WORKING
PAPER

Determining Access to Care and User Requirements for Diagnostic Tests in Developing Countries

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This is supporting material to Girsoi F, Olmsted SS, Keeler D, et al. Developing and Interpreting Models to Improve Diagnostics in Developing Countries. *Nature*. S1 3-8 (2006)

HEALTH

Preface

This working paper contains technical material supporting the article by Girosi F, Olmsted SS, et al. "Developing and Interpreting Models to Improve Diagnostics in Developing Countries." *Nature*. S1 3-8 (2006). It is intended to be read in conjunction with that article. This supplement includes additional material referred to in the published article. Although this technical supplement in its current form has not been formally peer-reviewed, an earlier version of this paper, which also contained material that appears in the corresponding *Nature* paper, was reviewed by two outside experts and was revised in response to their comments. The work was funded by the Bill & Melinda Gates Foundation to support the Global Health Diagnostics Forum.

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Introduction

In this technical supplement, we present additional material on the logistic regression model used to estimate access to care model in developing countries and the user requirements that were determined for each level of access to care.

Defining Health Care Settings in Developing Countries

Results from the access to care model are reported in Girosi, et al,[1] and shown here in Table 1. Our model describes access to five levels of care: hospital, clinic, community health worker, other, and no care. Each of these categories was assigned to an infrastructure level (no infrastructure, minimal infrastructure, moderate/advanced infrastructure). In reporting the results, we combined community health worker access with other access, because the community health worker numbers are relatively small (generally <1%). This category is reported with no care in the no infrastructure level. Country level results for the access to care model are reported in Appendix A.

A few countries were not modeled because we were unable to obtain data for them (Cuba, Somalia, etc). Argentina was excluded from the model results because the predicted value for urban community health worker access was 75%. One possible explanation for this high value is that Argentina has the lowest rural population density of any country in the model, which might have an influence upon this predicted value.

Access to hospitals in Latin America is substantially higher than in Asia and Africa. This is probably driven by the fact that the population in the 5 most populous countries in Asia (China, India, Indonesia, Pakistan, and Bangladesh) is between 53 and 75% rural and Africa (Nigeria, Ethiopia, Egypt, Democratic Republic of Congo, and South Africa) is between 43 and 85% rural. By contrast, the population for the 5 most populous countries in Latin America (Brazil, Mexico, Colombia, Argentina, and Peru) is between 10 and 26% rural. In general, rural access to hospitals is lower than urban access to hospitals.

Table 1: Access to Care by Infrastructure Category			
Region	Access to no infrastructure (%)	Access to minimal infrastructure (%)	Access to moderate/advanced infrastructure (%)
Africa	25	47	28
Asia	13	29	58
Latin America	5	5	90

Health Facility Capabilities and End User Requirements

We identified the capabilities associated with the infrastructure based health care settings, and some of the user requirements of the personnel who would be performing the test. The methods for defining the infrastructure levels is reported in Girosi, et al.[1] We reprint the health care setting table here (Table 2). We did not complete a market analysis or acceptability study, nor did we consider cost in our analysis.

The Forum technology experts spent time over the course of the project discussing and suggesting key elements of product design that are important to test developers. They identified a list of important requirements that included, as examples, the sample type, training level of users, maintenance required, availability of biomarkers, and sample throughput. Each of these requirements could be different based on the different health care settings. For instance, a test developed for a moderate infrastructure setting could rely on a laboratory technician to perform the test, while a test developed for a minimal infrastructure clinic would have to be performed by a nurse with less technical training.

