Naval Submarine Medical Research Laboratory

NSMRL REPORT 1191 2 FEBRUARY 1994

EVALUATION OF FIELD CLINICAL LABORATORY EQUIPMENT FOR FLEET MARINE SERVICES

P. L. Perrotta
C. Bolecek-Skeggs
E. M. Christ
D. W. Hobson

Released by:
P. K. Weathersby, CAPT, MSC, USN
Commanding Officer
Naval Submarine Medical Research Laboratory

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Report 1191

Naval Medical Research and Development Command
Research Work Unit 63706N M000095.005-5102

Approved and Released by

P.K. Weathersby, CAPT, MSC, USN
Commanding Officer
NAVSUBMEDRSCHLAB

Summary Page

Problem:

The Medical Company of the Marine Corps Service Support Group is tasked with the evaluation and procurement of clinical laboratory equipment for field-use. Capabilities are required in several broad areas which include testing of hematological, chemical and blood gas parameters. Instruments intended for hospital or clinic use are not designed to withstand the rugged conditions encountered during military operations. The goal of this project was to first identify and then test a variety of commercially available laboratory instruments under severe environmental and operational conditions.

Methods:

Clinical laboratory analyzers satisfying testing requirements were identified and purchased. These instruments were evaluated under each of the following conditions: ambient temperature range (40°F to 110°F), combined heat/humidity, extreme storage temperatures (-60°F and 160°F), simulated transport (vibration, drop testing), altitude (8500 ft), salt/fog and sand/dust operation.

Findings:

No single analyzer was capable of performing all of the laboratory tests required by the Marine Corps Therefore, units were evaluated within major diagnostic groups (e.g., hematology, chemistry, coagulation, etc.). Results of operational testing are presented for each of these classes of analyzers. Within a group there are no absolute "winners" or "losers", but comparative data is presented. In addition to these findings, the final decision on which specific units to procure must also be based on other considerations such as size, storage requirements, ease of use and cost.

Application:

Information presented in this report will be used by Marine Corps personnel involved with providing clinical laboratory equipment to operational forces.

Administrative Information

This work was completed under Naval Medical Research Development Command Research Work Unit 63706N-M000095.005-5102, Evaluation of Field Clinical Laboratory Equipment for Fleet Marine Service. The views expressed in this report are those of the authors and do not reflect the official policy or position of the Department of the Navy, Department of Defense, or the U.S. Government. This report was approved for publication on 2 Feb 1994 and designated NSMRL Report 1191.

Abstract

We evaluated clinical laboratory equipment being considered for purchase by the U.S. Marine Corps. This equipment will provide clinicians with rapid access to laboratory data during deployments. Capabilities were desired in the following areas: hematology, chemistry, coagulation, blood gas analysis and urinalysis. There is concern that severe conditions encountered in the field may affect machine performance.

Analyzers were evaluated under each of the following conditions: ambient temperature range (40°F to 110°F), combined heat/humidity, extreme storage temperatures (-60°F and 160°F), simulated transport (vibration, drop testing), altitude (8500 ft), salt/fog and sand/dust operation. Results are presented separately for each class of analyzer. No singular "winner" or "looser" stood out in any category. In general, instruments had difficulty with warm and cold temperature operation.

This information can be used by Marine Corps personnel involved with providing clinical laboratory equipment to operational forces. Other factors which should be considered include instrument size, storage requirements, ease of use and cost.

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Introduction

The Medical Company of the Marine Corps Field Service Support Group provides medical support for military and humanitarian missions. Clinical chemistry equipment can improve the quality of medical care during these deployments by providing clinicians with rapid access to laboratory data. This information facilitates diagnostic and therapeutic decision making for combat related injuries and non-combat illnesses. Ideally, testing would include capabilities in the following areas: hematology, chemistry, urinalysis, arterial blood gas analysis and blood banking procedures.

Most clinical laboratory instruments available on the Authorized Medical Allowance List (AMAL) have several limitations. Many of the analyzers are large and heavy. Reagents used by certain units require large amounts of storage space, space which may need to be refrigerated. Several units are not fully automated. Because military medical technicians have various levels of experience, lack of automation could increase the possibility of operator error.

The reliability of laboratory instruments could be adversely affected by severe environmental conditions encountered during use by the Marine Corps. Machines must survive minor impact and vibration encountered during transportation. Generally, temperature controlled storage space is not available. Once in the field, analyzers must provide results that would be clinically useful. Clinical laboratory instruments have not been tested under these type of conditions.

Marine Corps medical personnel are now investigating the operational use of clinical laboratory equipment. The requirement was first specified by the Commanding General, Marine Corps Research, Development, and Acquisition Command (1). This tasking emphasized the importance of identifying equipment which would meet the testing needs of the Marine Corps and then evaluating these alternatives under realistic field conditions.

The primary objective of this project was to evaluate the performance of currently available clinical laboratory equipment operating under a variety of environmental and operational conditions. Military laboratory technicians also assessed the subjective aspects of instrument use. In addition to performance characteristics, purchasing officials must also consider cost (e.g., cost per analyzer, cost per test). Previous procurement decisions have not included objective information on the performance of equipment under realistic field use scenarios.

Study Design and Methods

This study was conducted in four phases:

Phase 1: Identification and Procurement of Instruments

The Marine Corps required that instruments selected for evaluation be commercially available. Therefore, no items under development were considered. Instruments were to be capable of performing one or more of the following tests (1):

1. Blood glucose (GLU)
2. Blood urea nitrogen (BUN)
3. Blood gasses (pCO_2, pO_2 and pH)
4. Sodium (NA)
5. Potassium (K)
6. Chloride (CL)
7. Carbon dioxide (CO_2)
8. Hematocrit (HCT)
9. Hemoglobin (HGB)
10. Creatinine (CR)
11. Red blood cell count (RBC)
12. White blood cell count (WBC)
13. Routine and microscopic urinary analysis (UA)
14. Typing and crossmatching of whole blood (TCB)
15. Ova and parasite analysis (OPA)
16. Gram stain evaluations (GSE)
17. Rapid plasma reagin (RPR) determinations

A primary survey of Federal supply schedules identified potential instruments. A secondary survey found additional items not under Federal contracts. This involved reviewing commercial literature, interacting with manufacturer representatives and attending trade shows. At the conclusion of these surveys, product literature was solicited from approximately 125 vendors. This information included technical specifications and contract information and was reviewed by a committee of medical and technical personnel. The committee was composed of individuals with the following expertise:

- Scientist/Investigator (Ph.D., Biomedical Engineering)
- Physician (Military)
- Cardio-Pulmonary Technician (Military)
- 4 Advanced Laboratory Technicians (Military)
- Civilian Laboratory Technician (prior Active Duty service)

General guidelines were followed during the initial evaluation of the product literature. Smaller and lighter analyzers were favored over heavier items. Automatically calibrating units were preferable as were those whose reagents required less storage space. The committee reviewed the product information focusing on the following characteristics:

1. Weight
2. Size/Dimensions
3. Analyzer methodology
4. Calibration (automatic, semi-automatic, manual)
5. Type of reagents (cartridges, liquid, gas)
6. Tests performed by each analyzer
7. Cost per analyzer and cost per test

After evaluating the product literature, the committee observed instrument demonstrations at the Naval Submarine Medical Research Laboratory (NSMRL). Based on this initial survey, the committee selected instruments which were procured for analytical and operational performance evaluations in later phases of the study.

Phase 2: Baseline Analytical Performance Evaluation

Instruments selected in Phase 1 were procured, set up and calibrated using the manufacturer's recommended calibration standards. Once calibrated, baseline data were collected from commercially prepared blood or urine controls having known results at levels considered "normal" or "abnormal." These reference ranges were specified by the manufacturer of the controls. For each analyzer, an effort was made to collect data from ten samples of each control level each day for ten days (100 total samples per control level). The data was retained for later comparison with data obtained during operational testing.

After collecting baseline control data approximately 100 human blood and urine samples were collected and analyzed by the test instruments. Aliquots of these samples were submitted to Naval Hospital Clinical Pathology laboratories at either Groton, CT (NAVHOSP Groton) or Bethesda, MD (NNMC) to obtain laboratory reference values for each parameter measured. Specifically, the reference laboratory instrumentation consisted of the following:

Blood Gases:

Arterial parameters on CIBA 178, 280 @ NNMC
Venous parameters on CIBA 280 @ NAVHOSP Groton

Coagulation:

Ortho Diagnostics Coagulab 16S @ NAVHOSP Groton

Hematology:

Technicon H1 @ NAVHOSP Groton

Electrolytes and Clinical Chemistries:

Baxter Paramax 720 @ NAVHOSP Groton

Urinalysis:

Manual dipsticks @ NAVHOSP Groton

Data sets were arranged in files by general instrument type (e.g., clinical chemistry, electrolyte, hematology, etc.) using computer spreadsheets. Each human sample record contained a sample number, instrument identifier and data for each parameter measured. Results of human sample testing were compared to identify statistically significant differences in values obtained by the test instrument and the reference analyzer. Following an initial one-way analysis of variance (ANOVA) on the contrasting data sets, multiple comparisons were performed using Tukey's procedure (2). Statistically significant differences ($P<0.05$) were reviewed by medical personnel to determine if they were "clinically" significant. Clinically significant differences are those that could result in errors in diagnosis or treatment of an injury or illness. Statistics were performed on a VAX Computer System running the SAS System, Release 6.07.

Phase 3: Operational Performance Evaluation

Each instrument was tested under a variety of environmental conditions specified by the Marine Corps and in accordance with military standards (3). Additional input was provided by Commander, Marine Corps Systems Command (4). These conditions were divided into the following categories:

<u>Temperature Condition Testing</u>:

- Cold Operation (40°F, 50°F, 60°F)
- Warm Operation (110°F, 100°F, 90°F)
- Combined Heat and Humidity (90-100°F/90% relative humidity)

- Cold Storage (-60°F)
- Warm Storage (160°F)

Transport and other Condition Testing:

- Simulated transport
  - Vibration (High Frequency Exposure)
  - Loose Cargo Test (Low Frequency Exposure)
  - Drop Testing
- Post-Altitude Operation (8,500 feet)
- Salty and Foggy environment (combined)
- Sandy and Dusty environment (combined)

Most of the environmental testing was performed at Fort Detrick, Maryland in collaboration with their technical staff. Several of the storage tests were performed at NSMRL. Detailed descriptions of the test procedures follows:

Cold Operation

Analyzers were placed in an environmental chamber where the ambient temperature was controlled at 40, 50, or 60°F. After the unit equilibrated with ambient temperature it was operated in accordance with manufacturer's specifications. Initial chamber temperature was 40°F. If the unit did not function at 40°F the chamber temperature was raised in 10 degree increments and the test was repeated.

Warm Operation

This test was conducted as described under "Cold Operation" except that the initial chamber temperature was 110°F. Ambient temperature was decreased in 10 degree increments if the analyzer was non-operational.

Combined Heat and Humidity

Analyzers were placed in an environmental chamber with a relative humidity (RH) of 90 percent. Temperature was controlled at 90, 100 or 110°F depending on the results of warm operation testing. If a machine would not operate at 110°F but functioned at 100°F, the initial chamber temperature would be set at 100°F. If the unit did not operate the temperature was decreased in 10 degree increments and the test was repeated.

Cold and Warm Storage

In separate tests, units were placed in a chamber with

temperature controlled at either -60°F or 160°F. After 6 hours of storage the units were removed from the chamber and allowed to return to normal ambient temperature (75-85°F). Machines were tested after they were inspected for evidence of damage.

Simulated Transportation Testing

The goal of this test was to determine the ability of analyzers to withstand vibration and shock during shipment and deployment. The transportation test consisted of three portions which were conducted in the following sequence: 1. *High Frequency Vibration* 2. *Loose Cargo Vibration* 3. *Drop Test*. After completing the Drop Test, the unit was tested for reliability. Details of each of these tests follows:

High Frequency Vibration: Analyzers were packaged and secured to a high frequency slip table. Packaging consisted of 2 inches of 2-pound density foam inside either a steel medical chest or a hard plastic shipping container. The table produced a vibration profile that could occur in common carriers, two-wheeled trailers and composite wheeled vehicles. The vibration exposure lasted 30 minutes. The units were then removed from the packing and inspected for damage.

Loose Cargo Vibration: In the same packing configuration described above, analyzers were placed on a LAB Package tester. This test is designed to simulate transport in a truck crossing rough terrain. The tester was operated at 250-300 RPM for 45 minutes. Following the test, units were inspected for loose parts and damage.

Drop (Shock) Test: Each analyzer was dropped a vertical distance of 48 inches on to a 2 inch thick fir platform backed by a concrete floor. Packing was that used in the vibration testing. The units were dropped 5 times in any combination of the bottom, 2 sides, 2 ends and the top of the shipping container. The analyzer was then removed from the packing and inspected for damage. Following completion of the drop test, the unit was turned on and tested with control solutions to access reliability after simulated transport.

