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Portable Diagnostics Technology Assessment for Space Missions

Part 2: Market Survey

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Executive Summary

A mission to Mars of several years duration requires more demanding standards for all onboard instruments than a 6-month mission to the Moon or the International Space Station. In Part 1, we evaluated generic technologies and suitability to NASA needs. This prior work considered crew safety, device maturity and flightworthiness, resource consumption, and medical value. In Part 2, we continue the study by assessing the current marketplace for reliable Point-of-Care diagnostics.

The ultimate goal of this project is to provide a set of objective analytical tools to suggest efficient strategies for reaching specific medical targets for any given space mission as program needs, technological development, and scientific understanding evolve.

Purpose of This Study

The objectives of this study are to evaluate the commercial market in meeting the existing medical requirements of the most current medical requirements, which is denoted as the Crew Health Care System (CHeCS). The goals of this study are to:

- ***Identify currently available tools*** for point-of-care (POC) diagnostics
- Accumulate data necessary to ***evaluate space worthiness*** (mass, volume, power, supporting hardware, etc.) and future medical needs (a broader spectrum of assays)
- ***Assess the capabilities*** of these devices against CHeCS requirements
- ***Discern gaps*** in which no suitable POC devices yet exist
- ***Identify NASA-specific problem areas*** outside the scope of the manufacturers' interest, such as shelf life as a function of aging or radiation exposure
- ***Suggest suitable partnerships*** for tailoring diagnostics to NASA's need

This study focuses on existing medical requirements and does not include all commonly used medical assays, environmental diagnostics, biodetection, or genetic analysis. However, these can be added as specific requirements are developed.

Background

NASA's unique set of mission requirements for medical diagnostics translates into a different set of selection criteria than those commonly used to evaluate such technologies for terrestrial applications. Of course, for any assay, the fundamental measure of utility is the extent to which it informs medical diagnosis and recommendations. However, concerns such as optimization of system mass, volume, power requirements, astronaut time and safety, and waste generation also become critical in a resource-limited environment. Also, we must predict any issues with fluids handling or other potential design issues in hardware, operation and maintenance in a reduced gravitational environment. Fortunately, there is a rich history of such space system analysis at NASA, as well as documented flight experience.

The fundamental assumption of this study is that NASA will always have a specific set of targeted applications that must be met with limited resources. For efficient resource allocation, wherever possible, NASA should adapt well-tested technology platforms to its needs, rather than innovating new technology platforms.

The project is separated into three studies:

- **Phase I** assessed the suitability of ***generic types of technology platforms*** for particular mission scenarios from a variety of standpoints, including astronaut safety, resource requirements, biohazardous waste generation, design issues, and flight readiness.
- **Phase II** is a market survey of ***commercially available portable diagnostics***, which is then compared against the most current ISS Crew Health Care System (CHeCS) requirements (NASA JSC, 2004).
- **Phase III** will combine the evaluation techniques of Phase I and Phase II to ***evaluate specific, commercially available devices for NASA space missions***. It will identify ***gap areas*** in which scarce development dollars must be applied to adapt or, if necessary, develop diagnostic capabilities. Finally, it will ***recommend efficient strategies*** for meeting NASA's evolving priorities as diagnostic technologies continue their rapid development.

Each phase of the study is accompanied by reconfigurable spreadsheets so that recommendations can be updated as technologies and/or priorities evolve.

Market Analysis Methodology

We have sought to identify all urinalysis and blood analysis point-of-care (POC) devices that might be of interest to NASA for future space missions. Data for this market analysis was obtained from web searches of manufacturers, developers, medical sites, and NASA; company service representatives; trade show exhibits and conference presentations; articles in professional and trade journals; and medical books on clinical diagnostics. This information was catalogued in an Microsoft Excel-based tool described in Appendix A, which mapped each device against the Crew Health Care Standards (CHeCS) in order to rank their compliance with the current medical standards for space medicine. The complete set of data is given in Appendix B, and relevant portions are presented in the next section. The following devices have been investigated for this study:

Urinalysis

- ***Bayer***: Multistix line of products, Uristix, Albustix, Hemacombistix, and the Clinitek 50 reader
- ***Clearview Easy***: Generic pregnancy test
- ***Craig Medical***: URS line of products
- ***Roche***: Chemstrip line of products, Keto-Diabur Test, Diabur Test, and the Urisys 1100 reader

Blood Analysis

- ***Abaxis Picolo***: The Picolo express Chemistry Analyzer supports blood panels for standard blood chemistry, liver, metabolic, lipid, electrolyte and renal function panels
- ***Abbott Point-of-Care***: I-STAT reader and cartridges supporting blood gas, chemistry, coagulation and cardiac marker panels
- ***AccuSport***: Lactate analyzer
- ***Biosite***: Triage Meter Plus reader and cartridges for cardiac and shortness-of-breath panels, BNP, and D-dimer test

- ***ITC***: IRMA TruPoint Blood Analysis System, and its cartridges for blood gas, glucose, H3, H4, and GC panels; Hgb Pro; and ProTime Microcoagulation System
- ***Oxford Biosensors***: Multisense reader
- ***Response Biomedical***: RAMP Clinical Reader and troponin, CK-MB and myoglobin cartridges
- ***Roche Diavant***: Reflotron Plus reader and its associated cartridges; Cardiac Reader System; Accutrend GC; and CoaguChek S System
- ***SpectralDX***: I-Lynx reader and associated biochip cartridges

Bayer's Rapidpoint 405 was not considered for blood analysis, due to its more significant weight, 15.5 kg. For both blood and urine analysis, a final column labeled "Microscopy", supplemented by image analysis, is included for the most promising means of filling in the gaps in the CHeCS requirements, such as white blood cell count.

Urinalysis test strips typically have an active site or sites, consisting of a reagent embedded in a porous matrix. Exposure to urine generates a chemical reaction at the active site that is the basis of detection often through colorimetric or other optical measurement. Most of the blood analyzing devices passively filter out blood cells and move the remaining plasma to reaction chambers through microfluidic transport in a biochip. The biochip may take the form of a cartridge that plugs into a reader device for analysis. Since biochips for commercial use are usually developed in conjunction with a reader device, we will use the words "biochip" and "cartridge" somewhat interchangeably in this report.

Appendix A contains details on the specific devices and their supporting disposable components. We found that many biochips have functionality beyond the Crew Health Care System (CHeCS) requirements shown in Table 1, such as blood gas panels and cardiac panels. We have rated the devices in this survey against the CHeCS requirements specifically, but, in anticipation of evolving medical requirements, the additional tests performed by each system are noted. In future iterations of this study, additional assays can easily be included in the rating scheme. In the subjective considerations, the test time for each series of tests is noted, which is essential information for decisive treatment. Available data on supporting hardware, resource allocation, shelf life, certifications, etc. can also be found in Appendix A. The mass, volume and power resource requirements shown in Appendix A represent the reader devices, and do not reflect the impact of consumables. In particular, the system mass and volume should be considered a bare minimum.