To identify the differences between the health care settings in different regions of the world, we developed a questionnaire to gather information on health facility capabilities and user requirements. The questionnaire was designed by modifying a user requirements document developed by the Foundation for Innovative New Diagnostics (FIND) as part of their efforts to develop a molecular based diagnostic for tuberculosis. We used the questionnaire in interviews with approximately 20 Forum members with experience in developing countries. The information gathered during these interviews was summarized by region and by setting and then converted into the infrastructure based

Table 2: Health Care Settings as Defined by Infrastructure Categories				
Characteristics	No infrastructure	Minimal infrastructure	Moderate infrastructure	Advanced infrastructure
Examples of locations	In the community or home	Health clinics (Africa); rural health clinics (Asia and Latin America)	Hospitals (Africa); urban health clinics (Asia and Latin America)	Hospitals (Latin America and Asia)
Electricity	Not available	Not reliably available	Available	Available
Clean water	Not available	Not reliably available	Available	Available
Physical infrastructure	None	No laboratory	Poorly-equipped laboratories	Well-equipped laboratories
Staff	No expertise	Some nurses	Nurses, some physicians, poorly trained technicians	Nurses, physicians, well trained technicians

setting categories. These summaries were then sent to all of the Forum members who were given the opportunity to provide additional feedback.

The complete set of facility capabilities and user requirements are presented in Appendix B. Here we summarize some of the highlights. For each infrastructure category, the capabilities of that setting and the user requirements should be considered the lowest common denominator. For instance, while some hospitals in developing countries have the capability to perform culture testing for TB or PCR testing for sexually transmitted infections, the vast majority of them do not. Similarly, for the no infrastructure category, we have tried to describe what a test developed for use in the home by a family member should look like, even though a community health worker with some training could perform a more complex test. In assigning capabilities to each setting, we are describing the typical, or common, example, not the exemplary example. In addition, for the advanced and moderate category, we describe the capabilities and

requirements of the moderate settings, understanding that advanced infrastructure settings will have at least those characteristics.

The moderate and advanced infrastructure category includes hospitals across all the countries modeled, as well as urban clinics in Asia and Latin America. These settings tend to have good infrastructure, including reliable electricity often with back up generators and good sources of water. They are staffed by physicians and well trained nurses and all have some type of laboratory facility with a laboratory technician. However, the hospitals in Asia and Latin America are much more advanced in terms of technologies and laboratory capacity than the hospitals in Africa.

The minimal infrastructure category includes clinics in Africa and rural clinics in Asia and Latin America. The major distinction from the moderate and advanced category is that they are less likely to have reliable electricity or water and they are unlikely to have actual laboratories with laboratory technicians. Staff at these facilities tends to be minimally-trained nurses. In some cases, there might be a physician who comes to the clinic on a rotating basis, once a week or once a month, for instance.

Finally, the no infrastructure category captures people who treat themselves or their children. This includes both self treatment and treatment by community health workers or traditional healers. This is the hardest category to characterize, since where the test will be performed and by whom can vary so greatly from a pharmacist or community health worker with some training to a drug peddler or family member with no training.

Many of the requirements are similar across the three categories of sites. In all cases, we recommend that test equipment be designed so that it is fully automated and self-contained. In addition, any test equipment would need to have minimal maintenance requirements. Especially in some of the less developed countries, labs often have pieces of broken equipment with no service contract and no way to repair the equipment. In Africa, there is a dearth of trained personnel who are qualified to service lab equipment.

There are a number of other health care setting characteristics in developing countries that are different from the developed world. Across all three infrastructure categories, even at the moderate infrastructure level, there is a lack of understanding and

compliance with biosafety standards. We recommend that tests be developed that minimize the waste processing required of the test equipment and waste products. In addition, given the high prevalence of HIV in many of these areas, and cost-saving pressures, sample collection devices should ideally be self contained and packaged such that they cannot be reused.

In general, tests that minimize the number of steps required by the user including minimizing the number of external reagents that need to be added to the system are preferred. Across the infrastructure categories there was a lack of ability to properly calibrate a piece of equipment or run controls. In many cases, this is due to a lack of reagents at a site, and a lack of ability to replace consumed reagents, because of poor management, supply chains, and resources. It is also recommended that tests minimize the amount of sample preparation required before it is placed into a test device. For instance, ideal tests would be fully self contained, such that when you open the package, it includes the collection device, the test device or cartridge, any external reagents/controls either built directly into the device or in single use packaging. Auxiliary equipment available in minimal infrastructure settings is limited to simple rotators and microscopes. Slightly more auxiliary equipment is available in moderate and advanced infrastructure settings, including water baths and balances. However, items such as precision pipettes are not found consistently in any of the settings. Outside of tests for the advanced infrastructure category, test manufacturers should minimize the need for any auxiliary equipment.