Post-Altitude Operation

While in the operating mode units were placed in an altitude test chamber. Once a simulated altitude of 8500 feet was reached power was removed from the analyzer and then restored. After the unit was taken through its initialization procedures the altitude was returned to sea level. Following removal from the chamber and inspection, analyzers were again tested.

Salt/Fog Operation

Non-operating (powered down) analyzers were placed in a salt/fog chamber for 30 minutes (3). The salt spray consisted of a solution containing 5% salt by weight. The units were then removed from the chamber and excess salt mist was removed from the external surface. The machine was allowed to dry before completing the testing.

Sand/Dust Operation

Non-operating (powered down) units were placed in a dust chamber and exposed to a simulated dust storm for one minute (3). The chamber used Fuller's Earth (Attapulgite) to simulate a storm resulting in zero per cent visibility at 3 feet. The units were tested after inspecting them for dust penetration and removing excess dust.

In addition to information and data collected in Phases 1-3 of this study, summaries of instrument operational characteristics were prepared by NSMRL medical laboratory technical staff responsible for the operation and maintenance of these machines. Their technical reviews focused on the following: ease of set-up and operation, general durability during testing, maintenance requirements, difficulties of repair, availability of parts and technical support, availability of reagents and controls and shelf-life of reagents. These summaries are provided in Appendix A.

Phase 4: Summary and Reporting of Findings

In this phase, the findings from phases 2-4 were summarized in a format which could be easily interpreted by Marine Corps personnel. It was not possible to present the large volume of data collected within the body of this report. Rather, primary tests for each unit were summarized using a "Pass/Fail" method. This system was used at each level for each testing condition. A summary of the methodology and abbreviations used follows:

> Hard Failure (HF): During certain portions of the testing analyzers were severely affected and would not operate. Specific error codes reported by individual units are noted when available. Examples of this type of failure include inability to properly calibrate the unit and damage resulting from drop testing. "Hard Failures" includes cases where 3 samples could not be run under a test condition. Hard failures will be specifically addressed within the results.

Pass (P): If a "Hard Failure" did not occur, three or more samples were run at a each level. To receive a "Pass" at a specific level an analyzer reported results within the acceptable control range at least 65% of the time. To receive an overall "Pass" for an individual test (e.g., WBC, Na, etc.) at a particular test condition (e.g., cold operation, altitude, etc.) an instrument must achieve the 65% goal for each level control.

Fail (F): A "Fail" is noted when at least 3 samples were run on the analyzer but the results were within the acceptable control ranges less than 65% of the time. Instruments that failed only a single control level received an overall "Fail" for that clinical test. For example, if instrument A failed at level 1 control, but passed for levels 2 and 3, it would receive a "F1". Similarly, a F2,3 indicates failure at levels 2 and 3.

Not Tested (NT): In certain instances, analyzers could not be tested under a specific condition for reasons other than normal failures. For example, if a unit was damaged during a previous test and could not be replaced, the testing would be incomplete. A "Not Tested" is also used when other breaks in protocol occurred and data was not collected. These deviations in protocol will be addressed specifically.

Not Applicable (NA): This category applied only to operating temperature testing. If a machine "Passed" at 40°F it would not be tested at 50 or 60°F. Similarly, units functioning at 100 or 110°F would not be tested at 90°F. This was necessary to decrease the amount of time needed within the environmental chambers and to limit the amount of unnecessary data.

Results

Phase 1:

Based on information compiled in this phase, instruments were selected that appeared suitable for field use based on their physical size and clinical measurement capabilities. No commercially available instrument capable of performing all necessary tests was found. Automated instruments were not identified for TCB, OPA, GSE and RPR. Automated analyzers falling into six general classes would meet the measurement needs stated by the project objectives. They are listed below along with their primary testing requirements (please see the list of abbreviations for acronyms):

1. Blood gas analyzers

   Primary: pCO_2, po_2, pH
   Secondary: Hgb, Hct, Na, K, Cl, Ca, Glu

2. Coagulation analyzers

   Primary: PT, APTT
   Secondary: TT, FIB

3. Hematology analyzers

   Primary: WBC, RBC, Hgb or Hct, Plt
   Secondary: MCV, MCHC, MCH, GRAN/LYMPH/MONO counts

4. Clinical chemistry analyzers

   Primary: Glu, BUN, Cr
   Secondary: Cholesterol, Liver Function Tests, Na, K, Cl, CO_2, Ca, UA, CK, Amyl, TBili, Various Drug Levels

5. Electrolyte analyzers

   Primary: Na, K, Cl
   Secondary: CO_2

6. Urinalysis analyzers

   Primary: Glu, Bili, Ketones, SG, pH, Protein, Nitrates, Leukocytes

Specific analyzers from each of these groups were selected for further testing. They are as follows:

Blood Gas Analyzers

1.	Gemstat	Mallinckrodt
2.	CIBA 238	CIBA Corning
3.	CIBA 288	CIBA Corning
4.	NOVA 5	Nova Biomedical

Coagulation Analyzers

1.	Accustasis 2000	Sigma Diagnostics
2.	Coagamate XM	Organon Teknica
3.	Factor VI	International Technidyne
4.	Biotrack 512	CIBA Corning

Hematology Analyzers

1.	QBC Autoread	Becton Dickinson
2.	QBC Manual	Becton Dickinson
3.	Danam 510	Danam Corporation
4.	Danam 820	Danam Corporation
5.	CBC 5	Coulter Electronics
6.	Celldyn 610	Abbott Diagnostics

Clinical Chemistry Analyzers

1.	COBAS Ready	Roche Diagnostics
2.	I-Stat	I-Stat Corporation
3.	Vision	Abbott Diagnostics
4.	Ektachem (modules)	Eastman Kodak Co.
	a. DT 60 II	
	b. DTSC	
	c. DTE	
5.	Reflotron	Boehringer Mannheim
6.	Nova 12	Nova Biomedical

Electrolyte Analyzers

1.	986S	AVL
2.	644	CIBA Corning
3.	Lytening 5	Baxter Diagnostics

Urinalysis

1.	Clinitek 100	Miles Inc.

A more complete description of the 20 potential vendors is provided in Appendix B. Reference ranges of control reagents used by each analyzer are presented in Appendix C. The results of Phases 2-4 are summarized for each class of instruments below.

Blood Gas Analyzers

Four blood gas analyzers were selected in phase I for further testing (Table 1). The Gemstat and CIBA 238 are lighter and more compact than the other two units. All measurements are based on similar technologies and calibrate automatically. Each analyzer performs the primary tests expected of this group (pH, pO_2 and pCO_2), but the Gemstat, CIBA 288 and Nova Stat also perform hemoglobin/hematocrit and serum electrolytes (Table 2). There is a wide difference in cost per test among the analyzers with the highest cost being $7.00/test for the Gemstat and the lowest of $0.19 for the NOVA Stat 5.

Analytical performance evaluations using human blood samples revealed no statistically significant ($P<0.05$) differences between values obtained by the test instruments and the reference analyzer under baseline conditions (Table 3). Standard deviation were wide for both pCO_2 and pO_2 testing. This is because both venous and arterial samples were used and blood was obtained from hospitalized patients. These patients will exhibit wide variation in these parameters based on their clinical status.

The Gemstat had the fewest number of failures during testing at both 40°F and 50°F (Table 4). It received an overall "Fail" for both of these conditions because of level 3 failures for pO_2 testing (143-177 mmHg). The CIBA 238, CIBA 288 and Nova Stat all had multiple failures during 40 and 50°F operation. The CIBA 288 was the only unit to fail pH testing at 40°F. The Gemstat and CIBA 238 operated adequately at 60°F for all primary clinical tests and no units failed testing after being stored at -60°F.

Compared to the other units, the Gemstat recorded the fewest number of "Fails" when operated at 100°F. It also operated during combined high temperature/humidity testing. The Gemstat was not tested at 110°F because it failed testing at 100°F. The CIBA 238 had a heater failure when tested at 100°F. Data was collected during 90°F operation of the CIBA 238 but results were inadequate for pO_2(levels 2 and 3). The CIBA 238 received a passing score for all tests at an elevated temperature and humidity less than that used to test the Gemstat. The CIBA 238 was not tested at 110°F because a hard failure occurred at 100°F. The CIBA 288 failed at 90°F (for pCO_2) and 100°F (pCO_2, pH). Therefore, it was not tested at 110°F or high temperature/humidity. The Nova Stat experienced an air-bath temperature failure at 90°F and 100°F and was not tested at 110°F

or under elevated temperature/humidity. All units functioned adequately after storage at 160°F except the Nova Stat which had a blower motor failure.

Temperature operation was repeated by allowing the control reagents to remain at normal room temperature while the units stayed in the environmental chambers (Table 5). This was not done for the other groups of analyzers. The Nova Stat did not undergo this additional testing because it could not be replaced after being damaged during warm storage. With these changes, only the Gemstat operated adequately at 40°F with controls at room temperature. The 238 functioned adequately at 50°F whereas the 288 continued to fail level 3 pO_2 testing. The CIBA 288 also failed at 90°F for pCO_2 tests and was therefore not tested at 100°F. A minor break in protocol occurred and the CIBA 238 was not retested at 100°F after it passed 90°F operation.

Each of the four machines operated under simulated transportation and other operational conditions (Table 6) with the exception of the CIBA 288 which had a pressure sensor failure during altitude testing. After the CIBA 288 was returned to sea level, it was functional and did not require replacement of the pressure sensor. During the initial drop test of the Gemstat analyzer an isolation transformer was broken. A replacement machine was obtained and functioned satisfactorily during this part of the test.

TABLE 1 - SUMMARY OF BLOOD GAS ANALYZERS TESTED

MODEL	MANUFACTURER	DIMENSIONS (inches)	WEIGHT (pounds)	POWER REQUIREMENT	METHODOLOGY	CALIBRATION	REAGENT
GEMSTAT	MALLINCKRODT	8.4x18.3x9.1	27.0	120 V	Ion Selective Electrodes	Automatic	Cartridge
CIBA 238	CIBA CORNING	11.0x10.6x12.6	15.6	100-240 V	Ion Selective Electrodes	Semi-Automatic	Liquid & Gas
CIBA 288	CIBA CORNING	16.0x25.5x19.0	74.0	200 V	Ion Selective Electrodes	Automatic	Liquid & Gas
NOVA STAT 5	NOVA BIOMEDICAL	23.0x22.3x18.8	100.0	100/120, 200/220/240 V	ISE, Impedance, Enzyme	Automatic	Liquid & Gas

V=volt

TABLE 2 - SUMMARY OF TESTS OFFERED AND COSTS OF BLOOD GAS ANALYZERS

MODEL	pH	pO_2	pCO_2	Hgb/Hct	OTHER	SAMPLE SIZE (type)	TIME/TEST (seconds)	COST/TEST (U.S. dollar)*	COST/UNIT (U.S. dollar)*
GEMSTAT	X	X	X	Hct	K,Na,Ca	500 ul (wb)	109	7.00	25,000.00
CIBA 238	X	X	X			60-85 ul (wb)	60	0.86	9,500.00
CIBA 288	X	X	X	Hgb	Na, K, Ca or Cl	200 ul (art,ven,cap wb)	140	1.60	32,000.00
NOVA STAT 5	X	X	X	Hct	K,Na,Cl,Ca Glu,Osm	250 ul (wb)	90	0.19	30,000.00

wb=whole blood; art= arterial blood; ven=venous blood; cap=capillary blood
* All costs are 1992 U.S. dollar

TABLE 3 - MEAN (STANDARD DEVIATION) OF REFERENCE VALUES AND BLOOD GAS ANALYZERS TESTED

	N (number of samples)	pCO_2 Mean (S.D.)	pO_2 Mean (S.D.)	pH Mean (S.D.)
REFERENCE	151	51.3 (15.2)	72.1 (65.1)	7.35 (0.07)
GEMSTAT	111	50.5 (15.9)	61.9 (56.3)	7.35 (0.07)
CIBA 238	107	50.9 (13.1)	69.2 (74.8)	7.35 (0.07)
CIBA 288	105	51.0 (10.8)	59.8 (54.3)	7.35 (0.06)
NOVA STAT 5	103	47.2 (10.1)	65.4 (61.3)	7.36 (0.06)