TABLE 1.—ASSAYS REQUIRED BY THE CREW ENVIRONMENTAL HEALTH SPECIFICATIONS (CHeCS)

Urinalysis
specific gravity
pH
eukocytes
nitrites
protein
glucose
ketones
urobilinogen
bilirubin
blood
hemoglobin
urate
pregnancy test

Blood analysis, priority 1
bicarbonate (HCO3)
blood urea nitrogen (BUN)
chloride
creatinine
glucose
hematocrit
platelets
potassium
sodium

Blood analysis, priority 2
white blood cell count
alanine aminotransferase (ALT)
alkaline phosphotase (ALP)
amylase
aspartate aminotransferase (AST)
calcium
creatinine phosphokinase (CPK)
lipase
troponin

We have not evaluated these tests in detail against each other in terms of accuracy, sensitivity, reliability or maturity, although these may be significant issues. Some work in this area has already been done. A study by researchers at NASA Johnson Space Center (JSC) cast doubt on the accuracy of the i-STAT's hematocrit measurement as measured with the EC6+ cartridge, which may be related to its conductometric technique and/or the effect of the anticoagulant (Smith et al., 1997). On the i-STAT, the

hemoglobin reading is derived from the hematocrit, rather than directly measured, which calls into question its validity. Consequently, CARDIOLAB on ISS supplements the i-STAT with a hemoglobinometer and a hematocrit centrifuge (ISLWG, 2004).

We recognize that the choice of a set of diagnostic platforms is not as simple as matching an assay to every CHeCS requirement. Every assay will not be required for every instance of urine or blood analysis during a space mission. The guiding principle must be whether or not this specific information would change treatment or diagnosis in any specific case. If each test is not required for every sample, then different suites of analysis can be developed and prioritized, e.g., coronary or liver panel, or DNA repair capability. The suites can then be analyzed for frequency of use.

To complicate matters further, we must also consider things like device calibration and cleaning, generation of waste, minimization of resources, reconfigurable infrastructure, multifunction capability, and harmonious operation of multiple devices. We must defer comprehensive cost analysis until the requirements move beyond the draft stage and a downselect among the devices is completed. In support of that effort, we recommend that a baseline suite of medical tests be developed that represent the diagnostics prescribed over

(1) A short-term mission to the Moon, and
(2) A longer-term mission to Mars.

Many commercial devices include functionality beyond the CHeCS requirements. We have identified additional assays in Appendix A so that they may easily be included in future iterations of this work, if needed. We have also provided data that can be used to evaluate flight readiness.

Survey of Medical Diagnostics

In general, the devices in this study are in a dipstick or biochip/cartridge format. In either case, the analyte is brought into contact with a reagent, which can affect a signal through an electrochemical or bio-electrochemical response. Often, the signal is manually evaluated through a visually observed color change, but it can also be an automated measurement of reflectance, fluorescence, electronic properties, or image analysis. The two diagnostic modes (manual vs. automatic) offer significant differences in resource allocation and waste generation.

Urinalysis

In Appendix B, the major suppliers of multitest urine analyzer sticks are represented. The Multistix 10SG, Chemstrip 10MD, and URS-10 all have essentially the same assays. These three can meet most of the Crew Health Care Standards requirements. Readers are available for the Multistix and the Chemstrip, but not for the URS strip. The Clinitek 50 reader can read 7 different types of Multistix, which may give more flexibility in developing various panels when compared to Urisys 1100's capability of reading 3 types of Chemstrips. However, both competitors test for the same analytes on their group of dipsticks, and all have the option of being read manually. The Roche line of Chemstrips are preferred because:

- Chemstrips can infer the presence of blood from hemoglobin. The test paper contains organic peroxide, which oxidizes in the presence of hemoglobin and myoglobin. Intact erythrocytes undergo hemolysis on the test paper, and the liberated hemoglobin produces a green dot on the test paper.
- Roche's reader is smaller and lighter in weight.
- Very importantly, Chemstrips are rated with a 2-year shelf life, as opposed to the 1-year shelf life of Multistix and URS. Please see the attached spreadsheet for storage conditions.

Chemstrips come in a variety of assay sets, as shown in Table 2.

TABLE 2.—ASSAYS PERFORMED BY CHEMSTRIPS

Name	SG	pH	LEU	NIT	PRO	GLU	KET	UBG	BIL	BL
Combur 2 Test LN			x	x						
Combur 3 Test		x			x	x				
Combur 3 Test E					x	x				x
Combur 4 Test			x		x	x				x
Combur 4 Test N		x		x	x	x				
Combur 5 Test			x	x	x	x				x
Combur 5 Test D		x		x	x	x				x
Combur 6 Test			x	x	x	x		x		x
Combur 7 Test		x	x	x	x	x	x			x
Combur 9 Test		x	x	x	x	x	x	x	x	x
Combur 10 Test	x	x	x	x	x	x	x	x	x	x

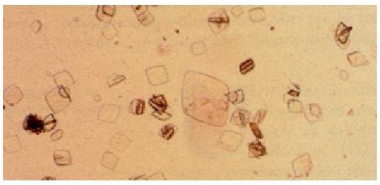


Figure 1.—Uric acid crystals at 100x (after Simerville et al., 2005).

Pregnancy testing for β-HCG is currently available only in stand-alone devices, such as the Clearview Easy. To decrease upmass, the sensor could perhaps be removed from the relatively bulky commercial device and placed in a simpler, custom-designed holder.

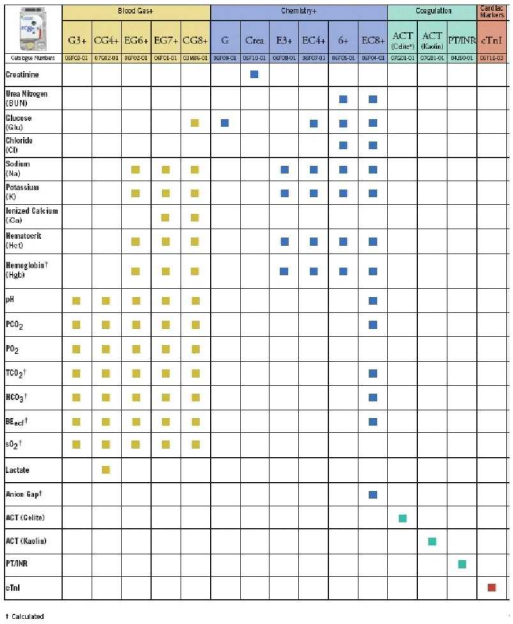
None of the above devices tests for urate. Microscopic evaluation can be more broadly used for identification of cells, crystals, casts and microbial flora and fauna. The capability to detect and identify crystals may provide valuable supporting medical data as well. For example, uric acid crystals may be a more specific indicator of gout than a measurement of uric acid content. (Rosenthal, 2005).

We give the Chemstrips 5, 7, and 10MD an edge, primarily due to its 2-year shelf life. However, this device will have to be supplemented with a pregnancy test and an assay for urate to meet the CheCS requirements.