Test throughput will vary significantly by health care setting as well as by disease of interest. There are three variables that influence throughput: how many samples are tested in a day, how the samples are tested, and how fast the results are required. At the no infrastructure level, tests need to be performed on an individual basis, whether they are performed at a pharmacy, by drug sellers in the market place or by community health workers during home visits. Results from these tests will need to be available almost immediately (within 15 minutes). In minimal infrastructure settings, the number of tests may vary. Often there will be approximately 4-10 tests in a given day for a specific disease, but for cases like malaria during the high transmission season, minimal infrastructure settings could see more than 25 cases in a day. These tests can either be

performed individually immediately, or performed in small batches. In either case, results should be available in 2-3 hours, although less than 1 hour would be preferred[a]. At moderate and advanced infrastructure sites, samples can also be tested on site in small batches, with the same requirement for results in 2-3 hours. In these cases, more samples can be expected for each disease (>25/day). For the non acute diseases, such as TB and pediatric HIV, samples could be done in large batches off site (both at minimal and moderate/advanced infrastructure sites), although this is not recommended since scheduling return visits by the patient creates a potential barrier to follow-up care.

The power requirements for tests also vary by infrastructure level. A test for the no infrastructure category should require no power, although a community health worker could possibly use a battery powered test. At minimal infrastructure settings, test devices could be battery (disposable, rechargeable, or car battery) operated, operated by solar power, or require no power. While moderate and advanced settings have reliable electricity, they could also use tests with battery or no power requirements. However, any power requirements, especially at minimal infrastructure sites, have limitations. Disposable batteries, if a standard size, tend to be pilfered to run other devices (flashlights, etc). Rechargeable batteries require a method for recharging. Solar panels require some maintenance. Given these considerations, developing a test that requires no power is preferred at many settings.

Storage of tests can be a critical issue in many of the settings described. For no and minimal infrastructure settings, tests should be packaged so that they are stable for at least 6 months after arriving in country at 40°C and 70% humidity. At advanced infrastructure settings, the tests can be stored in a refrigerator, so the temperature requirement drops to 4°C. However, in all cases, the tests should also be able to withstand transportation stresses of 48 hours at 50°C. In some countries most in need of improved diagnostics, items can be held up in customs for a long period of time, often as long as 3 months or more. While it would be ideal to develop tests that can withstand

[a] Our questionnaire used <15 minutes, <1 hour, 2-3 hours, and 2-3 days as choices for the time till a result is available. In most cases, <1 hour was preferred, although the experts were willing to accept 2-3 hours. In determining recommendations reported in the Nature Supplement, based on additional feedback from Forum members, for most tests we chose to recommend <2 hours as the time until results should be available.

higher heat and humidity (50°C and 100% humidity) for that period of time, technological barriers to maintaining biological materials stable for long periods of time restrict this as an option. These situations indicate a systems problem, which needs to be solved at the government or non-governmental organization level, not necessarily in development of the test.

Another important feature for a potential diagnostic test is the sample type. This varies greatly by disease and by biomarker. However, we have summarized the type of samples that each health care setting can potentially handle. In some cases, these are samples that are currently being collected at a given setting, and in some cases, they are samples that should be within the technological capabilities of the person collecting the sample. In all settings, finger prick blood samples are acceptable. In almost all cases, this is preferred to collecting venous blood, due to the lack of training in many sites for phlebotomy, as well as cultural issues with collecting a large amount of blood and, finally, because the high risk of HIV transmission associated with using needles. In fact, finger prick collection devices that are built into the test and are not able to be reused is ideal. For the complete list of potential sample types, see Appendix B.

For advanced infrastructure based tests, many of the staff performing the test would be able to speak and understand English, French or Spanish, and might be able to read these languages. At the minimal and no infrastructure settings, understanding of these three languages cannot be assumed nor can a standard level of education and training. Our recommendation is that test instructions be provided through a set of easy-to-comprehend, culturally appropriate pictures or drawings, to improve comprehension of the test requirements. Providing the instructions in the local language(s) is also useful.