S.D.=standard deviation

TABLE 4 - TEMPERATURE CONDITION TESTING OF BLOOD GAS ANALYZERS

	Baseline	40°	50°	60°	90°	100°	110°	TEMP/HUMID (°F/RH)	-60° STORAGE	160° STORAGE
GEMSTAT	**P**	**F**	**F**	**P**	**F**	**F**	**NA**	**P** (100/90)	**P**	**P**
pO_2	P	F3	F3	P	F3	F3		P	P	P
pCO_2	P	P	P	P	P	F2		P	P	P
pH	P	P	P	P	P	P		P	P	P
CIBA 238	**P**	**F**	**F**	**P**	**F**	**HF**	**NA**	**P** (90/90)	**P**	**P**
pO_2	P	F1,2,3	F1,2,3	P	F2,3			P	P	P
pCO_2	P	F1	P	P	P			P	P	P
pH	P	P	P	P	P			P	P	P
CIBA 288	**P**	**F**	**F**	**F**	**F**	**F**	**NA**	**NA**	**P**	**P**
pO_2	P	F1,2,3	F1,2,3	F3	P	P			P	P
pCO_2	P	F2	P	P	F3	F1,2,3			P	P
pH	P	F1,2,3	F	P	P	F1,3			P	P
NOVA STAT 5	**P**	**F**	**F**	**F**	**HF**	**HF**	**NA**	**NA**	**P**	**HF**
pO_2	P	F1,2,3	F1,2,3	F3					P	
pCO_2	P	P	F2	P					P	
pH	P	P	P	P					P	

P=pass; F=fail; HF=hard failure; NA=not applicable

TABLE 5 - TEMPERATURE CONDITION REPEAT TESTING OF BLOOD GAS ANALYZERS WITH CONTROLS AT ROOM TEMPERATURE

	40^{o}	50^{o}	90^{o}	100^{o}
GEMSTAT	**P**	**NA**	**NA**	**P**
pO_2	P			P
pCO_2	P			P
pH	P			P
CIBA 238	**F**	**P**	**P**	**NT**
pO_2	P	P	P	
pCO_2	F1	P	P	
pH	F1	P	P	
CIBA 288	**F**	**F**	**F**	**NA**
pO_2	F3	F3	P	
pCO_2	P	P	F1,2	
pH	P	P	P	
NOVA STAT 5	**NT**	**NT**	**NT**	**NT**

P=pass; F=fail; NT=not tested; NA=not applicable

TABLE 6 - TRANSPORTATION AND OTHER CONDITION TESTING OF BLOOD GAS ANALYZERS

	VIBRATION/ CARGO/DROP	ALTITUDE	SALT+ FOG	SAND+ DUST
GEMSTAT	**P**	**P**	**P**	**P**
pO_2	P	P	P	P
pCO_2	P	P	P	P
pH	P	P	P	P
CIBA 238	**P**	**P**	**P**	**P**
pO_2	P	P	P	P
pCO_2	P	P	P	P
pH	P	P	P	P
CIBA 288	**P**	**HF**	**P**	**P**
pO_2	P		P	P
pCO_2	P		P	P
pH	P		P	P
NOVA STAT 5	**P**	**P**	**P**	**P**
pO_2	P	P	P	P
pCO_2	P	P	P	P
pH	P	P	P	P

P=pass; F=fail; HF=hard failure

Coagulation Analyzers

Four blood coagulation analyzers underwent operational testing (Table 7). The Biotrack 512 is the smallest, lightest and most portable of the machines. The reagent cartridges used by the Biotrack 512 require the smallest amount of storage space while the Factor VI's pre-packaged reagent tubes needed the most storage space. No attempt was made to precisely quantify the necessary amount of storage space. Each analyzer offered tests of PT and PTT, while the Accustasis 2000 and Coagamate XM also performed thrombin times and fibrinogen assays (Table 8). Time required per test and cost per unit were similar, although the Biotrack cost about $1,000 less.

During analytical performance testing, all coagulation instruments performed in a statistically comparable fashion with the reference analyzer except the Factor VI (Table 9). Factor VI results were different statistically ($P<0.05$) than the reference analyzer for both APTT and PT. The mean values obtained for both these parameters were twice those of other instruments for APTT and nearly four times those for PT. When the manufacturer was consulted by the laboratory technician regarding this situation, he was told that the normal ranges for APTT and PT values measured on the Factor VI are different than other instruments. Clearly, differences of this magnitude could result in clinically significant differences in interpretation.

The Accustasis 2000 was the only unit to operate adequately at both 40 and 110°F (Table 10). It failed testing under combined high temperature/humidity where results were inadequate for PT and APTT. The test was not repeated at 90°F/90%RH. The Accustasis also failed -60°F storage testing. The Factor VI passed testing during 110°F and 100°F/90%RH operation. The Biotrack 512 only operated at 60°F and 90°F, reporting a "Room Temperature Error" during 40, 50, 100 and 110°F operation. It also could not tolerate elevated humidity and displayed a similar error code. The Biotrack was the only machine which would not operate (i.e., Hard Failure) after being stored at 160°F. The Coagamate XM would not function at 40°F and 110°F, reporting a "values out of range" error. It functioned adequately at 100°F ambient temperature but had difficulty at 50 and 60°F. Although it initially failed during testing at 110°F/90%RH, retesting at 100°F/90%RH was successful. Storage temperatures did not affect the Coagamate's performance. It should be noted that the Coagamate failed level 2 APTT baseline testing by reporting a scant 17/40 (43%) of samples within the reference range. The Factor VI operated inadequately at lower temperatures, with unsatisfactory results of control reagent testing at 40°F. Interestingly, although data could be collected at 40°F, a fault prompt occurred during 50°F operation and no data was obtained. The Factor VI was the only unit to pass elevated humidity testing.

There were no hard failures during the remainder of the operational testing (Table 11). There were a variety of failures noted for individual tests and conditions. The salt/fog and sand/dust operation caused the greatest amount of difficulty for this group of instruments. The Biotrack was the only unit to pass all of these tests.

TABLE 7 - SUMMARY OF COAGULATION ANALYZERS TESTED

MODEL	MANUFACTURER	DIMENSIONS (inches)	WEIGHT (pounds)	POWER REQUIREMENT	METHODOLOGY	CALIBRATION	REAGENT
ACCUSTASIS 2000	SIGMA DIAGNOSTICS	8.0x11.8x4	8.4	110 or 220 V	Turbo-Densitometry	Automatic	Lyophilized
COAGAMATE XM	ORGANON TEKNIKA	14.7x4.6x20.0	20.0	90 or 130 V	Photo Optical Clot Detection	Manual	Lyophilized
FACTOR VI	INTERNATIONAL TECHNIDYNE	9.5x11.5x6.0	7.0	120 V	Magnetic Clot Detection	Automatic	Prepared Pre-Packaged Tube
BIOTRACK 512	CIBA CORNING	3.6x6.7x1.9	1.2	9V battery or 110V	Laser Photometer	Automatic	Cartridge

V=volt

TABLE 8 - TESTS OFFERED AND COSTS OF COAGULATION ANALYZERS

MODEL	PT	APTT	TT	Fib	OTHER	SAMPLE SIZE (type)	TIME/TEST (minutes)	COST/TEST (U.S. dollar)*	COST/UNIT (U.S. dollar)*
ACCUSTASIS 2000	X	X	X	X		100 ul (citrated plasma)	1 - 3	1.00	3,450.00
COAGAMATE XM	X	X	X	X	Factor Assay	0.2 ml (plasma)	1 - 3	1.00	3,465.00
FACTOR VI	X	X	X			3.0 ml (citrated plasma)	1 - 3	2.60	3,500.00
BIOTRACK 512	X	X				25-45 ul (whole blood)	1 - 3	8.00	2,495.00

* 1992 U.S. dollars

TABLE 9 - MEAN (STANDARD DEVIATION) OF REFERENCE VALUES AND COAGULATION ANALYZERS TESTED

	N (number of samples)	APTT Mean (S.D.)	PT Mean (S.D.)
REFERENCE	100	30.0 (4.5)	12.4 (1.9)
ACCUSTASIS 2000	100	29.1 (4.2)	13.1 (0.9)
COAGAMATE XM	100	24.7 (3.6)	12.8 (1.3)
FACTOR VI	100	* 69.4 (8.3)	* 63.6 (10.2)
BIOTRACK 512	96	33.6 (8.9)	12.8 (2.8)

* Denotes statistically significant difference with reference analyzer
S.D.=standard deviation

TABLE 10 - TEMPERATURE CONDITION TESTING OF COAGULATION ANALYZERS

	Baseline	40°	50°	60°	90°	100°	110°	TEMP/HUMID (°F/RH)	-60° STORAGE	160° STORAGE
ACCUSTASIS 2000	**P**	**P**	**NA**	**NA**	**NA**	**NA**	**P**	**F** (100/90)	**F**	**F**
APTT	P	P					P	F1	P	F1
PT	P	P					P	F1,2	F2	P
COAGAMATE XM	**F**	**HF**	**F**	**F**	**NA**	**P**	**HF**	**F** (100/90)	**P**	**P**
APTT	F2		P	F2		P		F2	P	P
PT	P		F1	F1		P		P	P	P
FACTOR VI	**P**	**F**	**HF**	**P**	**NA**	**NA**	**P**	**P** (100/90)	**P**	**F**
APTT	P	F1,2		P			P	P	P	P
PT	P	F1,2		P			P	P	P	F1
BIOTRACK 512	**P**	**HF**	**HF**	**P**	**P**	**HF**	**HF**	**HF** (90/90)	**P**	**HF**
APTT	P			P	P				P	
PT	P			P	P				P	

P=pass; F=fail; HF=hard failure; NA=not applicable

TABLE 11 - TRANSPORTATION AND OTHER CONDITION TESTING OF COAGULATION ANALYZERS

	VIBRATION/ CARGO/DROP	ALTITUDE	SALT+ FOG	SAND+ DUST
ACCUSTASIS 2000	**F**	**P**	**F**	**F**
APTT	P	P	F1	F1,2
PT	F2	P	F2	F1
COAGAMATE XM	**P**	**F**	**F**	**F**
APTT	P	F2	F1	F1*
PT	P	P	P	P*
FACTOR VI	**F**	**P**	**F**	**F**
APTT	P	P	P	F1,2
PT	F1	P	F1	F1,2
BIOTRACK 512	**P**	**P**	**P**	**P**
APTT	P	P	P	P
PT	P	P	P	P

* Only tested at level 1
P=pass; F=fail

Hematology Analyzers

Six hematology analyzers were evaluated (Table 12). The QBC Autoreader was the smallest of the units tested. It required less time for calibration and the least amount of storage space for reagents. Although it normally uses whole blood controls in a clinic setting, the unit can also be calibrated with a "check rod" system which does not use whole blood. Additionally, it was the only unit which did not use whole blood controls. All analyzers perform white blood cell counts and measures of either hemoglobin or hematocrit (Table 13). The QBC Autoreader, Danam 820, QBC Manual and Celldyn 610 also perform platelet counts. Time to complete a single test was similar for each machine and analyzer cost ranged from $5,000 to $11,000.

Analytical performance results demonstrated several statistically significant ($P<0.05$) differences between values obtained by the reference analyzer and test instruments (Table 14). These differences are summarized for each of the primary parameters (and instrument) as follows: WBC (CBC 5 and Danam 510), Hct (CBC 5 and QBC Autoread) and RBC (CBC 5). No significant differences were found for platelet counts and Hgb. Although these differences were statistically significant, none were considered clinically significant.

None of the machines operated properly at 40°F because the cold environment caused crystallization of the reagents (Table 15). Several samples were run at 40°F for the QBC Manual, Danam 510 and CBC 5, but the results were unreliable and required multiple runs for each sample. Although these units operated marginally at 40°F their overall performance was not considered adequate. The QBC Autoreader and Danam 510 were the only analyzers to pass testing at 50°F. It should be noted that Hgb testing was not completed at 50°F for the 510 because of logistical problems. The CBC-5 was not tested at 50°F or 60°F despite a single test failure at 40°F.

The QBC Autoreader and the QBC Manual were the only analyzers capable of running samples at 110°F. The QBC Autoreader received an overall "Fail" because of inadequate performance for HCT and HGB tests. These two units were also the only units to pass testing under high humidity/temperature, with the QBC Manual capable of operating at the most extreme condition (110°F/90%RH). During testing of the QBC Autoreader at 110°F/90%RH, the plastic stoppers became tacky which caused the machine to jam. The Danam 510 reported a "room temperature too high" error code during 100°F operation.

The QBC Manual was not tested after -60 or 160°F storage because the unit was damaged after the drop test and could not be replaced. All of the other machines operated after warm and cold storage except the CBC 5 because its bellows became warped during

storage. When the bellows were replaced the machine operated, but it was not re-tested after 160°F storage. The QBC Autoreader recorded level 2 failures for all primary tests after -60°F storage.

