daily, with barometric pressures taken into into consideration. The temperature of the blood/gas equilibrium chamber was carefully monitored to maintain a constant tonometer temperature of 37.0 ± 0.1 °C. This procedure was repeated with a different cassette and calibration cartridge.

The differences of 10 consecutive measurements with the corresponding target value were calculated and averaged. The overall mean of all averaged differences was then taken as a measure for inaccuracy, either absolute or as a percentage of the target value.

Method comparison. Each participating laboratory analyzed 80–100 anaerobically handled blood samples in split-sample fashion with the SenDx 100 analyzer and the corresponding comparison instrument, according to NCCLS guidelines *(8)*.

Patient blood samples collected in heparin-containing syringes were taken at random from those submitted routinely to the laboratory by pneumatic tube or by hand delivery. The samples were remixed by hand immediately

and analyzed with the SenDx 100 and the comparison analyzer. The maximum allowable time interval between the two measurements was 3 min. In laboratory D, one-half the sample was transferred to a centrifuge tube, and plasma for electrolyte measurement on the CX3 was prepared by centrifugation. The other half was used for measuring blood gases on the SenDx 100 and the comparison analyzer.

Two different SenDx 100 cassettes were used (40–50 samples/cassette), each for at least 5 days. On each operating day, sampling of two Euro-Trol control materials was scheduled to ascertain that both analyzers were within 2 SD of the target value during the whole comparison period.

STATISTICAL DATA ANALYSIS

Before statistical analysis, all data were subjected to an outlier rejection procedure according to the NCCLS EP9-A guideline *(8)*. All data from different observation days and different lot numbers were processed together unless indicated. The significance of differences in the means were tested using the Student *t*-test. Patient-sample comparisons were pooled from all four institutions and analyzed by calculating the slope and intercept from a regression analysis according to Passing and Bablok *(9)*; bias and variability of differences were analyzed according to Bland and Altman *(10)*.

Results

IMPRECISION STUDIES

During the whole study, all cassettes and cartridges remained within the quality-control specifications up to their indicated expiration dates.

Generally, the within-day imprecision of the four instruments and the respective comparison analyzers showed similar CVs for pH, Po_2, Pco_2, and potassium (Table 1). Sodium and ionized calcium measurements on the SenDx 100 were less precise than those of the comparison analyzers. The between-day imprecision (Table 2) was better on most comparison instruments for pH, Pco_2, sodium, and ionized calcium, but was better on the SenDx 100 for Po_2 and potassium. There were no clinically significant differences (generally <2%) between different sensor cassettes and reagent cartridges. Table 3 summarizes the averaged data for all control materials in all four centers. The CV data for within- and between-day imprecision for electrolytes in laboratory D were obtained separately with a different sample type and given just for the purpose of comparison with a different technique (indirect measurement).

Table 1. Within-day imprecision.

	CV, %[a]							
	Laboratory A		Laboratory B		Laboratory C		Laboratory D	
	SenDx	Comp.[b]	SenDx	Comp.	SenDx	Comp.	SenDx	Comp.
pH								
7.179	0.004	0.003	0.003	ND	0.004	0.002	0.003	0.003
7.398	0.002	0.001	0.001	ND	0.007	0.003	0.005	0.003
7.572	0.003	0.003	0.001	ND	0.012	0.001	0.002	0.004
Pco_2, mmHg								
61.0	1.6	1.5	1.8	ND	2.2	1.0	1.3	1.6
38.5	1.7	1.0	1.0	ND	2.0	0.9	1.8	0.8
21.9	1.6	1.2	0.8	ND	3.7	0.8	2.0	1.1
Po_2, mmHg								
59.5	5.0	3.6	2.2	ND	2.5	5.2	3.2	7.1
99.8	4.2	2.3	1.4	ND	1.6	3.0	2.3	5.4
136.8	3.2	3.3	1.3	ND	1.4	1.6	2.2	4.8
Na^+, mmol/L								
121	0.6	0.4	0.3	ND	0.7	0.1	ND	ND
139	0.5	0.2	0.2	ND	0.6	0.1	ND	0.4
160	0.9	0.3	0.3	ND	1.0	0.1	ND	ND
K^+, mmol/L								
2.9	0.4	0.6	0.4	ND	0.6	0.2	ND	ND
4.3	0.3	0.4	0.2	ND	0.6	0.1	ND	0.4
5.8	0.6	0.4	0.2	ND	0.6	0.1	ND	ND
iCa^{2+}, mmol/L								
1.70	1.6	0.7	1.2	ND	1.3	0.3	ND	ND
1.18	1.4	0.5	0.5	ND	2.9	0.4	ND	ND
0.60	2.6	1.3	1.0	ND	3.8	0.5	ND	ND