Summary

We characterized the different health care settings found in developing countries in terms of basic infrastructure characteristics (availability of water, electricity, trained staff, and physical location). We then categorized the different settings into a few infrastructure categories to minimize the number of different types of diagnostic tests that might be required. Using access-to-care data from international surveys in developing countries, we modeled access-to-care throughout the regions that were modeled. Finally, we identified a set of health care setting capabilities and user requirements that diagnostic technology developers can use to produce appropriate tests for a given setting. Using all of this data, we are able to determine the health benefit of a given diagnostic test developed for a specific type of health care setting (see Nature S1, 2006). These tools should be of interest to policy makers, test developers, and funders, in an effort to reduce the burden of disease in developing countries.

References:

1. Girosi F, et al. Developing and Interpreting Models to Improve Diagnostics in Developing Countries. *Nature*. S1 3-8 (2006)

Appendix A: Results of access to care model at the country level								
Country	Region	Population (2004)	Rural Clinic	Rural Hospital	Rural Other	Urban Clinic	Urban Hospital	Urban Other
Armenia	Asia	3.05E+06	19.0	21.3	8.2	17.4	31.6	2.6
Azerbaijan	Asia	8.28E+06	17.6	12.9	47.0	11.9	8.8	1.8
Bahrain	Asia	7.25E+05	0.4	0.4	1.7	0.4	47.9	49.1
Bangladesh	Asia	1.40E+08	23.9	29.4	24.9	4.7	13.5	3.5
Bhutan	Asia	8.96E+05	48.1	4.7	34.3	10.5	1.8	0.5
Cambodia	Asia	1.36E+07	52.1	20.3	8.6	13.1	5.3	0.6
China	Asia	1.30E+09	24.8	36.9	5.2	9.2	22.4	1.5
Cyprus	Asia	7.76E+05	0.0	13.9	0.0	0.0	86.1	0.0
Georgia	Asia	4.52E+06	18.0	13.8	44.8	12.2	8.6	2.7
India	Asia	1.08E+09	29.6	26.6	13.1	8.8	19.5	2.4
Indonesia	Asia	2.18E+08	47.4	4.7	6.2	31.4	9.4	0.9
Iran	Asia	6.69E+07	27.3	7.3	0.2	29.7	34.6	0.8
Jordan	Asia	5.44E+06	0.3	36.5	0.0	0.2	62.7	0.2
Kazakhstan	Asia	1.50E+07	22.2	5.9	39.8	23.2	6.6	2.3
Kuwait	Asia	2.46E+06	2.9	0.0	0.0	79.6	0.0	17.5
Kyrgyzstan	Asia	5.10E+06	27.5	17.1	39.2	10.8	4.3	1.2
Lao PDR	Asia	5.79E+06	13.4	7.7	73.3	3.8	1.1	0.6
Lebanon	Asia	4.55E+06	0.0	63.3	0.0	0.0	36.7	0.0
Malaysia	Asia	2.52E+07	32.6	1.3	2.4	51.9	9.5	2.4
Mongolia	Asia	2.51E+06	22.9	23.9	15.4	18.0	17.9	1.8
Nepal	Asia	2.52E+07	44.8	14.4	27.6	9.7	2.8	0.8
Oman	Asia	2.66E+06	10.5	0.1	27.7	37.7	1.5	22.4
Pakistan	Asia	1.52E+08	49.1	7.4	12.1	21.8	8.7	0.9
Philippines	Asia	8.30E+07	24.0	8.7	11.1	23.0	30.5	2.7
Saudi Arabia	Asia	2.32E+07	12.9	0.0	0.2	78.8	3.7	4.3
Singapore	Asia	4.34E+06	1.3	0.0	0.1	45.1	0.1	53.4
Sri Lanka	Asia	1.94E+07	4.2	34.8	44.1	0.6	8.6	7.7
Syrian Arab Republic	Asia	1.78E+07	38.4	13.7	3.3	26.6	16.9	1.2
Tajikistan	Asia	6.43E+06	53.4	11.8	15.1	14.9	3.8	1.0
Thailand	Asia	6.24E+07	51.4	4.8	9.9	27.3	5.7	0.8
Turkey	Asia	7.17E+07	23.4	9.4	0.1	25.5	39.8	1.7
Turkmenistan	Asia	4.93E+06	13.0	51.7	2.0	5.5	26.8	1.1
United Arab Emirates	Asia	4.28E+06	1.6	0.0	0.1	9.9	1.2	87.2
Uzbekistan	Asia	2.59E+07	32.3	15.9	30.2	13.5	6.7	1.5
Vietnam	Asia	8.22E+07	20.0	34.2	24.0	4.6	14.0	3.3
Yemen, Rep.	Asia	1.98E+07	20.9	26.3	38.0	5.2	7.2	2.4