During the vibration exposure, the Celldyn 610 experienced an electronic failure and did not undergo drop testing (Table 16). A transducer broke during drop testing of the CBC 5 constituting a "Hard Failure". As previously mentioned, the QBC Manual was damaged during the drop test and could not complete environmental testing including salt/fog and sand/dust operation. The CBC 5 reported a "flow-time error" during altitude testing. The remainder of the machines operated under conditions of vibration, altitude, salt/fog and sand/dust except for several specific failures noted in Table 16.

TABLE 12 - SUMMARY OF HEMATOLOGY ANALYZERS TESTED

MODEL	MANUFACTURER	DIMENSIONS (inches)	WEIGHT (pounds)	POWER REQUIREMENT	METHODOLOGY	CALIBRATION	REAGENT
QBC AUTOREADER	BECTON DICKINSON	13.5x9.5x4	8.0	100-120 V 220-240 V	Reflective Type Liquid Crystal	Semi-Automatic	Precoated Glass Tube
QBC MANUAL	BECTON DICKINSON	10.0x14.0x12.0	10.0	120 V	Reflective	Semi-Automatic	Precoated Glass Tube
DANAM 510	DANAM CORPORATION	9.0x14.0x13.0	19.0	115-230 V	Electrical Resistance	Semi-Automatic	Liquid
DANAM 820	DANAM CORPORATION	13.8x14.0x13.0	31.0	115 V	Electrical Resistance	Semi-Automatic	Liquid
CBC 5	COULTER ELECTRONICS	7.0x15.0x14.0	17.0	115 V	Coulter Principle	Manual	Liquid
CELLDYN 610	ABBOTT DIAGNOSTICS	12.3x15.0x17.5	50.0	90-130 V, 210-260 V	Electronic Resistance/ Volumetric Metering	Semi-Automatic	Liquid

lb=pound

TABLE 13 - TESTS OFFERED AND COSTS OF HEMATOLOGY ANALYZERS

MODEL	WBC	RBC	Hgb	Hct	Plt	COUNT	OTHER	SAMPLE SIZE (type)	TIME/TEST (seconds)	COST/TEST (U.S. dollar)*	COST/UNIT (U.S. dollar)*
QBC AUTOREADER	X		X	X	X	LYMPH, MONO	MCHC	111 ul (whole blood)	180	1.69	8,175.00
QBC MANUAL	X			X	X	LYMPH, MONO	MCHC	111 ul (whole blood)	60	1.69	6,700.00
DANAM 510	X	X	X	X			MCV	40 ul (whole blood)	48	0.26	5,148.00
DANAM 820	X	X	X		X		MCV, MCH, MCHC	40 ul (whole blood)	60	0.23	11,156.40
CBC 5	X	X	X	X			MCV	45 ul (whole blood)	60	1.41	7,750.00
CELLDYN 610	X	X	X		X	GRAN, LYMPH	MCV	40 ul (whole blood)	180	1.29	9,114.00

* 1992 U.S. dollars
See list of abbreviations for acronyms

TABLE 14 - MEAN (STANDARD DEVIATION) OF REFERENCE VALUES AND HEMATOLOGY ANALYZERS TESTED

	N (number of samples)	WBC Mean (S.D.)	Hct Mean (S.D.)	Hgb Mean (S.D.)	RBC Mean (S.D.)	Plt Mean (S.D.)
REFERENCE	100	6.0 (1.3)	43.5 (2.9)	15.2 (1.1)	5.09 (0.40)	262 (51)
QBC AUTOREADER	98	6.4 (1.4)	* 45.3 (3.3)	14.7 (1.0)	NA	283 (57)
QBC MANUAL	98	6.1 (1.6)	44.2 (3.4)	NA	NA	278 (61)
DANAM 510	99	* 7.1 (4.4)	43.7 (3.3)	15.0 (1.1)	5.00 (0.40)	NA
DANAM 820	98	6.6 (1.5)	42.3 (3.4)	15.2 (3.3)	4.95 (0.44)	263 (52)
CBC 5	100	* 7.0 (1.8)	* 46.5 (3.6)	15.6 (1.1)	* 5.31 (0.45)	NA
CELLDYN 610	99	6.4 (1.5)	43.3 (3.0)	15.3 (1.1)	5.11 (0.40)	270 (56)

* Denotes statistically significant difference with reference analyzer
S.D.=standard deviation

TABLE 15 - TEMPERATURE CONDITION TESTING OF HEMATOLOGY ANALYZERS

	Baseline	40°	50°	60°	90°	100°	110°	TEMP/HUMID (°F/RH)	-60° STORAGE	160° STORAGE
QBC AUTOREADER	**P**	**HF**	**P**	**NA**	**NA**	**NA**	**F**	**P** (100/90)	**F**	**P**
WBC	P		P				P	P	F2	P
Hct	P		P				F2	P	F2	P
Hgb	P		P				F1,2	P	F2	P
Plt	P		P				P	P	F2	P
QBC MANUAL	**P**	**F**	**F**	**F**	**NA**	**NA**	**P**	**P** (110/90)	**NT**	**NT**
WBC	P	F1,2	F1	F1			P	P		
Hct	P	F2	F1,2	P			P	P		
Plt	P	F1,2	F1	P			P	P		
DANAM 510	**F**	**F**	**P***	**NA**	**P**	**HF**	**NA**	**F** (90/90)	**P**	**P**
WBC	P	P	P		P			P	P	P
Hct	P	P	P		P			P	P	P
Hgb	P	F2,3	NT		P			F2	P	P
RBC	F1	P	P		P			P	P	P
DANAM 820	**P**	**HF**	**NT**	**P**	**P**	**HF**	**NA**	**F** (90/90)	**P**	**P**
WBC	P			P	P			P	P	P
Hct	P			P	P			P	P	P
Hgb	P			P	P			F1	P	P
RBC	P			P	P			P	P	P
Plt	P			P	P			F1	P	P
CBC 5	**P**	**F**	**NT**	**NT**	**F#**	**F#**	**NA**	**NA**	**P**	**HF**
WBC	P	F2			F2	F2			P	
Hct	P	P			F2	F1,2			P	
Hgb	P	P			F2	F2			P	
RBC	P	P			P	P			P	
CELLDYN 610	**P**	**HF**	**HF**	**HF**	**HF**	**NA**	**NA**	**NA**	**P**	**P**
WBC	P								P	P
Hct	P								P	P
Hgb	P								P	P
RBC	P								P	P
Plt	P								P	P

* Hgb testing was not performed
# Level 3 testing not completed

P=pass; F=fail; NT=not tested; NA=not applicable; HF=hard failure

TABLE 16 - TRANSPORTATION AND OTHER CONDITION TESTING OF HEMATOLOGY ANALYZERS

	VIBRATION/ CARGO/DROP	ALTITUDE	SALT+ FOG	SAND+ DUST
QBC AUTOREADER	**P**	**P***	**P**	**P**
WBC	P	P	P	P
Hct	P	P	P	P
Hgb	P	NT	P	P
Plt	P	P	P	P
QBC MANUAL	**HF**	**P**	**NT**	**NT**
WBC		P		
Hct		P		
Plt		P		
DANAM 510	**P**	**P**	**P**	**P**
WBC	P	P	P	P
Hct	P	P	P	P
Hgb	P	P	P	P
RBC	P	P	P	P
DANAM 820	**F**	**P**	**P**	**F**
WBC	F2	P	P	P
Hct	P	P	P	P
Hgb	P	P	P	F1
RBC	P	P	P	P
Plt	P	P	P	P
CBC 5	**HF**	**HF**	**P**	**F**
WBC			P	P
Hct			P	P
Hgb			P	F2
RBC			P	P
CELLDYN 610	**HF**	**P**	**P**	**P**
WBC		P	P	P
Hct		P	P	P
Hgb		P	P	P
RBC		P	P	P
Plt		P	P	P

* Hgb testing not performed
P=pass; F=fail; NT=not tested; HF=hard failure

Chemistry Analyzers

Six clinical chemistry analyzers were procured for testing. The I-Stat, a hand-held instrument powered by 9 volt batteries, was impressively small, lightweight (19.0 oz) and compact. The NOVA 12, weighing 90 lb., was the most bulky (Table 17). The I-Stat had the highest average cost per test ($12.00/test), whereas the Reflotron had the lowest ($1.40/test) (Table 18). The Cobas Ready had the highest cycle time.

The tests performed by these units are shown in Table 19. The Cobas Ready, Vision, Reflotron analyzers and DT 60 II/DTSC modules provide the widest analytic capabilities. Included are liver and renal function tests, cholesterol panels and drug level testing.

Although phase II analytical performance evaluations revealed statistically significant ($P<0.05$) differences between several values obtained by the test analyzers and the reference instrument, none of these differences were judged to be clinically relevant by the physicians (Table 20).

The NOVA 12 was non-operational upon arrival at Fort Detrick for environmental testing. Following discussions with the Marine Corps project officer regarding repair of this instrument, it was decided to eliminate the NOVA 12 from further consideration due to its apparent lack of transportation durability and relatively heavy weight. Therefore, operational testing was performed with only five instruments.

Immediately before operational testing, the manufacturers of the I-Stat provided an enhanced version of their standard instrument. The enhanced version incorporated internal hardware and software changes that were purported to allow the unit to operate successfully at a wider ambient temperature range than the standard unit. Both the standard and enhanced versions of the I-Stat instrument were tested for operational performance although the majority of tests were performed with the enhanced model. Tables indicate which version of the I-Stat was tested.

The Cobas Ready and Vision were the only units to perform adequately at 40°F (Table 21). The Ektachem was considered overall non-operational at 40°F because two of the three modules (DT 60 II and DTE) failed to operate properly. Although 10 samples were run with the Enhanced I-Stat at 40°F, this analyzer displayed error codes during 5 of these tests and then shut down completely. Both of these units passed testing at 50°F. All of units experienced "Hard Failures" during testing at 110 and 100°F except the Cobas Ready. Although the Cobas Ready provided results at 100°F, values were out of range for level 1 and 2 BUN testing. All machines operated successfully at 90°F except the Vision which failed level 1 BUN testing. All machines operated

properly at elevated temperature and humidity except the Vision.

The Vision was the only instrument that failed after storage at -60°F. All chemistry analyzers passed the 160°F storage test except the Reflotron which was not tested because of the inability to obtain reagents. The manufacturer of the Reflotron then canceled their reagent contract with the Navy. It should also be noted that creatinine testing (a primary test of the chemistry analyzers) of the Reflotron was not completed because of this problem.

All instruments tested, except the Ektachem, passed the vibration, drop, altitude, salt/fog, and sand/dust tests (Table 22). Following the drop test, the Ektachem printer was non-operational and because the printer is a controlling element of the data logic flow for all three modules, none of the Ektachem modules were able to function when the printer was disabled by the test. This constituted a hard failure.

TABLE 17 - SUMMARY OF CHEMISTRY ANALYZERS TESTED

MODEL	MANUFACTURER	DIMENSIONS (inches)	WEIGHT (pounds)	POWER REQUIREMENT	METHODOLOGY	CALIBRATION	REAGENT
COBAS READY	ROCHE DIAGNOSTICS	17.7x13.8x7.5	39.7	120 V	Dual Wavelength Reflectometry	Automatic	Dry Reagent Strip
I-STAT	I-STAT CORPORATION	2.0x2.8x7.8	19.0 oz	9 V batteries	Micro Fabricated over electrodes	Automatic	Cartridge
VISION	ABBOT DIAGNOSTICS	23.0x17.0x23.0	70.0	110,120,220, 240 V	Absorbance & Ion	Manual	Pre-measured cassettes
EKTACHEM	EASTMAN KODAK			110-240 V			
DT 60 II		18.8x13.8x6.8	25.6		Dry Chemical	Manual	Prepackaged slides
DTSC		13.5x13.5x6.5	17.0		Dry Chemical	Manual	Prepackaged slides
DTE		5.95x13.9x6.5	9.5		Dry Chemical	Manual	Slides
REFLOTRON	BOEHRINGER MANNHEIM	12.0x14.0x7.8	12.75	115 or 230 V	Reflectance Photometry	Automatic	Dry Reagent Strip
NOVA 12	NOVA BIOMEDICAL	19.2x20.7x20.2	90.0	100,120,220, 240 V	Ion Selective Electrodes	Automatic	Liquid

V=volts

TABLE 18 - COSTS OF CHEMISTRY ANALYZERS

MODEL	SAMPLE SIZE (type)	TIME/TEST (minutes)	COST/TEST (U.S. dollar)*	COST/UNIT (U.S. dollar)*
COBAS READY	5-7ul (pla,ser)	6-11 (test dependent)	2.90	15,995.00
I-STAT	65ul (ser,pla,wb)	1.5	12.00	4,060.00
VISION	3-4drp (wb,ser,pla)	8-14 (test dependent)	2.25	16,495.00
EKTACHEM	10ul (ser,wb)			
DT 60 II		3	1.60	4,494.00
DTSC		3	1.75	2,614.00
DTE		3	2.05	2,696.00
REFLOTRON	32ul (wb,pla,ser)	1-3 (test dependent)	1.40	4,348.00
NOVA 12	70-300ul (ser,pla,urine)	1	2.15	16,393.00