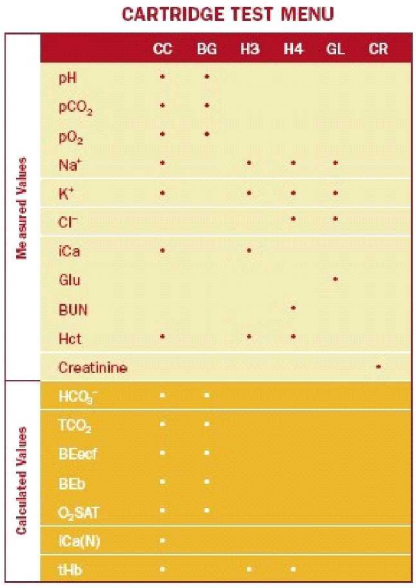
Blood Analysis

Broadest Performers

In terms of all-around versatility, four systems stand out: Abbott's i-STAT, ITC's IRMA TruPoint Blood Analyzer, Roche's Reflotron, and the Picolo express Chemistry Analyzer. (See full data on all systems in Appendix B). Substantial differences appear in comparing these blood analyzer. The i-STAT is by far the lightest and most compact device at about 0.5 kg, while the Picolo is the heaviest at almost 6 kg. Any of 17 diagnostic assays can be performed on the Reflotron Plus within 2 min, but it is the only device that is not multiplexed. Trupoint and i-STAT multiplexed cartridges (Fig. 2) offer efficient use of space, time and reagent consumption. I-STAT's cartridges return data on several assays within 2 min, except for troponin, which requires 10 min (as do the clotting tests for ACT and PT) The TruPoint is similarly fast in processing time, but the Picolo requires 15 min. On the other hand, the Picolo offers an assay for amylase that is not available in any of the other devices surveyed here. The i-STAT most closely matches the CHeCS requirements, in addition to its light and compact design.



(a) i-STAT's assay suite by cartridge type



(b) IRMA's assay suite by cartridge type

Figure 2.—Assay suite for i-STAT and IRMA. Note that many of these cartridges perform multiple assays at once.

Coagulation Panel

If a coagulation panel is desirable, the current status is:

- I-STAT includes several cartridges for single assays in its coagulation panel for ACT/celite, ACT/kaolin, and PT/NR.
- Roche uses a separate POC device, the CoaguChek S system for testing prothrombin time (PT).
- ITC has a separate POC device, the ProTime Microcoagulation System, to measure PT and INR.

Cardiac Markers

The place in which most of the other systems distinguish themselves is in the area of cardiac panels, which typically include troponin as well as other diagnostically significant markers (Bishop et al., 2005; Kaplan et al., 2003), such as CK-MB, myoglobin, BNP (Doust et al., 2004) and D-dimer (Keeling et al., 2005). (CK-MB is an isomer of the enzyme creatinine kinase that is more specific to cardiac muscle.) At this time:

- I-STAT has a single-assay cartridge for troponin.
- Biosite's Triage uses the Triage Meter Plus to read cartridges for troponin, CK-MB, myoglobin, BNP, and D-dimer.
- Response Biomedical's RAMP reader can measure troponin, CK-MB and myoglobin.
- Roche's Cardiac Reader System can detect troponin, myoglobin, D-dimer, and NT-proBNP.
- SpectralDX's i-Lynx measures troponin, CK-MB and myoglobin (note that heparinized blood is required for this test).

Of the top 3 performers listed above, i-STAT is the only system that integrates cardiac markers into its assay suite. However, the other devices listed above have more complete cardiac panels.

The i-STAT, which is currently being used on the International Space Station, is the lightest, most compact and most comprehensive of the blood analyzers in this survey.

Discussion of Results

In this section, we will discuss results obtained in the market survey and provide a brief analysis of operational challenges in spaceflight and technologies that are not yet mature, but should be monitored in a technology watch.

Scope of Assay Suite

No Point-of-Care (POC) device is on the market that performs all of the required assays. However, certain devices are better than others in completeness or specificity with respect to the Crew Health Care System requirements. Several of the diagnostic platforms have already been used successfully on the Shuttle or the International Space Station: Chemstrips, Reflotron blood analyzer, AccuSport lactate analyzer, and the i-STAT (referred to as the Portable Blood Analysis Device, PBAD, in the European CARDIOLab on ISS (ISLWG, 2004), and the Portable Clinical Blood Analyzer, PCBA, in prior space testing, Smith et al., 2004, 1997). Indeed, ***the results of this study indicate that space medicine is already using the most versatile platforms on the market for its specified needs***.

For the future, we expect that the medical requirements in the draft CHeCS document of 2004 will change to reflect the rapidly evolving field of medical diagnostics. We anticipate that the measurement of blood gases will become part of the diagnostic requirements; this is easily accommodated with existing devices, such as the i-STAT.

We also believe that it is reasonable that space medicine will closely monitor the explosive developments in molecular diagnostics (Pray et al., 2005; Tost and Gut, 2005; Marsh and Cardy, 2004; Petricoin et al., 2004; Perez et al., 2004; Semmes, 2004), particularly in light of concerns with respect to radiation damage and bone loss. The emerging understanding that disease can disturb the intricate balance in biological systems through genetic perturbations and/or environmental triggers and/or infectious agents is "beginning to revolutionize medicine" (Hood et al., 2004). Changes in genetic expression have been observed as a function of spaceflight (see, e.g., Semov et al., 2002), although we are far from understanding the key precipitating factors. Unavoidable radiation exposure in the space environment is likely to cause genetic mutations. The medical benefit of genetic identification of microbes and viruses is obvious. For all of these reasons, ***we believe that molecular diagnostics will eventually become a key player in space medicine***.

In areas such as biosensing, proteomics, genetic analysis, and nanomedicine, we also note that there are synergies with astrobiology (NASA astrobiology roadmap, goal 5), environmental monitoring, and NIH research (e.g., Sartor 2004).

Interpretation of Results

Some of the challenges associated with using these devices are a result of the unique experience of living in space. Most of the systems offer reference testing for continuing self-calibration or monitored manual calibration, so that the results are reproducible and consistent. However, the meaning of the actual resulting measurements may not be precisely correlated with that of measurements on earth, due to different methods of sample collection and processing, metabolic variation due to stress, environmental conditions, fluid shift or radiation, and/or aging of the hardware or consumables. To minimize astronaut invasiveness and accompanying issues in wound healing, it is preferable to use a pinprick sample of capillary blood than a venous sample. However, the ranges of quantitative measures of some components of capillary blood are different from that of venous blood, as confimed by space researchers at NASA

Johnson Space Center (JSC) (Smith et al., 1997). Since the test conditions in space are likely to be different from that on earth, the manufacturers themselves cannot offer guidance in interpretation of data for most space applications. Therefore, NASA must assume a leading position in this area in its own self-interest. We will discuss the issues of primary importance later in this document, and address risk mitigation strategy in Phase III.

Other variables include the baseline blood gas concentration in long-duration spaceflight, which will be a function of the gas composition of the environment. The environmental composition is not likely to be earthlike, may not be known at this time, and could change over the duration of a mission. The measurement of gases other than CO_2 and O_2 may be desirable. Concerns include gases that are inadvertently introduced during equipment operation into the closed environment and possibly functional issues in environments with high or low oxygen, or with inert diluents other than nitrogen.