[a] Imprecision for pH in SD.

[b] Comp., comparison method; ND, not determined; iCa^{2+}, ionized calcium.

Table 2. Between-day imprecision.

	CV, %[a]							
	Laboratory A		Laboratory B		Laboratory C		Laboratory D	
	SenDx	Comp.[b]	SenDx	Comp.	SenDx	Comp.	SenDx	Comp.
pH								
7.179	0.016	0.004	0.012	0.008	0.014	0.005	0.006	0.007
7.398	0.006	0.002	0.005	0.010	0.011	0.004	0.016	0.004
7.572	0.005	0.004	0.009	0.012	0.013	0.003	0.008	0.005
Pco_2, mmHg								
61.0	2.2	1.7	4.2	2.4	3.9	1.7	2.5	2.7
38.5	2.0	0.8	3.0	1.3	2.9	0.9	4.6	1.1
21.9	4.4	1.1	3.6	1.6	1.9	0.9	2.2	1.4
Po_2, mmHg								
59.5	3.7	6.8	7.6	10	14	13	4.5	8.5
99.8	2.9	3.8	9.5	7.0	4.1	6.0	4.3	4.2
136.8	2.9	4.2	5.1	4.8	4.4	4.1	5.0	7.3
Na^+, mmol/L								
121	1.4	0.7	0.8	1.2	0.8	0.2	ND	ND
139	0.9	0.5	0.5	1.0	0.1	0.2	ND	0.8
160	1.1	0.5	0.8	1.4	1.9	0.3	ND	ND
K^+, mmol/L								
2.9	0.9	2.3	0.6	1.3	0.2	0.4	ND	ND
4.3	0.9	1.4	0.4	1.7	0.2	0.3	ND	0.9
5.8	0.8	0.8	0.3	2.0	0.5	0.4	ND	ND
iCa^{2+}, mmol/L								
1.70	3.5	0.4	3.7	9.5	2.7	0.8	ND	ND
1.18	2.6	0.7	11	13	1.4	0.8	ND	ND
0.60	7.1	5.7	6.5	26	3.4	1.3	ND	ND

[a] Imprecision for pH in SD.
[b] Comp., comparison method; ND, not determined; iCa^{2+}, ionized calcium.

INACCURACY STUDIES

The tonometry data for both Po_2 and Pco_2 are shown in Table 4. The mean recoveries with the SenDx 100 at ~70 and 142 mmHg Po_2 were 98.5% and 95.2%, respectively; at ~36 and 72 mmHg Pco_2, the mean recoveries were 103.9% and 100.2%, respectively. The data on the comparison analyzers were somewhat more favorable. The data from one center were also used to evaluate the within-run and between-run imprecision with heparin-treated non-diseased human blood under controlled conditions. Table 5 shows that the imprecision values for Pco_2 in the treated whole blood were similar to the values for the Euro-Trol control materials; however, the imprecision values for Po_2 were much improved, as is expected when whole blood is used instead of an aqueous solution.

METHOD COMPARISON

The results of the comparison of the SenDx 100 with the comparison analyzers, using fresh patient samples are represented in Fig. 1 and Table 6 for all analytes assayed. The data from the four institutions are presented in one graph, with a different symbol for each participant. This makes it possible to discern general discrepancies caused by bias in one specific laboratory.

Table 3. Mean within- and between-day imprecision for all analyzers.