* 1992 U.S. dollars
wb=whole blood; pla=plasma; ser=serum

TABLE 19 - TESTS PERFORMED BY CHEMISTRY ANALYZERS*

MODEL	Na	K	Cl	CO_2	Glu	Hgb	Hct	BUN	Cr	ALT	AlkP	AST	GGT	ALB	Ca	UA	CK
COBAS READY					X			X	X	X	X	X	X	X	X	X	X
I-STAT	X	X	X		X	X	X	X									
VISION		X			X	X		X	X	X	X	X	X	X		X	
EKTACHEM DT 60 II					X	X		X	X							X	
DTSC									X	X	X	X	X		X		X
DTE	X	X	X	X													
REFLOTRON					X	X		X	X	X		X	X			X	X
NOVA 12	X	X	X	X	X			X									

* See List of Abbreviations for acronyms

TABLE 19 (CONTINUED)*

MODEL	Chol	HDL	LDL	Trig	LDH	Amyl	TP	TBili	T_4	Phos	OTHER
COBAS READY	X	X	X	X			X	X			
I-STAT											
VISION	X	X	X	X		X	X	X	X		Theophylline,CRP,Phenytoin, PT
EKTACHEM DT 60 II	X	X		X		X	X	X		X	NH_3, Mg
DTSC					X						CKMB,Theophylline, Lipase
DTE											
REFLOTRON	X	X		X		X		X			
NOVA 12											

* See List of Abbreviations for acronyms

TABLE 20 - MEAN (STANDARD DEVIATION) OF REFERENCE VALUES AND CHEMISTRY ANALYZERS TESTED

	N (# of samples)	Glu Mean (S.D.)	BUN Mean (S.D.)	Cr Mean (S.D.)	Na Mean (S.D.)	K Mean (S.D.)	Cl Mean (S.D.)
REFERENCE	100	88 (18)	15 (4)	1.0 (0.1)	142 (3)	4.42 (0.34)	101.5 (2.3)
COBAS READY	100	90 (19)	13 (4)	1.3 (0.2)	NA	NA	NA
I-STAT (Standard)	100	92 (16)	13 (5)*	NA	141 (2)	4.42 (0.34)	107.9 (2.2)*
VISION	100	92 (19)	16 (4)	1.1 (0.1)	NA	4.46 (0.33)	NA
EKTACHEM DT 60 II	99	91 (18)	13 (5)*	1.2 (0.1)	144 (7)*	4.50 (0.39)	107.1 (7.2)*
DTSC							
DTE							
REFLOTRON	100	88 (18)	16 (4)	0.9 (0.1)	NA	NA	NA
NOVA 12	100	95 (18)	15 (4)	NA	145 (2)*	4.60 (0.33)	107.2 (2.0)*

* Denotes statistically significant difference with reference analyzer
S.D.=standard deviation; NA=not applicable

TABLE 21 - TEMPERATURE CONDITION TESTING OF CHEMISTRY ANALYZERS

	Baseline	40°	50°	60°	90°	100°	110°	TEMP/HUMID (°F/RH)	-60° STORAGE	160° STORAGE
COBAS READY	**P**	**P**	**NA**	**NA**	**P**	**F**	**HF**	**P** (90/90)	**P**	**P**
Glu	P	P			P	P		P	P	P
BUN	P	P			P	F1,2		P	P	P
Cr	P	P			P	P		P	P	P
I-STAT (Enhanced)	**P**	**HF**	**P**	**NA**	**P**	**HF**	**HF**	**P** (90/90)	**P**	**P**
Glu	P		P		P			P	P	P
BUN	P		P		P			P	P	P
VISION	**P**	**P**	**NA**	**NA**	**F**	**HF**	**HF**	**HF**	**HF**	**P**
Glu	P	P			P					P
BUN	P	P			F1					P
Cr	P	P			P					P
EKTACHEM (DT 60)	**P**	**HF**	**P**	**NA**	**P**	**HF**	**NA**	**P** (90/90)	**P**	**P**
Glu	P		P		P			P	P	P
BUN	P		P		P			P	P	P
Cr	P		P		P			P	P	P
REFLOTRON	**P**	**HF**	**HF**	**F**	**P**	**HF**	**HF**	**P** (90/90)	**NT**	**NT**
Glu	P			F2	P			P		
BUN	P			P	P			P		
Cr*	NT			NT	NT			NT		
NOVA 12	**NT**	**NT**	**NT**	**NT**	**NT**	**NT**	**NT**	**NT**	**NT**	**NT**

* Creatinine not tested because of lack of reagents
P=pass; F=Fail; NT=not tested; HF=hard failure

TABLE 22 - TRANSPORTATION AND OTHER CONDITION TESTING OF CHEMISTRY ANALYZERS

	VIBRATION/ CARGO/DROP	ALTITUDE	SALT+ FOG	SAND+ DUST
COBAS READY	**P**	**P**	**P**	**P**
Glu	P	P	P	P
BUN	P	P	P	P
Cr	P	P	P	P
I-STAT (Enhanced)	**P**	**P**	**P**	**P**
Glu	P	P	P	P
BUN	P	P	P	P
VISION	**P**	**P**	**P**	**P**
Glu	P	P	P	P
BUN	P	P	P	P
Cr	P	P	P	P
EKTACHEM (DT 60)	**HF**	**P**	**P**	**P**
GL		P	P	P
BUN		P	P	P
Cr		P	P	P
REFLOTRON	**P**	**P**	**P**	**P**
Glu	P	P	P	P
BUN	P	P	P	P
Cr*	NT	NT	NT	NT
NOVA 12	**NT**	**NT**	**NT**	**NT**

* Not tested because of lack of reagents
P=pass; F=fail; NT=not tested; HF=hard failure

Electrolyte Analyzers

Three electrolyte analyzers underwent operational testing (Table 23). Although similar in overall dimensions, the Lytening 5 at 11.0 lb. was less than half the weight of the AVL 986S and slightly lighter than the Ciba 644 instruments. All instruments use ion selective electrodes and calibrate automatically.

The AVL 986S is more expensive than the other two instruments but it does offer an additional CO_2 parameter (Table 24). The Lytening 5 had the fastest cycle time per test (7 - 15 sec). Cost per test was identical for all three instruments.

Analytical performance testing with human serum samples (Table 25) revealed statistically significant ($P<0.05$) differences in the following parameter (and instrument) combinations relative to reference analyzer values: Na (986S), Cl (AVL 986S and Ciba 644). The only potentially clinically relevant difference occurred for Cl results obtained with the AVL 986S which were consistently higher than the reference analyzer.

The results of operational evaluation indicated that all three instruments functioned adequately at temperature extremes except for the AVL 986S which failed at single levels for Na and Cl testing (Table 26). This unit was not tested at 100°F or 90°F. The Ciba 644 was the only unit to pass testing at the extreme of combined temperature and humidity. The AVL 986S failed at 2 levels for Cl testing at 110°F/90%RH and was not tested at a lower temperature and relative humidity. Level 3 testing (for Na, K and Cl) was not completed for the Lytening 5 at 100°F/90%RH because an electrode error code was displayed after the completion of level 1 and 2 samples. This could be considered a "hard failure". Warm and cold storage did not present a problem for these units except that the Lytening 5 failed level 3 testing for potassium after 160°F storage. It should be noted that only level 1 potassium reagents were used to test the Ciba 644 after -60°F storage.

The results of all remaining tests demonstrated that this class of instruments generally had outstanding operational characteristics (Table 27). The single exception was the Lytening 5 which failed the drop test (shorting of a circuit board).

TABLE 23 - SUMMARY OF ELECTROLYTE ANALYZERS TESTED

MODEL	MANUFACTURER	DIMENSIONS (inches)	WEIGHT (pounds)	POWER REQUIREMENT	METHODOLOGY	CALIBRATION	REAGENT
AVL 986S	AVL	11.8x10.6x13.6	24.0	110,117,240 V	Ion Selective Electrodes	Automatic	Liquid
CIBA 644	CIBA CORNING	11.0x10.6x12.6	14.0	100,120,220, 240 V	Ion Selective Electrodes	Automatic	Liquid
LYTENING 5	BAXTER DIAGNOSTICS	9.3x9.3x15.0	11.0	110,220 V	Ion Selective Electrodes	Automatic	Liquid

V=volts

TABLE 24 - TESTS OFFERED AND COSTS OF ELECTROLYTE ANALYZERS

MODEL	Na	K	Cl	CO_2	SAMPLE SIZE (type)	TIME/TEST (seconds)	COST/TEST* (U.S. dollar)	COST/UNIT* (U.S. dollar)
AVL 986S	X	X	X	X	120-160 ul (wb,ser,plas,urine)	90	0.44	9,360.00
CIBA 644	X	X	X		65 ul (plas,ser,wb,urine)	35	0.44	5,135.00
LYTENING 5	X	X	X		90-180 ul (plas,ser,wb)	7-15	0.44	5,395.00

* 1992 U.S. dollars
wb=whole blood; ser=serum; plas=plasma

TABLE 25 - MEAN (STANDARD DEVIATION) OF REFERENCE VALUES AND ELECTROLYTE ANALYZERS TESTED

	N (number of samples)	Na Mean (S.D.)	K Mean (S.D.)	Cl Mean (S.D.)
REFERENCE	99	142 (3)	4.42 (0.34)	101.5 (2.3)
AVL 986S	100	150 (2)*	4.53 (0.34)	106.1 (2.1)*
CIBA 644	100	143 (2)	4.44 (0.34)	103.6 (1.8)*
LYTENING 5	100	143 (1)	4.40 (0.34)	102.5 (2.3)

* Denotes statistically significant difference with reference analyzer
S.D.=standard deviation

TABLE 26 - TEMPERATURE CONDITION TESTING OF ELECTROLYTE ANALYZERS

		Baseline	40°	50°	60°	90°	100°	110°	TEMP/HUMID (°F/RH)	-60° STORAGE	160° STORAGE
AVL 986S		**P**	**P**	**NA**	**NA**	**NT**	**NT**	**F**	**F (110/90)**	**P**	**P**
	Na	P	P					F3	P	P	P
	K	P	P					P	P	P	P
	Cl	P	P					F2	F2,3	P	P
CIBA 644		**P**	**P**	**NA**	**NA**	**NA**	**NA**	**P**	**P (110/90)**	**P**	**P**
	Na	P	P					P	P	P	P
	K	P	P					P	P	P*	P
	Cl	P	P					P	P	P	P
LYTENING 5		**P**	**P**	**NA**	**NA**	**NA**	**NA**	**P**	**F (100/85)**	**P**	**F**
	Na	P	P					P	F2**	P	P
	K	P	P					P	P**	P	F3
	Cl	P	P					P	P**	P	P

* Only level 1 was tested

** Level 3 not tested

P=pass; F=fail; NA=not applicable; NT=not tested

TABLE 27 - TRANSPORTATION AND OTHER CONDITION TESTING OF ELECTROLYTE ANALYZERS

		VIBRATION/ CARGO/DROP	ALTITUDE	SALT+ FOG	SAND+ DUST
AVL 986S		**P**	**P**	**P**	**P**
	Na	P	P	P	P
	K	P	P	P	P
	Cl	P	P	P	P
	CO_2	P	P	P	P
CIBA 644		**P**	**P**	**P**	**P**
	Na	P	P	P	P
	K	P	P	P	P
	Cl	P	P	P	P
LYTENING 5		**HF**	**P**	**P**	**P**
	Na		P	P	P
	K		P	P	P
	Cl		P	P	P

P=pass; HF=hard failure

Urinalysis Analyzer

Only one automated urinalysis instrument, the Clinitek 100, was identified by the initial review for evaluation (Table 28). This analyzer offers all basic studies required of this class of instruments (Table 29). In addition to the test unit, samples were run at the NAVHOSP Groton reference laboratory (Reference) and manually by a laboratory technician at NSMRL (Manual). The methods used by NAVHOSP Groton and NSMRL were the same. Primary comparisons were made between the test analyzer and both reference values.

Using human urine samples, the Clinitek yielded analytical performance results for the specific gravity and pH parameters which were not significantly different ($P>0.05$) than reference values (Table 30). For some of the qualitative parameters (Keto, Blood, Pro, and Uro) results from categorical statistical evaluations indicated that the Clinitek 100 results differed significantly ($P<0.05$) from those obtained by the reference laboratory. Data for categorical variables is presented in Appendix D. The difference for ketone analysis would have no clinical relevance. For blood testing the Clinitek read 1 sample as containing a "large" amount of blood and 1 as "medium" whereas the reference laboratory found the samples were negative for blood. Only 1 test for protein of 95 samples run could have had minor clinical relevance (Clinitek read >30mg/dl and the reference analyzer read negative). The test unit read various levels of urobilinogen for 74 samples that the reference analyzer noted as normal. Remaining categorical tests for bilirubin and nitrates were not statistically different from the reference analyzer.