Appendix A: continued

Country	Region	Population (2004)	Rural Clinic	Rural Hospital	Rural Other	Urban Clinic	Urban Hospital	Urban Other
Algeria	Africa	3.24E+07	8.7	11.1	41.6	7.3	21.8	9.6
Angola	Africa	1.40E+07	38.1	10.3	24.8	15.3	9.0	2.5
Benin	Africa	6.89E+06	33.2	10.3	25.2	17.9	10.4	2.9
Botswana	Africa	1.73E+06	37.6	5.8	2.1	25.4	28.0	1.1
Burkina Faso	Africa	1.24E+07	59.0	5.5	17.4	14.0	3.2	0.9
Burundi	Africa	7.34E+06	2.5	2.8	93.7	0.4	0.2	0.4
Cameroon	Africa	1.64E+07	34.9	8.9	11.3	23.2	18.6	3.1
Cape Verde	Africa	4.81E+05	24.9	11.3	3.3	14.6	43.4	2.5
Central African Rep	Africa	3.95E+06	12.1	5.5	72.5	6.5	2.0	1.5
Chad	Africa	8.82E+06	8.2	4.4	83.4	2.5	0.7	0.8
Comoros	Africa	6.14E+05	41.3	8.8	21.1	14.6	11.0	3.2
Congo, Dem. Rep.	Africa	5.48E+07	46.9	9.4	22.0	14.5	5.6	1.6
Congo, Rep.	Africa	3.85E+06	22.9	6.5	39.2	13.4	12.5	5.5
Cote d'Ivoire	Africa	1.71E+07	27.5	21.4	6.2	11.6	29.6	3.7
Djibouti	Africa	7.16E+05	0.0	0.6	0.0	0.0	0.2	99.3
Egypt	Africa	6.87E+07	6.1	29.6	23.7	1.5	30.0	9.1
Equatorial Guinea	Africa	5.06E+05	3.9	0.0	88.9	6.9	0.0	0.2
Eritrea	Africa	4.48E+06	41.8	13.2	30.2	8.1	4.8	1.8
Ethiopia	Africa	7.00E+07	40.0	9.4	39.7	7.4	2.4	1.1
Gabon	Africa	1.37E+06	22.6	0.8	0.6	54.9	19.8	1.2
Gambia, The	Africa	1.45E+06	45.4	10.8	25.0	12.1	5.1	1.5
Ghana	Africa	2.11E+07	43.9	9.0	10.4	22.4	12.4	2.0
Guinea	Africa	8.07E+06	33.9	16.7	22.6	10.7	12.4	3.7
Guinea-Bissau	Africa	1.53E+06	44.6	9.2	23.3	16.2	5.3	1.4
Kenya	Africa	3.24E+07	42.4	12.1	13.8	16.8	12.4	2.4
Lesotho	Africa	1.81E+06	46.6	11.0	26.6	9.6	4.6	1.5
Liberia	Africa	3.45E+06	23.3	9.8	46.0	11.9	6.1	2.9
Madagascar	Africa	1.73E+07	34.1	6.8	44.7	9.9	3.1	1.4
Malawi	Africa	1.12E+07	54.7	10.3	19.7	10.8	3.5	0.9
Mali	Africa	1.19E+07	53.0	5.8	14.4	20.2	5.4	1.2
Mauritania	Africa	2.91E+06	15.4	5.8	57.0	15.1	4.4	2.4
Mauritius	Africa	1.23E+06	37.6	0.3	22.9	30.9	2.8	5.6
Morocco	Africa	3.06E+07	21.2	11.7	20.6	16.9	24.1	5.5
Mozambique	Africa	1.91E+07	52.0	5.9	13.7	21.4	5.8	1.2
Namibia	Africa	2.03E+06	50.1	13.5	4.1	17.4	13.8	1.1
Niger	Africa	1.21E+07	7.0	2.6	87.7	2.0	0.3	0.4
Nigeria	Africa	1.40E+08	40.3	9.6	13.0	21.8	13.0	2.2
Rwanda	Africa	8.41E+06	45.3	11.2	27.7	9.2	4.8	1.7
Sao Tome & Principe	Africa	1.61E+05	9.0	49.1	3.8	1.6	31.3	5.2
Senegal	Africa	1.05E+07	38.3	9.3	8.4	22.6	18.7	2.6
Sierra Leone	Africa	5.44E+06	40.4	10.1	23.6	15.2	8.3	2.4
South Africa	Africa	4.56E+07	8.8	17.9	0.2	4.3	68.3	0.4
Sudan	Africa	3.44E+07	55.5	3.4	7.3	27.5	5.1	1.2
Swaziland	Africa	1.12E+06	56.7	11.2	7.4	13.3	10.2	1.1
Tanzania	Africa	3.66E+07	48.8	9.3	14.7	16.9	8.4	1.9
Togo	Africa	4.97E+06	6.9	62.0	0.3	1.4	28.7	0.7
Tunisia	Africa	1.00E+07	8.8	18.5	1.3	6.7	61.9	2.8
Uganda	Africa	2.59E+07	50.2	11.1	26.1	8.6	3.0	1.0
Zambia	Africa	1.05E+07	54.9	5.5	9.7	23.4	5.6	1.0
Zimbabwe	Africa	1.32E+07	3.5	62.3	0.2	0.5	33.3	0.3