	Within-day		Between-day	
	SenDx 100	Comparison	SenDx 100	Comparison
pH, SD ± SD′	0.004 ± 0.003	0.0025 ± 0.0010	0.010 ± 0.004	0.006 ± 0.003
Pco_2, CV ± SD, %	2.8 ± 0.7	1.1 ± 0.3	3.1 ± 1.0	1.4 ± 0.7
Po_2, CV ± SD, %	2.8 ± 1.2	4.0 ± 1.7	5.7 ± 3.2	6.7 ± 2.8
Na^+, CV ± SD, %	0.7 ± 0.2	0.2 ± 0.1	0.9 ± 0.5	0.7 ± 0.4
K^+, CV ± SD, %	0.5 ± 0.1	0.3 ± 0.2	0.5 ± 0.3	1.2 ± 0.7
iCa^{2+},[a] CV ± SD, %	2.3 ± 1.0	0.6 ± 0.4	4.7 ± 3.1	6.6 ± 8.8[b]

[a] Ionized calcium.
[b] One comparison analyzer showed an unexplained high CV in this experiment.

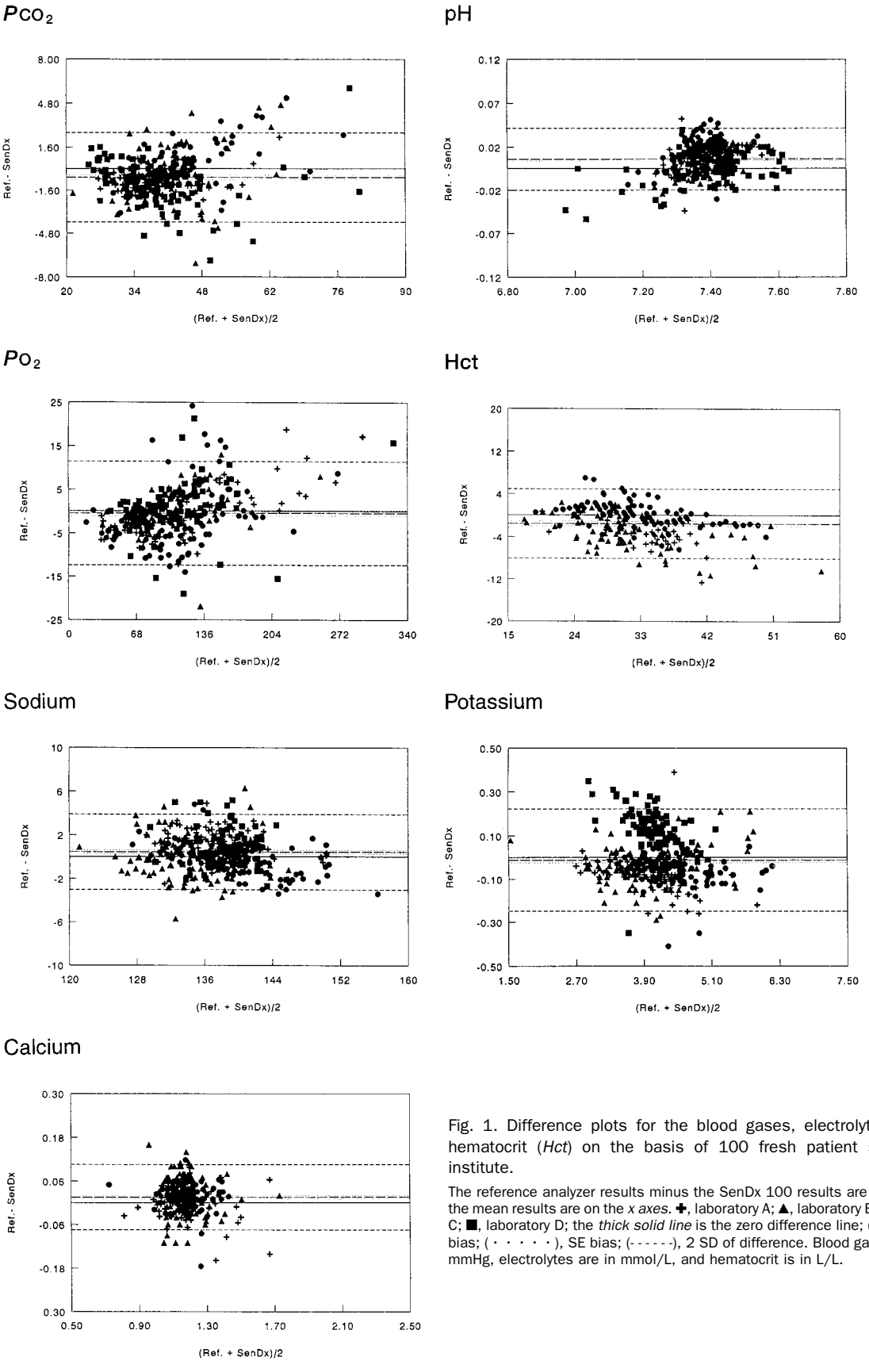

Fig. 1. Difference plots for the blood gases, electrolytes, pH, and hematocrit (*Hct*) on the basis of 100 fresh patient samples per institute.

The reference analyzer results minus the SenDx 100 results are on the *y axes*; the mean results are on the *x axes*. ✚, laboratory A; ▲, laboratory B; ●, laboratory C; ■, laboratory D; the *thick solid line* is the zero difference line; (– – –), mean bias; (· · · · ·), SE bias; (------), 2 SD of difference. Blood gas values are in mmHg, electrolytes are in mmol/L, and hematocrit is in L/L.

Table 4. Pco_2 and Po_2 in samples analyzed using tonometry.

		SenDx 100			Comparison analyzer		
			Difference			Difference	
Laboratory	Target, mmHg	Found,[a] mmHg	mmHg	%	Found,[a] mmHg	mmHg	%
Pco_2							
A	35.9	36.7	0.8	2.2	35.4	−0.5	−1.4
	13.9	14.5	0.6	4.3	14.5	0.6	4.3
B	35.1	38.5	3.4	9.6	36.2	1.1	3.1
	71.7	72.8	1.1	1.5	71.2	−0.5	−0.7
C	36.0	37.2	1.2	3.3	36.3	0.4	1.1
	71.7	70.9	−0.8	−1.1	71.7	0.0	0.0
D	35.9	36.2	0.3	0.8	34.5	−1.3	−3.6