Finally, we note that, for a given test, all assays are not equal. The specific gravity (SG) is measured on test strips to estimate osmolality, which is a measure of osmotically active particles in a volume of urine. However, this technique is notoriously unreliable outside the range of pH = 7 to 7.5. It is profoundly affected by the ionic strength of the urine, and therefore the urine's ionic composition and electrical charge-bearing proteins. Gravitometry measures osmolality directly, but requires time-intensive lab work and may be more challenging in microgravity. Refractometry is another indirect technique for acquiring SG. While it is consistently more accurate than the reagent strip method, it may also behave unlike osmolality when large molecules, such as mannitol, are present (Chadha et al., 2001).

Understanding the limitations of the diagnostics themselves may encourage exploration of alternate (and perhaps more suitable) assays and assay techniques, particularly for long-duration spaceflight.

Storage and Shelf Life

Replenishment of supplies is not a luxury available to long-term spaceflight, although the shelf life of consumables may be adequate for shorter lunar missions. However, devices and consumables must also be evaluated for conditions peculiar to long-term spaceflight, such as radiation exposure and other shelf life issues. (Please see the accompanying spreadsheet for any available manufacturer specification of storage and operating conditions). Many of these systems use magnetic strip encoding to identify the assay type and lot number. Whether or not this could be compromised in a long-duration spaceflight is at this time unknown. No point-of-care (POC) device on the market has yet been tested for shelf life as a function of radiation exposure, and limited data exist with regard to aging.

The least problematic will be urinalysis; many Roche dipsticks remain stable for up to 2 years. In contrast, the shelf life of the consumables for blood analysis in terrestrial applications is typically on the order of a few weeks to, at best, a year for some assays. For long-duration spaceflight using commercial devices, NASA must test the devices and their consumables to push the boundaries of shelf life.

The cartridges for i-STAT, which are based on liquid chemistry, are rated by the manufacturer at 4 to 6 months, when refrigerated at 2 to 8 °C. (The lower bound is dictated by the concern that, for ionized calcium, the calcium in the calibrant fluid will precipitate out of solution.) Smith et al. (2004) studied the stability of the EC6+ cartridge, which measures glucose, blood urea nitrogen (BUN), chloride, sodium, potassium and hematocrit. Refrigerated and re-refrigerated cartridges (6 months at room temperature) were within acceptable limits for all analytes at 12 months. Even cartridges stored at room temperature were stable up to 4 months for all analytes and up to 12 months for glucose, sodium, potassium and hematocrit. These results are encouraging, particularly since 7 of the 15 cartridges in the i-STAT suite perform these assays. Similar testing should be done on other cartridges, particularly for troponin, which, unlike the others, uses an immunoassay. Other untested assays for the i-STAT are creatinine, pH, pCO_2, pO_2, lactate, ACT/celite, ACT/kaolin, and PT/NR.

We have been unable to find other devices for which similar shelf life testing has been undertaken. Shelf life testing is critical, particularly for long-duration space missions. This must include the effects of aging, temperature, and exposure to radiation on consumables and their supporting hardware.

Microgravity Operation

Practical application of medical diagnostics has been established on the Shuttle and on the Space Station. Dipsticks are straightforward in that the body fluid is deposited directly on the reaction substrate. Other, more sophisticated technology platforms fundamentally rely on seamless operation of fluid flow, mixing, filtering and separation, and bioelectrochemistry. These include sample collection, preparation and introduction and cleaning for the environment external to the testing platform. Within the testing platform, there are issues in wetting, multiphase flow, bubble mitigation, and electrokinetic flows. We believe that ***there are still open questions in microgravity operations***, particularly during long-duration space missions.

Other Measurements or Measurement Techniques

Although lactate measurement is not in the medical requirements, it has medical value in exercise testing. AccuSport is specifically made for this measurement and has been used successfully on ISS. The i-STAT cartridge CG4+ also tests for lactate. The Picolo has disposable discs available for liver, lipid and metabolic panels. Like the Oxford Biosensor's Multisense, the Picolo uses dry chemistry, which may be important in extending shelf life to the durations required for spaceflight. .

Noninvasive Technologies on the Horizon

Concern over wound healing in space may also point to a need for using emerging noninvasive technologies. Resource minimization favors those that require no (or few) consumables. These beneficial attributes must be balanced with lower maturity levels. The FDA has approved one noninvasive glucose monitor for diabetes management (although proper calibration remains an issue) based on near-infrared imaging. Near-infrared imaging has also been used to measure hemoglobin concentration (Pogue et al., 2004; Kanashima et al., 2005) and assess cutaneous edema (Elkje et al., 2005). This leads us to suggest that the smaller experience base may be mitigated by unique new capabilities. Ultrasound already holds a substantial role in medical diagnostics (Dalecki, 2004). New uses for it are still being found, e.g., it can detect pulmonary embolisms (Perrier et al., 2004), intracranial pressure (Tsung et al., 2005), cerebral emboli (Mackinnon et al., 2003), and perform drug delivery through the bursting of microbubbles (Tsutsui et al., 2004). Many portable noninvasive technology platforms are still in the research or prototyping stage; however, some space-targeted devices do exist. "Space Goggles", developed through the NASA GRC John Glenn Biomedical Engineering Consortium, use dynamic light scattering and associated techniques to detect blood glucose (Ansari, 2004, 2005). For added benefit, the device also detects diabetic retinopathy, cholesterol levels, macular degeneration, radiation damage, Alzheimer's and environmental toxicity.[1] Noninvasive technologies including ultrasound, near infrared measurements, and Raman light spectroscopy are not yet mature, but should be a prime topic of exploration. Not only does this reduce issues of astronaut health and safety, but it may mitigate problems of shelf life, biohazardous waste generation and resource consumption.

The i-STAT stands out among the other commercial platforms for blood analysis. However, it is not a complete test suite for CHeCS. We have identified the commercial assays that are currently available, as well as those that are not. The data and accompanying suggestions should be medically evaluated for diagnostic value, and can be used to develop the next set of medical requirements.

[1] See http://www.nasa.gov/vision/earth/everydaylife/biomed_eyes.html

Conclusions

This study provides a living tool that can adapt to evolving technology and mission priorities. We expect that there will be additional iterations of this work, as there will be tradeoffs in juggling different sets of priorities in choosing medical and environmental diagnostics for lunar and Martian missions. At this time, we can conclude the following, based on the CHeCS requirements:

- Generally speaking, the space medical community is already using the most versatile tools for urinalysis and blood analysis. However, ***no commercial device yet does it all***, although some come close.
- For long-duration missions, ***testing is vital for quantification of shelf life*** in both urine and blood analysis. Investigations must include aging, radiation exposure, and temperature storage for both the consumables and for the reader devices.
- Another critical component for unreplenished, closed-system, long-duration missions is ***analysis of long-duration microgravity operations***, including sample collection, preparation, and cleaning, wetting, mixing, separations, filtering, multiphase flow, bubble control.
- While they are not ready to use today, new ***advances in noninvasive technologies may be needed, especially in long-term missions, due to shelf life concerns.*** Near-term assays are likely to be available for glucose and hemoglobin concentration. Another benefit of this class of devices is increased safety to astronauts. Finally, these technology platforms may simultaneously offer new strategies for diagnosis and treatment, without the need for a massive development effort.
- **Urinalysis**
  - For lunar missions, a complete set of urinary diagnostics can be obtained with ***Chemstrips, pregnancy tests and microscopy***.
  - For Martian missions, Chemstrips' shelf life is closest to what is needed for urinalysis. However, shelf life in the space environment for multi-year time spans is not clear. Pregnancy tests must be evaluated for stability, and microscopy must supplement the above tests.
- **Blood Analysis**
  - For short-duration missions, the ***i-STAT system*** is the strongest candidate due to its versatility, flight experience and cooperation with JSC, compactness, and continuing development by the manufacturer. It can perform all assays in Priority 1, and 3 of 9 in Priority 2. Gaps are ALT, amylase, AST, CPK, lipase, and white blood cell count. The latter can be measured through microscopy or other methods. For the other assays, the medical necessity should be re-evaluated. ***Other assays identified in this report could be substituted, or development of new assays and/or diagnostic platforms will be required***.
  - For long-duration missions, the i-STAT *may* be adequate for most required assays, but ***requires further testing on shelf life and storage issues in reduced-g space habitation***.
  - ***Noninvasive testing and novel measurement techniques are likely to be necessary*** for long-term missions to preserve crew health, minimize resources, and maximize shelf life.

Recommendations

Measurement of red blood cells, white blood cells, hematocrit and platelets can be achieved through measurement of the fluid electronic properties and/or image analysis from microscopy. We view the latter as more desirable, since: (1) it can be used for analysis of any fluids or tissue; (2) it needs few consumables and causes minimal waste generation; (3) it can also be used to detect casts and crystals, identify microbial invaders, and visualize cell pathology; and (4) it can be a shared resource with other scientific and applied disciplines. We have not addressed the issue of software requirements, however.

Ignoring the potentially damaging effects of radiation and long-term storage, we find the following:

Urinalysis

- ***On shorter lunar missions, Multstix, URS sticks, or Chemstrips will all provide 10 of the 14 medical requirements***. They are available in several permutations if it is unnecessary to perform all assays with every urine sample (see spreadsheet). Abbott's Clinitek 50 and Roche's Urisys 1100 readers provide automation of the Multistix and Chemstsrip assays.
- ***For longer duration flight, Roche's Chemstrip line of products is a decisive winner due to its 2-year shelf life***. However, NASA should develop a plan to partner with Roche to extend the shelf life to a minimum of 3 years. Any of the strips in this product line can be processed in a manual mode, and three of the strips can be processed in an automated fashion with the Urisys 1100 reader. The Chemstrips 5, 7, and 10MD also measure blood and hemoglobin simultaneously.
- ***None of these assay suites include a pregnancy test***, and the single-stick devices are fairly bulky. The sensor could be retrofitted with a smaller holder to conserve resources. However, shelf life remains unknown.

Blood Analysis

For lunar and Mars missions:

- The ***i-STAT has a clear edge over its competitors***, because it has an expanding line of multiplexed cartridges that can feed into a single reader. It also has flight experience. Critically, JSC's evidence supports a lifetime of 12 months for the EC6+ cartridge under refrigeration, in contrast to the manufacturer's recommended 4 months. Testing on other cartridges and assays are crucial. ***For multiyear missions, the primary issues will be shelf life and microgravity operation, and these issues remain largely uncharted***
- ***To round out the panel, microscopy or other tools are needed to measure hematocrit, platelets, and white cell count***. Microscopy can also be used to identify bacteria and fungi as well as cell pathology.

Appendix A.—The Market Survey Tool

In this section, we describe the Excel-based survey tool used for the market survey, which can be reconfigured through modification of the following parameters:

1. Relative importance of each category of testing (urine analysis, blood analysis priorities one and two). The weighting factor is automatically updated upon changing this parameter.
2. Importance of each assay relative to every other one in the category.
3. New tests or substitutions for present tests can be easily accommodated.
4. The assays required by CHeCS (Table 1) are separated into three categories, and each category is comprised of many assays. In this study, the categories of urinalysis and blood analysis, Priority 1, are given equal rating in importance, but blood analysis, Priority 2 is arbitrarily rated as 40 percent less important. Within each category, each assay is considered equally important relative to each other test. However, the scoring can be modified with appropriate input from the medical community. For example, medical needs may dictate that troponin be increased in importance. The cardiac marker could be moved from Priority 2 to Priority 1; it could remain in Priority 2, but be elevated in importance relative to the other assays in Priority 2. Either of these changes could affect the specific device(s) that are specifically recommended for a given space mission.

For blood analysis, alkaline phosphotase (ALP), a Priority 2 analyte for CHeCS, is available in some commercial systems, but alkaline aminotransferase (ALT) is not commonly available. If ALP is sufficient for medical diagnosis, the importance of ALP may remain at a high importance value, but ALT may be downgraded or even eliminated.

These capabilities allow for thoughtful iterative analysis by bouncing the tool among program leads, medical specialists, space device experts and market analysts.

Within the body of the spreadsheet, each specific device is assessed against each medical requirement. The assay is given a score of two if it is commercially available today and a score of one if it is not yet available but could be with some effort.

Some devices do not perform any of the CHeCS assays, and are given a score of zero. However, they have other features that may render them useful in future incarnations of the medical requirements. A category labeled "*Other considerations*" is included for each device under the medical requirements. Of particular interest to the medical community may be the first row, "*other tests*". This includes data on other assays that are included in the system as set up, but not included in the CHeCS requirements.

This commercial survey tool can be used for dynamically changing needs and/or capabilities. Some examples of potential modifications are given. An analysis of this type must be iterative, juggling the needs of medicine, the availability of appropriate, mature technology, and the changing program priorities and resources.

Appendix B.—Market survey of Point-of-Care Diagnostic Devices for Urinalysis and Blood Analysis

Urinalysis

			Bayer								Craig Medical		
Desired attributes	**Importance**	**Weighting factor**	Multistix 10 SG	Multistix 8 SG	Multistix 7	Multistix 5	Multistix SG	Hema-combistix	Uristix 4	Albustix	Clearview Easy	URS-10	URS-K	URS-3
Sample type			urine							urine	urine	urine	urine	urine
Assay type			dipstick (colorimetric, reflectance)							dipstick (colorimetric)	dipstick	dipstick	dipstick	dipstick
Urinalysis	5													
specific gravity	1	0.07	2	2			2					2		
pH	1	0.07	2	2	2		2	2				2		2
leukocytes	1	0.07	2	2	2	2			2			2		
nitrites	1	0.07	2	2	2	2			2			2		
protein	1	0.07	2	2	2	2	2	2	2	2		2		2
glucose	1	0.07	2	2	2	2	2	2	2			2		2
ketones	1	0.07	2	2	2		2					2	2	
urobilinogen	1	0.07	2				2					2		
bilirubin	1	0.07	2				2					2		
blood	1	0.07	2	2	2	2	2	2				2		
hemoglobin	1	0.07												
urate	1	0.07												
erythrocytes	1	0.07												
pregnancy (beta HCG)	1	0.07									2			
category sum	14	1.00												
		Score	**0.7**	**0.6**	**0.5**	**0.4**	**0.6**	**0.3**	**0.3**	**0.1**	**0.1**	**0.7**	**0.1**	**0.2**
Other considerations														
support system requirements			visual or Clinitek 50 reader							none	none	none	none	none
system mass, volume			235x15.2x15.5 mm3, 1.25 kg							minimal	minimal	minimal	minimal	minimal
system power			9V DC batteries (lithium or 6AA) or AC transformer 240V AC							none	none	none	none	none
operating conditions			18 - 30 C, RH=20-85%											
exernal interface			RS-232							none	none	none	none	none
test time			1 minute							1 minute	3 minutes	1 minute	1 minute	1 minute
certifications			CLIA waived											
shelf life			app 1 year							app 1 yr		1 year	1 year	1 year
Comments			upgradeable software for future product development											
ASSAY SCORE			**0.7**	**0.6**	**0.5**	**0.4**	**0.6**	**0.3**	**0.3**	**0.1**	**0.1**	**0.7**	**0.1**	**0.2**
DEVICE SCORE			**0.7**							**0.1**	**0.1**	**0.7**	**0.1**	**0.2**

