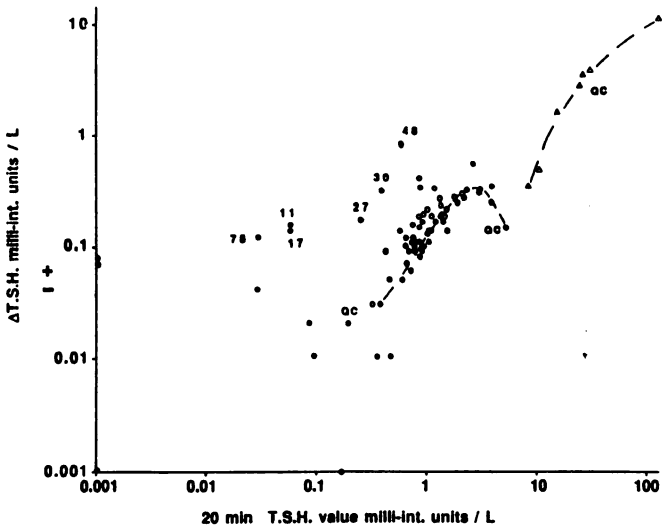

Fig. 1. Results for serum, plasma, quality-control (*QC*) samples
● serum, ○ plasma: ΔTSH is negative; ▲ serum, △ plasma: ΔTSH is positive

Addition of thrombin solution to such plasma samples (1/100 by vol) largely removes this phenomenon:

	Plasma		Plasma plus thrombin		Serum	
Reading time, min	5	20	5	20	5	20
	TSH, milli-int. units/L					
Patient 1	0.74	0.72	0.90	0.87	0.88	0.84
2	0.12	0.02	0.04	0.00	0.00	0.01
3	0.62	0.55	0.73	0.71	0.86	0.82
4	0.26	0.25	0.38	0.38	0.44	0.44
5	0.00	0.00	0.00	0.00	0.00	0.00
6	0.22	0.06	0.07	0.03	—	—
7	0.21	0.03	0.03	0.00	—	—
8	0.28	0.03	0.00	0.00	—	—
9	0.32	0.06	0.05	0.00	—	—

Moreover, serum samples over the range 0.12–13.8 milli-int. units/L usually give higher results than plasma when measured at a 10-min reading time ($P < 0.001$ by Student's *t*-test).

Regression analysis (n = 28) gave the equation TSH (plasma) = 0.84 TSH (serum) − 0.06.

Thus we recommend that only serum samples be used for TSH assay by this system to avoid possible misclassification of thyroid status in those patients having TSH values near the lower limit of the reference interval.

The above inaccuracies have been brought to the attention of Amersham, who is taking steps to modify the assay protocol and to further investigate these anomalies.

Technicon "CHEM 1" Direct Bilirubin Assay Evaluated,

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In the method for "direct" bilirubin in serum that is used in the CHEM 1 (Technicon Instruments Corp., Tarrytown, NY 10591), Fast Red B salt converts conjugated bilirubin to azobilirubin. This pigment, which is proportional to the concentration of direct bilirubin, is measured at equilibrium as an increase in absorbance at 550 nm, vs that for a serum calibrator, to give the direct bilirubin concentration.

We used the CHEM 1 reagents according to the manufacturer's instructions, calibrating daily or after the introduction of a new batch of cassettes. The linear range of the assay was >450 μmol/L, well exceeding that quoted by the manufacturer, 280 μmol/L. The CV for 48 determinations at 29.3 μmol/L was 2.6% within-batch, 5.3% between-batch; at 96.7 μmol/L, 1.2 and 5.0%; and at 174.1 μmol/L, 1.3 and 4.5%. We assessed reagent carryover between direct bilirubin and 18 other methods currently used in the CHEM 1, with the protocol outlined by the ECCLS (*1*), and we found it acceptable (<1%). Comparison of patients' results obtained with the CHEM 1 (y) and a manual method (x) (*2*) gave the regression equation $y = 0.85x - 7.15$ μmol/L ($r = 0.99$). Hemoglobin causes a negative interference, 1 g of hemoglobin decreasing the true direct bilirubin value by 15%. Moderately lipemic samples do not affect the assay but grossly lipemic specimens (sample blank absorbance >2.0) can give erratic results, and this type of specimen should not be analyzed. Ascorbic acid interferes with the formation of azobilirubin (*3*), so we investigated its effect on the assay. One gram of added ascorbic acid per liter in a serum pool caused a decrease in apparent direct bilirubin of 32 μmol/L. For physiological concentrations of ascorbic acid (2–20 mg/L) this amount of effect is acceptable (<2 μmol/L). Addition of 100 mg of L-dopa per liter and a methyldopa increase apparent direct bilirubin concentrations by 3 and 4 μmol/L, respectively, confirming the findings of Singh et al. (*4*).

Cost compares favorably with other automated methods and throughput time is ~17 min.

We thank Technicon Instruments for providing reagents for this study.

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Analytical Evaluation of the Ministat-s Analyzer,

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The Ministat-s (BioKinetix Corp., Stamford, CT) is a high-sensitivity rate photometer containing four rate analysis modes and a separate mode for endpoint assay. The analyzer has a mercury light source, five interference filters, double-beam optics, and a dry-heat incubator accommodating 12 10-mm square cuvettes. Undiluted serum (10–100 μL) is added to reagent (1000 μL), mixed, incubated at 25, 30, or 37 °C, and measured with a chemical standard (endpoint) or the built-in electronic calibrator (rate).