	73.7	74.1	0.3	0.5	70.5	−3.3	−4.5
Po_2							
A	142	137.5	−4.5	−3.3	142.4	0.4	0.03
	50	50	0.0	0.0	50.5	0.5	1.0
B	141	136.5	−4.6	−3.3	140.0	−1.0	−0.7
	70.3	67.8	−2.5	−3.5	69.5	−0.8	−1.1
C	144	133.6	−10.5	−7.3	144.2	0.1	0.1
	72.1	70.2	−2.9	−4.0	72.5	0.5	0.7
D	142	134.3	−7.7	−5.4	139.9	−2.2	−1.5
	85.1	87.4	1.4	1.6	83.5	−2.6	−3.1

[a] All data presented are the means of 10 consecutive measurements.

Table 5. Pco_2 and Po_2 in samples analyzed using tonometry in a single institute.[a]

	SenDx 100			Comparison analyzer		
Target, mmHg	Found/expected, %	Mean SD, mmHg	Mean CV, %	Found/expected, %	Mean SD, %	Mean CV, %
Pco_2						
35.94	102.3	0.65	1.8	99.1	0.54	1.5
13.91	104.3	0.36	2.6	104.3	0.15	1.1
Po_2						
142.2	96.7	0.14	1.0	100.0	1.85	1.3
50.08	100.7	1.10	2.2	101.7	0.95	1.9

[a] Data are the mean results of blood samples after tonometry from six analyses on different days with different cartridges of two different lot numbers within one laboratory.

Table 6. Patient-sample comparison.

Analyte	Unit	n	Slope	Intercept	$S_{y/x}$	r	Average difference	SD of difference	SE difference
pH		352	0.984	0.109	0.027	0.984	0.010	0.017	0.00091
Pco_2	mmHg	349	1.002	−0.459	1.763	0.964	−0.65	1.66	0.089
Po_2	mmHg	354	0.943	6.472	5.600	0.985	−0.49	5.95	0.32
Na^+	mmol/L	390	1.058	−8.181	2.208	0.914	0.44	1.73	0.09
K^+	mmol/L	397	1.038	−0.135	0.138	0.968	−0.013	0.118	0.006
iCa^{2+}[a]	mmol/L	302	1.068	−0.095	0.073	0.933	0.015	0.045	0.0026
Hct	L/L	211	1.223	−0.0535	2.156	0.904	−0.016	0.032	0.0022

[a] iCa^{2+}, ionized calcium; Hct, hematocrit.