LEGEND
2=currently available
1=possible

Urinalysis

Desired attributes	Importance	Weighting factor	Roche									
			Chemstrip 10 MD	Chemstrip 7	Chemstrip 5	Chemstrip 9	Chemstrip 6	Chemstrip 5 D	Chemstrip 4 N	Chemstrip 4	Chemstrip 3 E	Chemstrip 3
Sample type			urine			urine	urine	urine	urine	urine	urine	urine
Assay type			diipstick (colorimetric, reflectance)			dipstick (colorimetric)	dipstick (colorimetric)	dipstick (colorimetric)	dipstick (colorimetric)	dipstick (colorimetric)	dipstick (colorimetric)	dipstick (colorimetric)
Urinalysis	**5**											
specific gravity	1	0.07	2									
pH	1	0.07	2	2		2		2	2			2
leukocytes	1	0.07	2	2	2	2	2			2		
nitrites	1	0.07	2	2	2	2	2		2			
protein	1	0.07	2	2	2	2	2	2	2	2	2	2
glucose	1	0.07	2	2	2	2	2	2	2	2	2	2
ketones	1	0.07	2	2		2		2				
urobilinogen	1	0.07	2			2	2					
bilirubin	1	0.07	2			2						
blood	1	0.07	2	2	2	2	2	2		2	2	
hemoglobin	1	0.07				2						
urate	1	0.07										
erythrocytes	1	0.07										
pregnancy (beta HCG)	1	0.07										
category sum	14	1.00										
		Score	**0.7**	**0.5**	**0.4**	**0.7**	**0.4**	**0.4**	**0.3**	**0.3**	**0.2**	**0.2**
Other considerations												
support system requirements			visual or Urisys 1100 reader			none	none	none	none	none	none	none
system mass, volume			150x290x95 mm3, 0.8 kg			minimal	minimal	minimal	minimal	minimal	minimal	minimal
system power			1.3-15W, 120-240V, 50/60 Hz			none	none	none	none	none	none	none
operating conditions			15-32 C, RH=20-90%									
exernal interface			serial			none	none	none	none	none	none	none
test time			70 sec (reader)									
certifications			UL, cUL									
shelf life			2 years			2 years	2 years	2 years	2 years	2 years	2 years	2 years
Comments			blood, hemoglobin from same assay									
ASSAY SCORE			**0.7**	**0.5**	**0.4**	**0.7**	**0.4**	**0.4**	**0.3**	**0.3**	**0.2**	**0.2**
DEVICE SCORE			**0.7**			**0.7**	**0.4**	**0.4**	**0.3**	**0.3**	**0.2**	**0.2**

LEGEND
2=currently available
1=possible

Urinalysis

Desired attributes	Importance	Weighting factor	Chemstrip 2 LN	Keto-diabur Test 5000	Diabur Test 5000	Microscopy
Sample type			urine	urine	urine	blood, tissue, urine
Assay type			dipstick (colorimetric)	dipstick (colorimetric)	dipstick (colorimetric)	microscopy
Urinalysis	**5**					
specific gravity	1	0.07				
pH	1	0.07				
leukocytes	1	0.07	2			1
nitrites	1	0.07	2			
protein	1	0.07				
glucose	1	0.07		2	2	
ketones	1	0.07		2		
urobilinogen	1	0.07				
bilirubin	1	0.07				
blood	1	0.07				
hemoglobin	1	0.07				1
urate	1	0.07				1
erythrocytes	1	0.07				1
pregnancy (beta HCG)	1	0.07				
category sum	14	1.00				
Score			**0.1**	**0.1**	**0.1**	**0.1**
Other considerations						
support system requirements			none	none	none	
system mass, volume			minimal	minimal	minimal	
system power			none	none	none	
operating conditions						
exernal interface			none	none	none	
test time						minutes
certifications						
shelf life			2 years			
Comments						
ASSAY SCORE			**0.1**	**0.1**	**0.1**	**0.1**
DEVICE SCORE			**0.1**	**0.1**	**0.1**	**0.1**

LEGEND
2=currently available
1=possible

Blood analysis

Attribute	Impor-tance	Abaxis: Picolo comprehensive metabolic panel	Abaxis: Picolo liver panel plus	Abbott Point- of-Care: i-STAT blood gas panel	i-STAT chemistry panel	i-STAT coagulation panel	i-STAT cardiac markers	AccuSport/AccuTrend lactate analyzer
Sample type		blood, serum or plasma	blood, serum or plasma	whole capillary or venous blood	whole capillary or venous blood	whole capillary or venous blood	heparinized venous blood	whole capillary or venous blood
Assay type		optical measurements of enzymatic reactions at 9 wavelengths	optical measurements of enzymatic reactions at 9 wavelengths	ion-selective electrode potentiometry, amperometric, conductometric	ion-selective electrode potentiometry, amperometric, conductometric	amperometric	immunoassay (ELISA), (amperometric)	immunoassay (reflectance photometry)
Blood analysis (Priority 1)	5							
bicarbonate (HCO3)	1			2	2			
blood urea nitrogen (BUN)	1	2			2			
chloride	1	2			2			
creatinine	1	2			2			
glucose	1	2		2	2			
hematocrit	1			2	2			
hemoglobin	1			2	2			
platelets	1							
potassium	1	2		2	2			
sodium	1	2		2	2			
category sum	10							
	Score	0.6	0.0	0.6	0.9	0.0	0.0	0.0
Blood analysis (Priority 2)	3							
white blood cell count	1							
alanine aminotransferase (ALT)	1	2	2					
alkaline phosphatase (ALP)	1	2	2				2	
amylase	1		2					
aspartate aminotransferase (AST)	1	2	2					
calcium	1	2		2				
creatine phosphokinase (CPK, CK)	1							
lipase	1							
troponin	1						2	
sum	9							
	Score	0.4	0.4	0.1	0.0	0.0	0.2	0.0
Other considerations								
other tests		ALB, TBIL, tCO, TP	GGT, TBIL,TP	pH, pCO2, pO2, TCO2, BE_ecf, sO2, lactate	pH, pCO2, TCO2, anion gap	ACT/kelite, ACT/kaolin, PT/INR	pH, pCO2, pO2, TCO2, Beecf, SO2, AGP (blood)	lactate
support system requirements		Picolo xpress chemistry analyzer		i-STAT reader				AccuSport reader
system mass/volume		324x152x203mm3, 5.8 kg		64x210x52 mm3, 0.5 kg				115x82x19 mm3, 0.1 kg
system power		100-240V AC, 5-60 Hz; or 15V DC, 5.0A		2 x 9V lithium batteries				3 x 1.5V AAA batteries
operating conditions		15-32 C, RH=0-80%		16-30 C, RH=0-90%, 40-133 kPa				5-31 C
external interface		USB port		infrared transmitter and receiver, LIS/LIH software				serial, 3-pin socket
test time		12 min	12 min	2 minutes	2 minutes	2 minutes	10 min	60 sec
certifications		CLIA waived, moderately complex		FDA, not CLIA waived; moderately complex, ETL-listed				
shelf life		6-18 mo at 2-8C with no exposure to sunlight	6-18 mo at 2-8C with no exposure to sunlight	12 mo refrig, 4-12 mo unrefrigerated	4-6 mo, refrigerated			
Comments		0.1cc sample; other test combinations available on 13 types of reagent disks; most closely matching to CHeCS shown here	sample volume and temperature are measured optically, dry reagents, enzymatic control for each reagent and rotor	space-tested, various test combinations with 5 cartridges (G3+, CG4+, EG6+, EG7+, CG8+); some results are calculated; see text	space-tested, various test combinations with 8 cartridges (G, Crea, E3+, EC4+, 6+, EC8+); some results are calculated; see text	space-tested, various test combinations with 3 cartridges (ACT/celite, ACT/kaolin, PT/INR); see text	space-tested, cartridge cTnI	space-tested
ASSAY SCORE		0.54	0.17	0.42	0.56	0.00	0.08	0.00
SYSTEM SCORE		0.58		0.69				0.00