The Clinitek 100 produced satisfactory test results under all temperature condition testing except for a minor failure at $40^{o}F$ operation (Table 31). This was consistent with baseline testing, where the Clinitek reported only 59/102 pH values within the control range for pH. We cannot identify the acid/base disturbance which caused this failure. Transportation and other operational condition testing presented no difficulties for the Clinitek (Table 32).

TABLE 28 - SUMMARY OF URINALYSIS ANALYZER TESTED

MODEL	MANUFACTURER	DIMENSIONS (inches)	WEIGHT (pounds)	POWER REQUIREMENT	METHODOLOGY	CALIBRATION	REAGENT
CLINITEK 100	MILES	15.5x12.6x4.4	8.5	110,115,220, 240 V	Photo Electric	Manual	Dry Reagent Strip

V=volts

TABLE 29 - TESTS OFFERED AND COSTS OF URINALYSIS ANALYZER

MODEL	TESTS	SAMPLE SIZE (type)	TIME/TEST (minutes)	COST/TEST* (U.S. dollar)	COST/UNIT* (U.S. dollar)
CLINITEK 100	Glu, Bili, Ketones, SG, Blood, pH, Pro, Urobil, Nit, Leukocytes	1.0 ml (urine)	1	0.34	1,645.00

* 1992 U.S. dollars
Glu=glucose; Bili=bilirubin; SG=specific gravity; Pro=protein; Urobil=urobilinogen; Nit=nitrates; ml=milliliter

TABLE 30 - MEAN (STANDARD DEVIATION) OF REFERENCE VALUES AND URINALYSIS ANALYZER TESTED*

	N (number of samples)	SG Mean (S.D.)	pH Mean (S.D.)
REFERENCE (NAVHOSP)	95	1.026 (0.014)	5.74 (0.58)
REFERENCE (MANUAL)	98	1.024 (0.006)	5.58 (0.67)
CLINITEK 100	98	1.025 (0.004)	5.72 (0.58)

S.D.=standard deviation; SG=specific gravity
* All tests performed on human urine specimens

TABLE 31 - TEMPERATURE CONDITION TESTING OF URINALYSIS ANALYZER

	Baseline	40°	50°	60°	90°	100°	110°	TEMP/HUMID (°F/RH)	-60° STORAGE	160° STORAGE
CLINITEK 100	**F**	**F**	**P**	**NA**	**NA**	**NA**	**P**	**P** (110/90)	**P**	**P**
Glucose	P	P	P				P	P	P	P
Bilirubin	P	P	P				P	P	P	P
Ketones	P	P	P				P	P	P	P
Specific Gravity	P	P	P				P	P	P	P
Blood	P	P	P				P	P	P	P
pH	F	F	P				P	P	P	P
Protein	P	P	P				P	P	P	P
Urobilinogin	P	P	P				P	P	P	P
Nitrate	P	P	P				P	P	P	P
Leukocytes	P	P	P				P	P	P	P

P=pass; F=fail; NA=not applicable

TABLE 32 - TRANSPORTATION AND OTHER CONDITION TESTING OF URINALYSIS ANALYZER

	VIBRATION/ CARGO/DROP	ALTITUDE	SALT+ FOG	SAND+ DUST
CLINITEK 100	**P**	**P**	**P**	**P**
Glucose	P	P	P	P
Bilirubin	P	P	P	P
Ketones	P	P	P	P
Specific Gravity	P	P	P	P
Blood	P	P	P	P
pH	P	P	P	P
Protein	P	P	P	P
Urobilinogen	P	P	P	P
Nitrates	P	P	P	P
Leukocytes	P	P	P	P

P=pass

Discussion

We found no single analyzer that could perform the majority of tests desired by the Marine Corps. Additionally, the units tested did not operate ideally under simulated field conditions. It will be necessary to procure several analyzers with specific clinical capabilities. Although there is a degree of overlap between specific categories of machines, most analyzers are designed to provide a specific group of related tests.

The final selection of any analyzer must take into account a number of factors such as cost per analyzer, cost per test and size/weight restrictions as well as performance during simulated field conditions. These factors must be weighed by those responsible for procuring these instruments for the Marine Corps. Our intent was not to provide a "cost-effectiveness" analysis of these instruments, but instead to present test results in a clear and concise manner to facilitate final purchasing decisions. Although the scope of operational testing was clearly defined, we had no basis for which to rank in order of importance those stated conditions. Also, it was unclear if there were any conditions that these machines must operate under, with failure to perform resulting in disqualification.

This study suffered from several design problems. Initially, there were no pre-established criteria for the "passing" or "failing" of machines during the operational testing. The experience of the laboratory technician appeared to influence the test results as more experienced technicians could often trouble-shoot small problems and keep the instrument running. This was especially evident during testing under conditions of temperature extremes. It was noted that the smaller machines could be "put under an arm" allowing them to operate during cold exposure, even if only briefly. Except during testing of blood gas analyzers, no effort was made to determine if temperature was affecting the analyzer, the control solutions or both of these.

The comparison of machines within each group was complicated by the fact that analyzers used different single control solutions. Individual controls were supplied by the analyzer's manufacturer. The acceptable levels of each control were different for each machine and not all levels were available for every analyzer. This opens up the potential bias that a manufacturer might deliberately set a more tolerant "acceptable" control range. There were several problems encountered finding a single standardized control that could be used within each class of analyzer so this effort was abandoned. Further efforts in this area should consider standardized controls or more reliance on human samples.

Except in a limited number of instances, it was not possible to compare the performance of analyzers within a group. Many units simply failed under a given condition (e.g., did not operate, an inadequate number of data points) or were not tested for other reasons. If a machine operated at 110°F, it usually was not tested at 90°F or 100°F. This was necessary to decrease the number a days within the environmental chamber. Obviously, it is unfair to compare a machine tested at 110°F and one evaluated at 100°F. Since analyzers perform different batteries of tests, it is not possible to compare all possible test and condition combinations (e.g., NA during 100°F operation). Instead, we focused on primary tests for each category of machines.

One potential method of minimizing these difficulties would be to develop a standardized testing procedure which could minimize the variation in technique among operators. These procedures would also simplify machine comparisons. It is unfair to "rank" machines during operational testing if the decision process used during the data collection process was unique to a machine. By clearly defining what constitutes a "hard" failure (the unit would not turn on, not report results or give readings out of range) it would be possible to weed out inappropriate units early in the process. Analyzers that survive the initial round of testing could undergo more extensive evaluation.

Additional analyzers considered for procurement should demonstrate capabilities which are similar to or exceed those of the units tested. An expedited review process could be developed to evaluate new technologies or advanced versions of existing equipment. It would be reasonable to focus on the temperature tolerance of units because most of the failures we encountered occurred during temperature testing. Most units operated satisfactorily during other aspects of testing. We believe that useful information could be gained in a short time by minimizing the amount of data collected and focusing on critical aspects of operational relevance.

In general, the analyzers that we evaluated were not designed to operate under these severe conditions. Although some problems could be corrected with small changes in design, others would require serious modifications. Close collaboration with companies committed to continual improvement of their products would be an effective method of minimizing in-house research and development efforts.

Finally, there continues to be rapid progress in clinical laboratory testing and biomedical instrumentation. Advances should be closely followed by those involved in maintaining laboratory capabilities for military operations. New technologies will certainly be developed which may better withstand the rugged conditions found in the field.

References

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Acknowledgements

The authors are indebted to the laboratory technicians who without there perseverance and ingenuity this project would not have been possible. They include HM1 R. Hutchinson, HM1 K. King and Mr. L. Mooney.

List of Abbreviations

%	Percent
Alb	Albumin
AlkP	Alkaline Phosphatase
ALT	Alanine Aminotransferase
Amyl	Amylase
APTT	Activated Partial Thromboplastin Time
art	Arterial blood sample
AST	Aspartate Aminotransferase
Bili	Bilirubin
BUN	Blood Urea Nitrogen
Ca	Calcium
Chol	Cholesterol
CK	Creatinine Kinase
CKMB	MB Fraction of Creatinine Kinase
Cl	Cloride
CO_2	Carbon Dioxide
Cr	reatinine
CRP	C-Reactive Protein
dl	deciliter
Fib	Fibrinogen
GGT	Gamma-Glutamyltransferase
Glu	Glucose
GRAN%	Granulocyte percent
GRAN#	Granulocyte number
GSE	Gram Stain Evaluation
Hct	Hematocrit
HDL	Hight density lipoprotein
Hgb	Hemoglobin
K	Potassium
Keto	Ketones
LDH	Lactate dehydrogenase
LDL	Low density lipoprotein
Leu	Leukocytes
LYM%	Lymphocyte percent
LYM#	Lymphocyte number
MCH	Mean Cell Hemoglobin
MCHC	Mean Cell Hemoglobin Concentration
MCV	Mean Corpuscular volume
mEq	milli-equivalent
Mg	Magnesium
mg	milligrams
N	Number of samples
Na	Sodium
Nit	Nitrate
NH_3	Ammonia
OPA	Ova and Parasite analysis
OSM	Osmolality
pH	pH (ACID/BASE)
Phos	Phosphorus
Plt	Platelets
pCO_2	Partial pressure carbon dioxide

pO_2	Partial pressure oxygen
Pro	Protein
PT	Prothrombin time
RBC	RED BLOOD COUNT
RPR	Rapid plasmin reagin (Syphilis test)
S.D.	Standard deviation
ser	serum sample
SG	Specific gravity
T_4	Thyroid hormone
TBili	Total bilirubin
TCB	Type and crossmatch of whole blood
TP	Total Protein
Trig	Triglycerides
TT	Thrombin Time
UA	Uric Acid
Urobil	Urobilinogen
V	Volts
wb	whole blood sample
WBC	White Blood Cell count

APPENDIX A

LABORATORY TECHNICIAN'S

INSTRUMENT TECHNICAL PROFILES

Blood Gas Analyzers

GEMSTAT

This analyzer is relatively small, compact and easy to operate. Reagents are provided in a self-contained cartridge form that eliminates the use of gas tanks. Cartridges provide sufficient reagent for 50 samples or until 72 hours after the cartridge was inserted. Cartridges are stored at room temperature. Installation and simple repairs are not complicated. Laboratory technicians with average skills can operate this unit. During the initial drop test an isolated transformer became disconnected. A replacement instrument did not experience this problem after repeating the drop test.

CIBA 238

This unit is small, compact unit and lightweight. All reagents are contained in a pack which includes both buffer and wash solutions. Analyzer requires one gas tank for operation (a "mini" size is available). Installation and troubleshooting is aided by flow chart instructions which were found to be uncomplicated. A heater failure occurred during 100°F operation. The machine subsequently functioned when returned to room temperature.

CIBA 288

This relatively large unit requires five different reagents and two gas tanks during operation. Installation and troubleshooting of unit is more complicated than the other units tested despite a well written operator's manual. It did not operate during altitude testing presenting a pressure sensor failure message at high altitude. The analyzer did operate normally after returning to sea level.

NOVA STAT 5

This analyzer is very large, heavy and requires a reagent pack and two gas tanks for operation. Installation and troubleshooting procedures are more complicated than the other units evaluated, necessitating an operator with a higher than average skill. The NOVA STAT 5 reported air bath temperature failure error codes during high temperature testing before the analyzer ceased to function. After storage at 160°F the blower assembly failed so that the analyzer was unable to reach the normal operating temperature of 37°F.

COAGULATION ANALYZERS

ACCUSTASIS 2000

This instrument is small, compact and rugged. It is similar to the fibrometer except that it uses turbo-densitometry for clot detection. Most reagents are premixed and easily transportable, however, they do require refrigeration. Operation could be improved with the addition of a second time clock. Technical support could be improved.

COAG-A-MATE XM

This analyzer is slightly larger and heavier than the other units tested in this group. It has the ability to perform several tests simultaneously. The reagents require more skill to reconstitute and APTT testing requires a higher operator skill level than average. Difficulties were encountered during both high and low temperature operation due to the inability of reagents to coagulate. The COAGAMATE requires a technician with above average skills who has received proper instrument instruction.

FACTOR VI

The FACTOR VI is relatively small, lightweight and compact. This unit requires individually wrapped tubes and a new reagent vial for every four samples tested resulting in the need for large amounts of refrigerated storage space. When tested in extreme temperature conditions of 110°F and 90°F the sample tubes sometimes overheated causing the coagulation levels to be above the expected control ranges. Operation requires too many technical steps to process samples efficiently and the skill level of the operator must be above average.