Appendix A: continued

Country	Region	Population (2004)	Rural Clinic	Rural Hospital	Rural Other	Urban Clinic	Urban Hospital	Urban Other
Bahamas, The	Latin America	3.20E+05	0.0	5.6	0.0	0.0	94.4	0.0
Barbados	Latin America	2.72E+05	0.0	31.3	0.0	0.0	68.7	0.0
Belize	Latin America	2.83E+05	25.4	18.0	4.8	13.9	33.8	4.1
Bolivia	Latin America	8.99E+06	15.5	16.1	6.8	12.4	43.9	5.3
Brazil	Latin America	1.79E+08	2.6	12.4	0.1	3.1	80.1	1.7
Chile	Latin America	1.60E+07	6.9	4.1	1.2	14.4	68.9	4.6
Colombia	Latin America	4.53E+07	0.6	23.6	0.2	0.4	73.7	1.5
Costa Rica	Latin America	4.06E+06	0.0	55.6	0.0	0.0	44.4	0.0
Dominican Republic	Latin America	8.86E+06	3.9	31.4	0.4	1.8	61.0	1.5
Ecuador	Latin America	1.32E+07	8.5	23.8	1.9	5.1	57.3	3.3
El Salvador	Latin America	6.66E+06	0.7	34.7	0.1	0.2	63.8	0.5
Guatemala	Latin America	1.26E+07	15.7	25.1	6.9	6.0	42.1	4.1
Guyana	Latin America	7.72E+05	46.6	8.6	12.2	19.7	10.4	2.5
Haiti	Latin America	8.59E+06	29.4	19.5	26.5	9.2	11.5	4.0
Honduras	Latin America	7.14E+06	11.1	31.3	21.2	4.4	24.5	7.5
Jamaica	Latin America	2.66E+06	2.6	32.5	1.5	0.8	61.0	1.6
Mexico	Latin America	1.04E+08	0.1	12.6	0.0	0.1	87.1	0.1
Nicaragua	Latin America	5.60E+06	10.7	31.7	7.7	6.0	39.2	4.6
Panama	Latin America	3.03E+06	0.0	50.8	0.0	0.0	49.1	0.0
Paraguay	Latin America	5.78E+06	21.6	17.3	4.8	14.4	38.4	3.4
Peru	Latin America	2.75E+07	19.8	7.0	8.2	26.4	33.5	5.3
St. Lucia	Latin America	1.64E+05	0.0	87.3	0.0	0.0	11.8	0.9
Suriname	Latin America	4.43E+05	0.9	12.3	0.2	0.6	85.6	0.3
Trinidad & Tobago	Latin America	1.32E+06	18.9	0.0	4.6	65.1	1.7	9.6
Uruguay	Latin America	3.40E+06	0.0	8.9	0.0	0.0	90.8	0.2
Venezuela	Latin America	2.61E+07	14.0	2.1	1.5	33.9	39.3	9.3