LEGEND
2=currently available
1=possible

Blood analysis

Attribute	Impor-tance	Biosite Inc: Triage Cardiac Panel	Biosite Inc: Triage BNP	Biosite Inc: Triage Profiler SOB Panel	Biosite Inc: Triage D-Dimer Test	Chempaq XBC	ITC: IRMA TruPoint BG panel	ITC: IRMA TruPoint H3 panel	ITC: IRMA TruPoint GC panel	ITC: IRMA TruPoint H4 panel
Sample type		whole blood	whole blood	whole blood	whole blood	whole capillary or venous blood	capillary blood	capillary blood	capillary blood	capillary blood
Assay type		immunoassay (fluorescence)	immunoassay (fluorescence)	immunoassay (fluorescence)	immunoassay (fluorescence)	impedance measurment, photometry	electrochemical			
Blood analysis (Priority 1)	5									
bicarbonate (HCO3)	1						2			
blood urea nitrogen (BUN)	1									2
chloride	1									2
creatinine	1									
glucose	1									
hematocrit	1					2		2	2	2
hemoglobin	1					2				
platelets	1					2				
potassium	1							2	2	2
sodium	1							2	2	2
category sum	10									
	Score	0.0	0.0	0.0	0.0		0.1	0.3	0.3	0.5
Blood analysis (Priority 2)	3									
white blood cell count	1					2				
alanine aminotransferase (ALT)	1									
alkaline phosphatase (ALP)	1									
amylase	1									
aspartate aminotransferase (AST)	1									
calcium	1							2	2	
creatine phosphokinase (CPK, CK)	1									
lipase	1									
troponin	1	2		2						
sum	9									
	Score	0.1	0.0	0.1	0.0		0.0	0.1	0.1	0.0
Other considerations										
other tests		CK-MB, myoglobin	BNP	CK-MB, myoglobin, troponin, BNP (Shortness Of Breath panel)	D-dimer	monocytes, granulocytes	pH, pCO2, pO2 (calculated: HCO3, TCO2, Beb, Beecf, sO2)	calculated: tHb	pH, pCO2, pO2 (calculated: HCO3, TCO2, Beb, Beecf, sO2, tHb, Ca(7.4))	calculated: Hb
support system requirements		Triage Meter Plus electronic reader				Chempax XBC Reader	IRMA Blood Analyzer			
system mass/volume		21.6x15.9x7 cm3 0.73 kg				300x180x130 mm3, 1.8 kg	282x241x127 mm3, 2.4 kg			
system power		6V DC @1A/4 AA batt				120-240V, 50-60 Hz, 400 mA	7.2V 2A NiH3 batt, AC adapter 100-240V AC, 50-60 Hz			
operating conditions		15-30C, RH=10-85%				18-35 C	37+-1 C, RH=0-80%			
external interface		RS-232				printer	serial RJ-45 9-pin, phone modem, ethernet			
test time		15 minutes				3 min	< 2 min	< 2 min	< 2 min	< 2 min
certifications						510(k) clearance, CLIA waiver in process	UL, cUL, FDA			
shelf life							26 wks	26 wks	12 wks	14 wks
Comments		sensitivity: troponin 0.05 ng/mL; CK-MB 1.00 ng/mL; myoglobin 5.00 ng/mL	sensitivity: BNP 5 pg/mL			reader storage 4-30C, biochip 6 mo at 4-30C, RH=70	store cartridges 15-30 C, reader at 12-30 C			
ASSAY SCORE		0.04	0.00	0.04	0.00		0.06	0.23	0.23	0.31
SYSTEM SCORE		0.04					0.48			

LEGEND
2=currently available
1=possible

Blood analysis

Attribute	Impor-tance	IRMA TruPoint GL panel	Hgb Pro	ProTime Microcoagulation System	Oxford Biosensors Multisense	Response Biomedical RAMP Troponin I Test	RAMP CK-MB Test	RAMP Myoglobin Test
Sample type		capillary blood	whole capillary blood	whole capillary blood	whole capillary blood	whole blood	whole blood	whole blood
Assay type					immunoassay (multiplexed sensor, dry enzyme, microelectrodes)	immunoassay (fluorescence)	immunoassay (fluorescence)	immunoassay (fluorescence)
Blood analysis (Priority 1)	5							
bicarbonate (HCO3)	1							
blood urea nitrogen (BUN)	1							
chloride	1	2						
creatinine	1							
glucose	1	2						
hematocrit	1							
hemoglobin	1		2					
platelets	1							
potassium	1	2						
sodium	1	2						
category sum	10							
Score		0.4	0.1	0.0	0.0	0.0	0.0	0.0
Blood analysis (Priority 2)	3							
white blood cell count	1							
alanine aminotransferase (ALT)	1							
alkaline phosphatase (ALP)	1							
amylase	1							
aspartate aminotransferase (AST)	1							
calcium	1							
creatine phosphokinase (CPK, CK)	1							
lipase	1							
troponin	1					2		
sum	9							
Score		0.0	0.0	0.0	0.0	0.1	0.0	0.0
Other considerations								
other tests				PT, INR	HDL, LDL, triglycerides	CK-MB, myoglobin		
support system requirements			Hgb Pro analyzer	ProTime analyzer	Multisense reader	RAMP Clinical Reader		
system mass/volume						27x25x15 cm3, 2.1 kg		
system power			3V lithium battery			rechargeable battery		
operating conditions								
external interface						RS-232, integrated keyboard		
test time		< 2 min	30 sec			< 15 min	< 15 min	< 15 min
certifications			CLIA-waived			FDA		
shelf life		20 wks						
Comments					no refrigeration required, agreement with Pfizer, not yet extensively tested, new tests under development	sensitivity: 0.03 ng/mL		
ASSAY SCORE		0.25	0.06	0.00	0.00	0.04	0.00	0.00
SYSTEM SCORE			0.06	0.00	0.00	0.04		