BIOTRACK 512

This unit is relatively small, compact and lightweight, using a newer technology which makes the analyzer basically reagent free. It is easily portable and reagents require very little storage space. The operation is not complicated. The BIOTRACK will not operate in extreme heat and cold. It failed to function at 40°F and 110°F/90%RH, directly affecting the laser lights (2) and LED's with radical temperature changes. The instrument was not affected by extreme storage temperatures. Redesign of the cartridge to allow more room for sampling ease would be helpful. Cartridge equilibration requires an incubation period of 45 seconds per sample. Total sample time for PT is

approximately 70 seconds, and approximately 3 minutes for APTT. A minimal amount of excess equipment is required.

HEMATOLOGY ANALYZERS

OBC AUTOREAD and OBC MANUAL

These analyzers did not function at 40°F because the layering of phases was not distinct. These instruments are unable to make readings when cell layers are poorly defined. During human sample testing 2 samples out of 100 could not be analyzed by the machines because of the absence of layering. This was probably caused by anemia in these subject's specimens which affected red cell distribution in the tube. These results would need to be verified by further testing, using an alternative hematology method.

These units did not function smoothly at high temperature and high humidity because the rubber closures at the end of tubes became tacky and caused the tubes to stick in the instrument. The AUTOREAD was unable to read tubes at 110°F/90%RH because it continually jammed (although it did operate at 100°F/90%RH).

HC 510 and HC 820

Extremes in temperature affected the reagents of these instruments which are isotonic solutions. Cold temperatures (below 50°F) cause salt to precipitate out of solution, changing the conductivity of reagents which results in machine alerts and unreliable test results. High temperatures (above 90°F) cause evaporation of solutions which also changes the concentration of salts in solution and affects test results. Both instruments are easy to operate and extremely reliable in a stable environment. They are also reliable after being moved once they are restabilized and recalibrated.

CBC 5

The bellows of this instrument were damaged after being stored in high temperature conditions. The bellows control the amount of reagent and samples that are aspirated for analysis. It also would not function during high frequency testing because a capacitor was lost from the main computer card. Extremes in temperature affected isotonic reagents as described above for the HC 510 and HC 820. This unit would not give results at high temperatures (90°F), although it produced a few results for certain tests at low temperatures (40°F).

CELLDYNE 610

The dilutor of this analyzer was affected by exposure to extreme temperatures. The expansion and contraction of seals during operation in hot and cold temperatures caused inaccurate aspiration and subsequent dispensing of reagents and samples. An unprotected reagent inlet tip on the dilutor was broken after storage at -60°F. This instrument would not pass initial internal checks after the high frequency test. A power source assembly needed to be replaced during testing.

CHEMISTRY ANALYZERS

I-STAT

The I-STAT is a relatively small, lightweight and compact hand-held unit that requires no maintenance, no manual calibration and uses only an electronic simulator to verify proper operation of the unit. It is powered by two 9-volt batteries and is capable of storing the results of fifty patient samples at a time. These results can be reviewed in any order and printed using a hand-held printer unit that is also battery operated. The I-STAT can also be interfaced with a computer system if desired.

This system requires only a pre-packaged, pre-measured reagent cartridge to achieve patient results. Reagents and controls require a minimum amount of refrigeration space. A 65ul patient sample is needed. The I-STAT analyzes patient samples in 90 seconds and samples are easily repeated. It is recommended that a storage case (e.g. Playmate cooler) that could protect the unit from these conditions be considered.

COBAS READY

The COBAS READY is a small, compact and reasonably lightweight instrument. It utilizes a dry chemical reagents in a stick form. These are prepackaged, compact and do not require refrigeration. Calibration is achieved through an innovative "credit card" type program. Calibration fluids and controls require a small amount of refrigerated storage space.

This unit is capable of performing six individual tests or one "profile" at a time requiring approximately seven minutes per cycle for the parameters tested. A minimal patient sample is needed and operation can be learned during a small amount of training. The instrument can be left unattended during operation

and hard copy results are automatically printed when each cycle is complete.

Minimal damage was sustained during the drop test. This model requires very little maintenance and is user friendly.

Since this unit was purchased and tested, Roche/Baxter has ceased producing and marketing this instrument. Production has been resumed by a new company, Hichem, located in Lincoln, Rhode Island. The unit is now marketed under the name "SPOT CHEM" which requires updated software to utilize new reagents manufactured by Hichem versus reagents used by the COBAS READY. This unit should be investigated as a suitable replacement for the COBAS READY.

VISION

The VISION is heavier and larger than the other units tested, however, it is unique in its operation. It has a self-contained centrifuge and uses a pre-measured reagent pack. No additional reagents are necessary for the operation of this piece of equipment with the exception of controls and calibration fluids which require a small amount of refrigerated storage space. The prepackaged reagent packs also require refrigeration.

This unit is capable of performing up to ten tests (with the exception of prothrombin time) in any test combination with a minimum of patient sample needed. It is precalibrated on installation and does not need to be recalibrated until control lot number changes or the instrument is transported. Calibration was well maintained during testing and it can operate unattended during the cycle.

The VISION requires minimal maintenance and troubleshooting is rarely necessary. If repairs are needed, they are usually facilitated by using an exchange program with the manufacturer. It was noticed during environmental testing that the VISION has limited temperature tolerance. Cold storage was not well tolerated and caused sensor failure. This unit was replaced and testing continued. The VISION is easy to use and can be operated with a small amount of training.

REFLOTRON

The REFLOTRON is a light weight and compact unit which operates with or without the keyboard. Reagents utilize a dry chemical technology in strip form that does not require refrigeration. A minimal patient sample is needed to complete testing. Controls are lyophilized and require refrigeration.

This unit performs one test at a time, requiring approximately three minutes per test strip. Minimal maintenance

is required. Calibration requires only a "CHECK STICK". Storage tests were not completed on this unit.

The REFLOTRON appeared to function slowly. This instrument was not well supported by the company during our testing. It was very difficult for us to obtain reagents. Reflotron's purchasing department's lack of responsiveness made it impossible to complete the last two testing conditions.

KODAK DT 60 II

The DT 60 II is heavier and bulkier than the other instruments in this category. It utilizes three modules, the DT 60 II, DTE, and DTSC, all of which are dependent on the DT 60 II module for operation. It utilizes dry chemistry technology provided in prepackaged, prepared slide format that requires refrigeration. Controls and calibrators require refrigeration and/or freezer space. Recalibration is required when the instrument is unplugged and moved and it has no memory capabilities. Calibration requires approximately 60 minutes to complete for our testing needs.

The DTSC and DTE modules can perform only one test at time, with one in waiting status, while the DT60 II module can analyze three to six samples at a time. Each test requires approximately three minutes. They utilize pre measured electronic and manual pipettes but it was noted that the plastic pipette tips do not stay securely on pipettes and reagents tend to stick on the tip resulting in numerous dispensing errors. The slides do not move smoothly on the tracks, often becoming out of alignment causing the corners of the slides to become caught in the mechanism resulting in numerous error codes and wasted slides. Opening covers to the modules for slide adjustments results in loss of time and causes additional warming of the modules.

This unit does not operate in extreme high or low temperatures, reporting temperature too hot or temperature too low error codes. The printer was damaged during the drop test sequence. Although all modules were operational after this portion of testing, the instrument could not display results. During 160^{o}F storage the DTSC module experienced warping of plastic casing and rubber chain links causing mechanical breakdowns during the testing sequence. The unit overheated at approximately 1000 feet during altitude testing.

NOVA 12 CRT

This analyzer is large and bulky. It requires a prepackaged reagent pack for operation and the control solutions require refrigerated storage space. The NOVA 12 utilizes three membraned ISE electrodes which require frequent replacement. It requires

more maintenance and troubleshooting than other units in this category.

This unit operated in the laboratory under controlled conditions after significant amounts of daily maintenance and repair. It experienced frequent BUN and Glu membrane replacements and reagent flow error requiring time consuming troubleshooting and repair sessions before daily operation could be resumed.

On transport to the environmental testing chambers, this analyzer would not achieve satisfactory calibration and/or ceased to operate completely. It could not be tested under any environmental condition. Repair technicians were present and repairs initiated on four separate occasions during the environmental test period.

ELECTROLYTE ANALYZERS

AVL 986 S

The AVL 986 s is a small, compact and relatively light-weight instrument. Installation and disassembly is uncomplicated. It operates using a single membraned ISE electrode. Liquid reagents are supplied in small prefilled bottles that are readily accessible and easily replaced. Operation is simple and once one is familiar with the software tree, can be performed easily by the average technician. Trouble-shooting is easy to manage and maintenance is simple. Daily electrode maintenance must be performed before routine operations can be started. This usually involves about ten minutes of a technicians attention.

Controls are provided in ampule form and require a minimal amount of refrigerated storage space. Bottled reagents require a small amount of shelf space but are stored at room temperature.

Warping of the plastic cover was noted after heat storage test and the housing cracked after drop test. However, the unit continued to function during both of these tests. This analyzer can be assembled and disassembled in approximately ten to fifteen minutes. Electrodes can be assembled and placed into position in approximately five minutes or less.

This unit is self-calibrating and no manual calibration was required during environmental testing. It would calibrate within one or two cycles after set-up. It is recommended that hinges replace magnets on the front panel because magnets become loose from the housing with continued use.

LYTENING 5

The LYTENING 5 is a small, compact and light-weight instrument. It operates with single membraned ISE electrodes. Replacement of the reference electrode membrane and reference tablets is required every two weeks. Maintenance is simple to perform, however, special attention is required when replacing the reference electrode.

Reagents are supplied in pre-filled bottles that are housed on the outside of the instrument and are easily replaced. Controls are provided in ampule form that requires little storage space. Neither reagents or controls require refrigeration. During temperature condition testing the reagents would change temperature rapidly because of lack of thermal protection, causing the electrodes to have difficulty analyzing samples. A large amount of moisture would collect under the front cover and in the electrode sleeves which could cause malfunctioning. The fluids inside the reference electrode would become very hot and perforate the membrane cap.

After storage at -60^{o}F, the printer ceased to function. This instrument is dependent on the printer for communication and will not analyze samples if the printer is not capable of retrieving results from the system. The printer assembly can be easily replaced by the operator or biomedical repair person.

Few problems resulting in down time were encountered. It is recommended that a cover be placed over the reagent compartment to aid in temperature control if this unit is considered for field use.

CIBA 644

The CIBA 644 is a small, compact, and lightweight instrument with prepared reagent packs housed on the outside of the unit. Controls are furnished in an ampule form that requires a small amount of shelf space. No refrigeration is required. This unit has interchangeable electrodes with no membranes. Electrodes are interchangeable with those from any CIBA analyzer in the 200 or 600 series. Basic maintenance is required only when the reagent pack is changed approximately once weekly depending on usage. This involves approximately ten minutes.

The CIBA 644 is self-calibrating and requires no manual calibrations. Reagents are housed on the outside of the instrument and are unprotected from extreme environmental changes which may cause analytical difficulties because of rapid fluctuations in the temperature of solutions passing through the electrodes. A cover over the reagent compartment could lessen this problem. Troubleshooting and maintenance of the instrument can be accomplished by the average technician.

It was noted that the installation and transportation of the instrument was accomplished with ease over a short period of time. The unit would usually calibrate within one or two cycles after assembly.

URINALYSIS ANALYZER

CLINITEK 100

This unit is lightweight, compact and user friendly. It utilizes dry chemical strips as reagents. The printer had difficulty after sand exposure. Maintenance requirements are minimal and troubleshooting is rarely necessary. It can be operated with minimal instruction and does not require the operators attention during the test cycle.