Notes: Shaded countries are the countries on which the model is based.

Appendix B: User Requirements and Capabilities				
Feature/ Question	**No Infrastructure** Point of Care/Decision Tests (Community Health Worker, Pharmacist, Family member)	**Minimal Infrastructure** Clinics (Africa, Rural Latin America and Asia)	**Moderate to Advanced Infrastructure** Urban Clinics (Asia, Latin America); Hospitals	**Comments**
1. **Sample type** What are acceptable samples for the given health care setting? Assume person collecting the sample and performing the test in No Infrastructure has no training, Minimal is a minimally trained nurse, mod/adv is a nurse, lab technician, or physician.	✓ Finger prick blood ✓ Dried blood spot ✓ Saliva ✓ Stool ✓ Sweat ✓ Nasal Swabs ✓ Urine ✓ Vaginal swabs ✓ Breath	✓ Finger prick blood ✓ Dried blood spot ✓ Saliva ✓ Stool ✓ Sweat ✓ Nasal Swabs ✓ Urine ✓ Vaginal swabs ✓ Breath ✓ Sputum ✓ Urethral swabs	✓ Finger prick blood ✓ Dried blood spot ✓ Saliva ✓ Stool ✓ Sweat ✓ Nasal Swabs ✓ Urine ✓ Vaginal swabs ✓ Breath ✓ Sputum ✓ Urethral swabs ✓ Pleural Fluid ✓ Endocervical swab ✓ Venous blood	Finger prick blood preferred in all settings in Africa. Experts did not identify breath or sweat, but the simplicity of the samples should rule them in.
2. **# of Samples** How many samples can be expected to be processed in a day for your disease? (What is the demand)	✓ 0-3 ✓ 4-10	✓ 4-10 ✓ 10-25 ✓ >25 (malaria)	✓ >25	
3. **Throughput** What are the acceptable ways to process samples for your disease (current standard or what would be acceptable to patients at each setting)?	✓ Samples tested individually ✓ Samples tested almost immediately in small batches	✓ Samples tested individually ✓ Samples tested almost immediately in small batches ✓ Samples tested in large batches off site (maybe, for HIV, other non acute disesase)	✓ Samples tested individually ✓ Samples tested almost immediately in small batches ✓ Samples tested in large batches on site ✓ Samples tested in large batches off site	Samples tested on site, with no requirement for a return visit is the preference for all diseases and settings.
4. **Time-to-result** What is the max acceptable time till a result is available?	✓ < 15 minutes ✓ < 1 hour	✓ < 15 minutes ✓ < 1 hour ✓ 2-3 hours	✓ < 15 minutes ✓ < 1 hour ✓ 2-3 hours ✓ 2-3 days (not preferred)	