For the pH, an average bias of only 0.010 was found, with an insignificant positive trend (slope = 0.984). The Pco_2 showed a bias of −0.65 mmHg, which was independent of the partial pressure of CO_2. The Po_2 had a very small positive slope (0.943), suggesting a slight dependence on the partial pressure of O_2. Otherwise there was no significant difference from zero for the average bias of −0.49 mmHg.

With respect to sodium, a statistically significant but otherwise small bias of 0.44 mmol/L was found in the sample comparison study; there was no significant concentration dependency. The comparison for potassium

showed no significant bias for all participants taken together; however, a discrepancy was found for the comparison analyzer in one laboratory (D), which gave consistently higher results than the SenDx 100 analyzer. Without these data, a small negative bias probably would have occurred. Again, there was no apparent concentration dependency of the bias. The majority of ionized calcium values were within close limits; therefore, it is difficult to confirm or deny whether the differences between analyzers were concentration-dependent. The average bias is small, 0.015 mmol/L, but statistically significant.

The hematocrit showed a slightly negative slope and an average bias of −0.016 L/L, with an SD of 0.032 L/L.

Discussion

The analytical performance of the SenDx 100 blood gas/electrolyte analyzer was found to be comparable with that of the various established laboratory bench analyzers. The within-day imprecision for pH, P_{CO_2}, sodium, and ionized calcium was slightly worse in the SenDx 100; the within- and between-day imprecision for P_{O_2} and potassium was generally better in the SenDx 100. The differences were small and without much clinical significance when compared with the analytical performance indicators based on biological variation *(11)* or with the CLIA'88 performance rules *(12)*. Importantly, any contributions of different reagent cartridge and sensor cassette lot numbers to the overall imprecision are included in the data.

This is also applicable to the accuracy measurements. Although the SenDx 100 analyzer demonstrated a larger bias than the respective comparison analyzers, in particular for the P_{O_2}, the overall accuracies for P_{O_2} and P_{CO_2} were quite satisfactory in comparison with established performance indicators for these analytes.

Different sensor systems react differently toward various matrices of quality-control materials. Differences in performance between instruments can therefore be judged best from split patient-sample comparisons. With respect to differences between cartridge lots, no significant differences were found for any of the investigated analytes with the exception of ionized calcium, for which the difference in bias between cartridges reached a significant value of 0.05 mmol/L (n = 44). Clinically, this is of little importance. For P_{O_2}, the average biases found at 70 and 140 mmHg were of the same magnitude as with the tonometry experiment. The average SD of the individual differences appears rather large (almost 6 mmHg). This implies a CV of ~6% around the average P_{O_2}. This is in fact not much larger than the CV of 4.2% for P_{CO_2} in the same experiment. Nevertheless, individual differences of ±25 mmHg are disturbing. The majority of these differences are, however, from one laboratory and therefore cannot be attributed solely to the SenDx analyzer.

In comparison with other point-of-care blood gas/electrolyte analyzers, the SenDx 100 performs equally well *(13)*. The SenDx 100 provides a hematocrit value on the basis of conductivity measurement. Stott et al. *(14)* have demonstrated that such hematocrit determinations are relatively insensitive to changes in the electrolyte composition of the plasma in comparison with electronic particle-counting devices, which use sample dilution in isotonic saline; however, they are particularly sensitive to changes in plasma protein composition in contrast hematocrits obtained with electronic particle counting or centrifugation.

In conclusion, the SenDx 100 analyzer fulfills most of the requirements for a portable blood gas/electrolyte analyzer: acceptable precision and accuracy, comparability with laboratory bench analyzers, ease of use, and fast results.

A. van Kessel served as a scientific adviser to SenDx Medical Inc. until May 1, 1998.

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