APPENDIX B

NAMES AND MANUFACTURERS OF

INSTRUMENTS TESTED

Blood Gas Analyzers

Ciba 288 + Ciba 238	Ciba-Corning Diagnostics 63 North Street Medford, MA 02052
Nova Stat 5	Nova Biomedical 200 Prospect Street Waltham, MA 02254-9141
Gemstat	Mallinckrodt Sensor Systems 122 Eisenhower Place Ann Arbor, MI 48108

Coagulation Analyzers

Biotrack 512	Ciba Corning Diagnostics 63 North Street Medfield, MA 02052
Accustasis 2000	Sigma Diagnostics P.O. Box 14508 St. Louis, MO 63178
Coagamate-XM	Organon Teknika 100 Akyo Avenue Durham, NC 27704
Factor VI	Baxter Diagnostics, Inc. 1430 Waukegan Road McGaw Park, IL 60085-6787

Hematology Analyzers

QBC Manual + QBC Autoread	Benton Dickinson, Primary Care Diagnostics 7 Loveton Circle, P.O. Box 370 Sparks, MD 21151-0370
Cell-Dyn 610	Abbott Diagnostics Division 850 Maude Ave Mountain View, CA 94043
Danam HC 510 + HC 820	Danam Electronics 4230 Shilling Way Dallas, TX 75237
CBC 5	Coulter Electronics Corporation 1090 Northchase Parkway Marietta, GA 30067

Chemistry Analyzers

Nova 12 CRT	Nova Biomedical 200 Prospect Street Waltham, MA 02254-9141
Vision	Abbott Diagnostics One Abbott Road Abbott Park, IL 60064-3500
I-Stat	I-Stat Canada, Ltd 436 Hazeldean Road Kanata, Ontario K2L1T9
Cobas Ready	Roche (Baxter Scientific) One Sunset Avenue Monclair, NJ 07042-5199
Reflotron	Boehringer-Mannheim Corporation 9115 Hague Road Indianapolis, IN 46256
DT60 II	Eastman Kodak Company 343 State Street Rochester, NY 14650

Electrolyte Analyzers

Ciba 644	Ciba Corning Diagnostics 63 North Street Medfield, MA 020502
Lytening 5	Baxter Healthcare Corporation Scientific Products Division 1430 Waukegan Road McGaw Park, IL 60085-6787
AVL 986S	AVL Scientific Corporation 33 Mansell Court, P.O. Box 337 Rosewell, GA 30077

Urinalysis Analyzer

Clinitek 100	Miles Laboratories, Inc. Diagnostic Division P.O. Box 3100 Elkhart, IN 46515-3100

APPENDIX C

REFERENCE RANGES FOR CONTROL REAGENTS

CONTROL LEVEL REFERENCE RANGES FOR BLOOD GAS ANALYZERS

	Control Level	pO_2 (mmHg)	pCO_2 (mmHg)	pH (mmHg)
GEMSTAT				
	1	60-98	61-81	6.98-7.08
	2	101-131	35-42	7.33-7.39
	3	143-177	16-24	7.52-7.61
238				
	1	60-70	66.3-76.3	7.129-7.169
	2	97.4-107.4	38.2-48.2	7.391-7.431
	3	135.2-155.2	18.8-22.8	7.606-7.646
288				
	1	53.8-67.8	67.4-77.4	7.137-7.177
	2	95.4-109.4	47.9-41.9	7.394-7.434
	3	141-161	23.7-20.9	7.593-7.633
NOVA STAT 5				
	1	54-66	57.5-67.5	7.108-7.158
	2	96-108	37.1-43.1	7.325-7.375
	3	128-148	17.6-22.6	7.578-7.628

CONTROL LEVEL REFERENCE RANGES FOR COAGULATION ANALYZERS

	Control Level	APTT (seconds)	PT (seconds)	TT (seconds)
Accustasis				
	Low (1)	24-32	11-13	10.5-11.7
	Normal (2)	39-46	18-26	NA*
Coagamate XM				
	Low (1)	18-30	10-13	10.1-12.9
	Normal (2)	26-40	16-21	11.0-13.5
Factor IV				
	Low (1)	53-95	41-73	38-68
	Normal (2)	89-159	85-151	59-105
Biotrack 512				
	Low (1)	50.4-69.9	11.5-13.9	NA*
	Normal (2)	73.6-101.6	18.2-23.6	NA*

* Not available for unit

CONTROL LEVEL REFERENCE RANGES FOR HEMATOLOGY ANALYZERS

	Control Level	HCT (%)	PLT (x 10^3/uL)	WBC (x 10^3/uL)	MCV (fL)	GRAN (x 10^3/uL)	RBC (x 10^6/uL)	HGB (g/dL)
Danam 510								
	1	17.8-21.8	NA*	2.2-3.0	79.0-86.0	NA*	2.25-2.55	6.3-6.9
	2	35.6-40.6	NA*	8.6-9.8	85.7-92.7	NA*	4.09-4.45	12.5-13.3
	3	44.4-51.4	NA*	22.3-25.3	88.1-96.1	NA*	5.00-5.40	15.6-16.8
Danam 820								
	1	18.5-22.5	53-77	2.2-3.0	78.8-85.8	NA*	2.34-2.64	7.2-7.8
	2	33.5-38.5	221-291	8.0-9.2	81.8-88.8	NA*	4.04-4.40	12.3-13.1
	3	43.1-50.1	490-590	20.7-23.9	86.5-94.3	NA*	4.95-5.35	15.4-16.6
QBC Auto								
	1	29.8-34.2	209-375	6.7-12.7	NA*	3.6-7.4	NA*	10.0-11.4
	2	25.5-29.5	73-155	12.0-21.2	NA*	5.4-10.2	NA*	8.7-10.1
Cell-Dyne 610					NA*		NA*	
	1	17.2-20.2	62-80	2.2-2.8	74-78	1.5-2.3		6.3-6.9
	2	34.8-39.8	211-261	8.2-9.2	83-89	4.3-5.3	4.19-4.49	12.7-13.5
	3	44.3-51.3	457-547	20.3-23.3	86-92	7.8-9.8	5.17-5.57	16.5-17.5
CBC-5								
	1	18.5-22.5	NA*	2.5-3.3	79-85	NA*	2.3-2.61	6.6-7.4
	2	35.3-39.3	NA*	7.5-8.7	86-92	NA*	4.04-4.38	12.4-13.4
	3	48.1-53.1	NA*	16.8-19.2	92-100	NA*	5.05-5.49	16.9-18.1
QBC Manual								
	1	25.5-29.9	80-138	9.1-17.6	NA*	5-8.3	NA*	NA*
	2	31.4-36	214-356	21.4-35.6	NA*	5.1-8.5	NA*	NA*

* Not Available

CONTROL LEVEL REFERENCE RANGES FOR CHEMISTRY ANALYZERS

	Control Level	Creat (mg/dl)	Cl (mEq//L)	Na (mEq//L)	K (mEq//L)	BUN (mg/dl)	Glu (mg/dl)
Nova 12							
	1	NA*	80-88	123-129	2.0-2.4	9-15	58-72
	2	NA*	95-103	136-142	3.6-4.0	25-35	98-114
	3	NA*	105-113	152-162	6.0-6.6	50-64	316-366
I-Stat							
	1	NA*	75-81	112-116	5.5-5.9	3-5	186-224
	2	NA*	91-97	130-134	3.5-3.9	8-12	96-108
	3	NA*	104-110	140-144	2.5-2.9	56-72	55-65
Cobas Ready							
	1	0.5-1.0	NA*	NA*	NA*	14-23	66-98
	2	3.6-6.7	NA*	NA*	NA*	48-72	277-415
Reflotron							
	1	NA*	NA*	NA*	NA*	19.3-26.1	102-138
	2	NA*	NA*	NA*	NA*	37.1-50.1	224-302
	3	NA*	NA*	NA*	NA*		
DT60II							
	1	0.7-1.1	75-85	113-123	2.6-3.2	15-21	73-95
	2	5.3-6.3	105-115	133-145	5.4-6.0	46-58	281-323
	3						
Vision							
	1	0.8-1.7	NA*	NA*	3.9-4.3	12.3-16.7	77.0-94.0
	2	5.0-6.7	NA*	NA*	6.8-7.5	41.6-50.9	270-331.0

* Not available

CONTROL LEVEL REFERENCE RANGES FOR ELECTROLYTE ANALYZERS

	Control Level	Cl (mEq//L)	Na (mEq//L)	K (mEq//L)
Lytening-5				
	1	76-82	118-125	1.7-210
	2	99-105	138-144	3.76-4.16
	3	122-128	157-164	6.35-7.25
644				
	1	96-104	111-117	1.73-2.13
	2	121-129	133-139	4.10-4.5
	3	138-146	145-151	6.91-7.31
986S				
	1	73-79	117-123	2.7-3.1
	2	104-110	147-153	4.3-4.7
	3	122-128	167-173	6.0-6.4

APPENDIX D

RESULTS OF CATEGORICAL VARIABLE ANALYSIS

FOR URINALYSIS ANALYZER

URINE BILIRUBIN

	N (number of samples)	Negative	Small
REFERENCE (NAVHOSP)	95	91	4
REFERENCE (MANUAL)	98	96	2
CLINITEK 100	98	90	8

URINE KETONES

	N (number of samples)	Negative	Trace
REFERENCE (NAVHOSP)	95	77	18
REFERENCE (MANUAL)	98	97	1
CLINITEK 100	98	63*	35*

* Denotes statistically significant difference between both reference analyzers

BLOOD IN URINE

	N (# samples)	Large	Medium	Moderate	Negative	Small	Trace
REFERENCE (NAVHOSP)	95	0	0	1	91	1	2
REFERENCE (MANUAL)	98	0	0	2	90	0	6
CLINITEK 100	98	1	1	0	81	7	8

URINE PROTEIN

	N (number of samples)	100 (mg/dl)	30 (mg/dl)	Negative	Trace
REFERENCE (NAVHOSP)	95	1	0	81	13
REFERENCE (MANUAL)	98	1	1	63*	33*
CLINITEK 100	98	1	1	78	18

* Denotes statistically significant difference between both reference analyzers

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1a. REPORT SECURITY CLASSIFICATION UNCLASSIFIED	1b. RESTRICTIVE MARKINGS
2a. SECURITY CLASSIFICATION AUTHORITY	3. DISTRIBUTION/AVAILABILITY OF THE REPORT Approved for public release; distribution unlimited
2b. DECLASSIFICATION/DOWNGRADING SCHEDULE	
4. PERFORMING ORGANIZATION REPORT NUMBER(S) NSMRL Report 1191	5. MONITORING ORGANIZATION REPORT NUMBER(S) NA
6a. NAME OF PERFORMING ORGANIZATION Naval Submarine Medical Research Laboratory 6b. OFFICE SYMBOL *(If Applicable)*	7a. NAME OF MONITORING ORGANIZATION Naval Medical Research and Development Command
6c. ADDRESS *(City, State, Zip Code)* Box 900, Naval Submarine Base NLON, Groton, CT 06349-5900	7b. ADDRESS *(City, State, Zip Code)* 8901 Wisconsin Avenue Bethesda, MD 20889-5606
8a. NAME OF FUNDING/SPONSORING ORGANIZATION Same as 7a 8b. OFFICE SYMBOL *(If Applicable)*	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER
8c. ADDRESS *(City, State, Zip Code)* Same as 7b	10. SOURCE OF FUNDING NUMBERS PROGRAM ELEMENT NO. 63706N; PROJECT NO. M000095; TASK NO. 005; WORK UNIT ACCESSION NO. DN241527
11. TITLE *(Include Security Classification)* Evaluation of field clinical laboratory equipment for Fleet Marine Service	
12. PERSONAL AUTHOR(S) P. L. Perotta, C. Bolecek-Skeggs, E. M. Christ, and D. W. Hobson	
13a. TYPE OF REPORT Interim 13b. TIME COVERED FROM TO	14. DATE OF REPORT *(Year, Month, Day)* 15. PAGE COUNT
16. SUPPLEMENTARY NOTATION	
17. COSATI CODES FIELD / GROUP / SUB-GROUP	18. SUBJECT TERMS *(Continue on reverse if necessary and identify by block number)* Clinical laboratory equipment, Field laboratory

19. ABSTRACT *(Continue on reverse if necessary and identify by block number)*

We evaluated clinical laboratory equipment being considered for purchase by the U.S. Marine Corps. This equipment will provide clinicians with rapid access to laboratory data during deployments. Capabilities were desired in the following areas: hematology, chemistry, coagulation, blood gas analysis and urinalysis. There is concern that severe conditions encountered in the field may affect machine performance.

Analyzers were evaluated under each of the following conditions: ambient temperature range (40oF to 110oF), combined heat/humidity, extreme storage temperatures (-60oF and 160oF), simulated transport (vibration, drop testing), altitude (8500 ft), salt/fog and sand/dust operation. Results are presented separately for each class of analyzer. No singular "winner" or "looser" stood out in any category. In general, instruments had difficulty with warm and cold temperature operation.

This information can be used by Marine Corps personnel involved with providing clinical laboratory equipment to operational forces. Other factors which should be considered include instrument size, storage requirements, ease of use and cost.

20. DISTRIBUTION/AVAILABILITY OF ABSTRACT X UNCLASSIFIED/UNLIMITED __ SAME AS __ DTIC USERS	21. ABSTRACT SECURITY CLASSIFICATION
22a. NAME OF RESPONSIBLE INDIVIDUAL Susan D. Monty, Publications Office	22b. TELEPHONE *(Include Area Code)* (203) 449-3967 22c. OFFICE SYMBOL

DD Form 1473, JUN 86 *Previous editions are obsolete.* S/N 0102-LF-014-6603

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