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5. Power What types of power do each site have or are capable of using? (Include what the site currently can do, & what would be reasonable)	✓ No power required ✓ Disposable Battery ✓ Rechargeable Battery	✓ No power req'd (preferred) ✓ Disposable Battery ✓ Rechargeable Battery ✓ Car Battery (mobile clinic) ✓ Solar powered	✓ No power req'd ✓ Disposable Battery ✓ Rechargeable Battery ✓ Car Battery ✓ Solar powered ✓ Electricity req'd (115/220 V)	
6. Test stability / storage What are the current long term storage requirements for a test at each site and in transport?	✓ Storage at 40°C, 70% humidity for 6 months (minimum) ✓ Transport stress (48h at 50°C)	✓ Storage at 40°C, 70% humidity for 6 months (minimum) ✓ Transport stress (48h at 50°C)	✓ Storage at 4°C for 6 months (minimum) ✓ Transport stress (48h at 50°C)	
7. Sample preparation What type of sample preparation can be performed?	✓ No preparation before placing sample into test device	✓ No preparation before placing sample into test device ✓ Simple 1-2 step procedure (<30 minutes)	✓ No preparation before placing sample into test device ✓ Simple 1-2 step procedure (<30 minutes) ✓ Complex procedure with centrifugation (1-2 hours)	
8. Biosafety What type of biosafety capabilities do the sites have?	✓ No biosafety equipment or sterilization capabilities ✓ Consumables should be able to be discarded as routine waste without further treatment	✓ No biosafety cabinet ✓ Boiling or bleach sterilization	✓ No biosafety cabinet ✓ Autoclave or boiling sterilization	

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9. Test and Auxiliary equipment What type of equipment can the sites use or do they have?	✓ Only sample collection device ✓ Test equipment self contained or fully automated.	✓ Only sample collection device ✓ Test equipment self contained or fully automated. ✓ Only robust equipment with minimal maintenance needs (>3 months between service events). ✓ More complex equipment: o Centrifuge o Microscope	✓ Only sample collection device ✓ Test equipment self contained or fully automated. ✓ Only robust equipment with minimal maintenance needs (>3 months between service events). ✓ More complex equipment: o Balance (non electronic) o Centrifuge o Microscope o Refrigerator o Water bath	
10. Sample identification	✓ Manual worksheet	✓ Manual worksheet	✓ Manual worksheet	
11. Instrument design	✓ Handheld ✓ Operates at 35°C	✓ Handheld ✓ Benchtop (<50kg) ✓ Operates at 35°C	✓ Handheld ✓ Benchtop (<50kg) ✓ Operates at 35°C	
12. Controls	✓ Internal reagent control (no separate procedure)	✓ Internal reagent control (no separate procedure)	✓ Internal reagent control (no separate procedure)	
13. Water Is clean water always available?	✓ No	✓ No	✓ Clean water available	

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14. System design What kind of test systems can each site handle?	✓ Closed system requires only addition of sample aliquot	✓ Closed system requires only addition of sample aliquot ✓ Closed system that requires only addition of sample aliquot to (at max) one consumable reagent.	✓ Closed system requires only addition of sample aliquot ✓ Closed system (requires only addition of sample to (at max) one consumable reagent.) ✓ Closed system with dedicated reagents & minimal reagent preparation.	
15. Reagents What types of reagents are acceptable?	✓ No external reagents	✓ No external reagents ✓ Ready-to-use reagents, no reconstitution	✓ No external reagents ✓ Ready-to-use reagents, no reconstitution ✓ Reconstituted reagents can be stored for 8h at 37^{o}C or 4^{o}C	
16. Calibrators	✓ Self-calibrating	✓ Self-calibrating	✓ Self-calibrating	
17. Training How much training could the new test require?	✓ 0 training required (if family member) ✓ <1 day training required (for health care person)	✓ 1-5 days training	✓ 1-5 days training	
18. Staff education What are the education levels of the staff?	✓ None	✓ None ✓ Nurse (low level A3)	✓ None ✓ Nurse ✓ Lab Tech ✓ MD	
19. Language What language can the test instructions be in?	✓ Pictures	✓ Pictures ✓ Local language	✓ Pictures ✓ English, French, Spanish (maybe) ✓ Local language	Picture instructions are best for all settings. Culturally appropriate