LEGEND
2=currently available
1=possible

Blood analysis

Attribute	Impor-tance	Roche Diavant							
		Reflotron Plus Creatinine	Reflotron Plus Glucose	Reflotron Plus Hemoglobin	Reflotron Plus Potassium	Reflotron Plus Urea/BUN	Reflotron Plus Amylase	Reflotron Plus Phosphotase	Reflotron Plus other
Sample type		capillary or venous blood, serum, plasma	capillary or venous blood, serum, plasma	capillary or venous blood, serum, plasma	capillary or venous blood, serum, plasma	capillary or venous blood, serum, plasma	capillary or venous blood, serum, plasma	capillary or venous blood, serum, plasma	capillary or venous blood, serum, plasma
Assay type		immunoassay (reflectance photometry)	immunoassay (reflectance photometry)	immunoassay (reflectance photometry)	immunoassay (reflectance photometry)	immunoassay (reflectance photometry)	immunoassay (reflectance photometry)	immunoassay (reflectance photometry)	immunoassay (reflectance photometry)
Blood analysis (Priority 1)	**5**								
bicarbonate (HCO3)	1								
blood urea nitrogen (BUN)	1					2			
chloride	1								
creatinine	1	2							
glucose	1		2						
hematocrit	1								
hemoglobin	1			2					
platelets	1				2				
potassium	1								
sodium	1								
category sum	10								
Score		0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0
Blood analysis (Priority 2)	**3**								
white blood cell count	1								
alanine aminotransferase (ALT)	1								
alkaline phosphatase (ALP)	1							2	
amylase	1						2		
aspartate aminotransferase (AST)	1								
calcium	1								
creatine phosphokinase (CPK, CK)	1								2
lipase	1								
troponin	1								
sum	8								
Score		0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1
Other considerations									
other tests									cholesterol, GGT, GOT, GPT, HDL, triglycerides, uric acid
support system requirements		Reflotron Plus reader and integrated printer							
system mass/volume		300x350x210 mm3, 5.3 kg							
system power		115-230V AC (+-22%), 47-63 Hz, opt 10-30V DC							
operating conditions		15-34 C, RH max=85%							
external interface		RS-232, 5-pin DIN, DB25 socket							
test time		2-3 min	2-3 min	2-3 min	2-3 min	2-3 min	2-3 min		2-3 min
certifications		CLIA-waived/moderately complex							
shelf life		10-15 months refrigerated							
Comments		magnetic encoding on strips, flight tested, phosphotase not sold in US							single assay tests
ASSAY SCORE		0.06	0.06	0.06	0.06	0.06	0.04	0.04	0.04
SYSTEM SCORE		0.44							

LEGEND
2=currently available
1=possible

Blood analysis

Attribute	Impor-tance	Cardiac Reader System	Accutrend GC	CoaguChek S System	SpectraIDX: i-Lynx Troponin I	SpectraIDX: i-Lynx Myoglobin/Troponin I	SpectraIDX: i-Lynx CK-MB	Microscopy
Sample type		heparinized whole venous blood	whole capillary blood, EDTA blood	capillary or venous whole blood	heparinized whole blood, plasma or serum	heparinized whole blood, plasma or serum	heparinized whole blood, plasma or serum	blood, serum, plasma, tissue, urine
Assay type		immunoassay	immunoassay (reflectance photometry)	immunoassay (reflectance photometry)	immunoassay	immunoassay	immunoassay	microscopy
Blood analysis (Priority 1)	5							
bicarbonate (HCO3)	1							
blood urea nitrogen (BUN)	1							
chloride	1							
creatinine	1							
glucose	1		2					
hematocrit	1							1
hemoglobin	1							1
platelets	1							1
potassium	1							
sodium	1							
category sum	10							
Score		0.0	0.1	0.0	0.0	0.0	0.0	0.2
Blood analysis (Priority 2)	3							
white blood cell count	1							1
alanine aminotransferase (ALT)	1							
alkaline phosphatase (ALP)	1							
amylase	1							
aspartate aminotransferase (AST)	1							
calcium	1							
creatine phosphokinase (CPK, CK)	1							
lipase	1							
troponin	1	2			2			
sum	9							
Score		0.1	0.0	0.0	0.1	0.0	0.0	0.1
Other considerations								
other tests		myoglobin, D-dimer, NT-proBNP	cholesterol (180 sec)	prothrombin time (PT)		myoglobin	CK-MB	
support system requirements		Cardiac reader	Accutrend reader	CoaguChek reader	i-Lynx reader			
system mass/volume		250x200x95mm3, 1.31 kg	115x62x18 mm3, 100g w/o batt	173x125x45 mm3, 0.454 kg (w/batt)				
system power		110-240 V AC, 50-60 Hz, 0.4-0.2 A	3 x 1.5V AAA batteries	4 x 1.5V AAA batteries, AC adapter 90-260V, 48-61 Hz				
operating conditions		18-30C, RH=20-80%	25-65 C(?), RH max=85%	18-32 C, RH=10-85%				
external interface		2 RS-232, integrated keypad	serial, 3-pin connector	RS-232				
test time		8-12 min	12 sec	< 1 min	< 15 min	< 15 min	< 15 min	
certifications		CE, UL, cUL	DIN, VDE, IEC (German)	CLIA-waived/moderately complex				
shelf life				app 2 months				
Comments		storage 2-8 C, magnetic strip encoding, RECALL 1/05	RECALL 7/05	monitor storage -15 - 65 C, RH=10-90%, 700-1060 kPa, AC adapter storage 1-40 C		also have another system for endotoxemia		
ASSAY SCORE		0.04	0.06	0.00	0.04	0.00	0.00	0.11
SYSTEM SCORE		0.04	0.06	0.00	0.04			0.11

LEGEND
2=currently available
1=possible

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
A mission to Mars of several years duration requires more demanding standards for all onboard instruments than a 6-month mission to the Moon or the International Space Station. In Part 1, we evaluated generic technologies and suitability to NASA needs. This prior work considered crew safety, device maturity and flightworthiness, resource consumption, and medical value. In Part 2, we continue the study by assessing the current marketplace for reliable Point-of-Care diagnostics. The ultimate goal of this project is to provide a set of objective analytical tools to suggest efficient strategies for reaching specific medical targets for any given space mission as program needs, technological development, and scientific understanding evolve.

15. SUBJECT TERMS
Aerospace medicine; Diagnosis; Technology assessment; Blood; Chemical analysis; Urinalysis

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