We evaluated linearity, precision, and accuracy for nine analytes during five months. Reagents used with the Ministat-s were glucose, urea nitrogen (urea N), creatinine, amylase (EC 3.2.1.1), lipase (EC 3.1.1.3) (Boehringer Mannheim Diagnostics, Indianapolis, IN); calcium (American Monitor Corp., Indianapolis, IN); creatine kinase (CK; EC 2.7.3.2, Diagnostic Chemicals Ltd., Monroe, CT); and CK-MB (*1*) and lactate dehydrogenase (EC 1.1.1.27) isoenzymes and 1 and 2 (LD-1, 2) (*2*) (Roche Diagnostic Systems, Nutley, NJ).

Day-to-day precision with commercial quality-control products and pooled patients' serum showed CVs of <6.3% except for CK-MB (mean 4.0 U/L; CV 10%), and lipase (mean 6.4 U/L; CV 7.8%). Linearity, determined with low and above-normal patients' serum, extended up to: glucose 44 mmol/L; urea N 25 mmol/L; creatinine 1326 μmol/L; calcium 4.5 mmol/L; CK 800 U/L; CK-MB 100 U/L; LD-1,2 280 U/L; amylase 400 U/L; and lipase 100 U/L.

Good results were obtained with the Ministat-s (*y*) when compared with (*x*) the Astra 4 (Beckman Instruments, Brea, CA), KDA (American Monitor Corp., Indianapolis, IN), Cobas-Bio (Roche Diagnostic Systems, Nutley, NJ), and Model 91 amylase-lipase nephelometer (nephel) (Perkin-Elmer, Norwalk, CT):

Analyte	n	Comparison method	y-intercept	Slope	r
Glucose, mmol/L	60	Astra	−0.07	1.006	.999
Urea N, mmol/L	60	Astra	0.16	0.982	.996
Creatinine, umol/L	64	Astra	−3.54	1.015	.997
Calcium, mmol/L	41	KDA	0.18	0.927	.993
CK, U/L	100	Cobas-Bio	3.30	0.967	.999
CK-MB, U/L	100	Cobas-Bio	2.49	0.996	.901
LD-1,2, U/L	141	Cobas-Bio	1.67	0.903	.987
Amylase, U/L	71	nephel	2.40	0.521	.973
Lipase, U/L	80	nephel	1.32	10.656	.933

Thus, we found the Ministat-s satisfactory in analytical and operational performance. The electronic calibrator was extremely stable and required no adjustment during the test period. Kit and instrument reagents are easily adaptable. The analyzer is simple to use and seems suited for physician's offices, satellite locations, and laboratories with a moderate volume of work.

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Correlation between Testosterone Not Bound to Sex-Hormone-Binding Globulin (SHBG) and the Testosterone/SHBG Ratio,

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The rate of testosterone production is increased in hirsute women (*1*), but total testosterone (T) concentrations in plasma are normal in about half of them (*2*). The ratio of T to sex-hormone-binding globulin (T/SHBG) was shown to be a better index of hyperandrogenism than total T (*2, 3*). The T/SHBG ratio is assumed to be an indirect measurement of unbound T, although there are controversies over whether measurements of unbound T have the same diagnostic efficiency as measurements of the T/SHBG ratio in hirsutism (*3, 4*). It was also suggested that the measurement of non-SHBG-bound testosterone, consisting mainly of albumin-bound and unbound testosterone, is a better marker for hyperandrogenism than unbound T (*5, 6*).

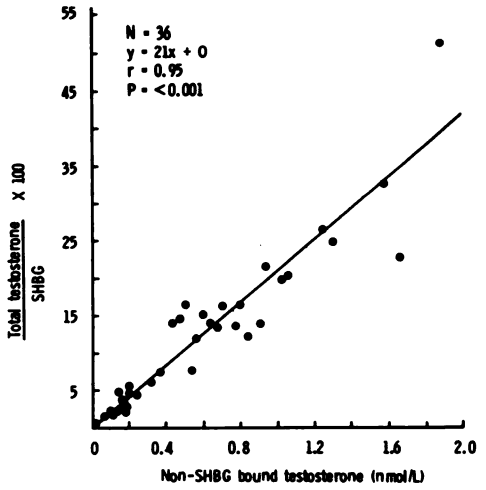

Fig. 1. Correlation between non-SHBG-bound testosterone and the testosterone/SHBG ratio

In this study, we examined the relationship between the non-SHBG-bound testosterone concentration and the T/SHBG ratio in the plasma of female patients sent for routine measurements of total T (Radioassay System Laboratories, Inc., Carson, CA) and non-SHBG-bound T (*7*). Thirty-six samples with a range of concentrations of non-SHBG-bound T and total T were selected and stored at −20 °C. SHBG was assayed with an IRMA kit (Farmos Diagnostica, Oulunsalo, Finland).

Figure 1 shows that there is a good correlation between non-SHBG-bound T and the T/SHBG ratio, suggesting that the two measurements provide equivalent information. The relative diagnostic efficiency of the two assays remains to be studied.

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