

Laboratory Diagnostics Performance in Uganda: A Survey of Test Availability and Constraints Across 100 Laboratories

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Abstract

Background

Clinical laboratory services are a critical component of the health system for effective disease diagnosis, treatment, control and prevention. However, many laboratories in Sub Saharan Africa remain dysfunctional. The high costs of tests in the private sector also remain a hindrance to accessing testing services. This study aimed at assessing the functionality of laboratories based on test menus and the associated constraints in Uganda.

Methods

This cross sectional quantitative study involved an assessment of 100 laboratories randomly selected in 20 districts from four regions of the country. Sixteen percent of the studied laboratories were regional hub laboratories. Laboratory in charges and managers in each of the selected laboratories were interviewed. A checklist for laboratory supplies adapted from the Essential Medicines and Health supplies list for Uganda, (2012) was used to assess availability of testing supplies. Data was analyzed using excel and STATA 14.

Results

At the point of assessment, generally, all laboratories were able to perform malaria tests and HIV tests. All the hub laboratories conducted malaria tests and TB screening. Less than half had electrolytes tests due to lack of equipment, nonfunctioning equipment and lack of reagents. Full blood count tests were missing in 25% of the hub laboratories mainly due to lack of equipment. The lack of reagents (66.7%) and the lack of equipment (58.3%) caused the majority 10/16 of the hubs to routinely referred specimens for tests that are supposed to be carried out in these laboratories due to lack of reagents (66.7%) and non-functional equipment (58.3%). Although officially recognized as an operational structure, Hub laboratories lacked a list of essential and vital supplies.

Conclusions

Most laboratories performed well for the common tests. However, many laboratories did not meet testing requirements especially for the advanced tests according to standard testing menus for Uganda due to non-functioning equipment, lack of equipment and reagents. Hubs lack list of essential supplies. Therefore, there is need to provide equipment to laboratories, repair the non-functional ones and develop an essential list of supplies for the hub laboratories.

Background

Clinical laboratory services are a critical component of the health system because they aid effective disease diagnosis, treatment, control and prevention (1). Over the past decade, there has been an increased demand for laboratory testing services to manage infectious and non-infectious diseases including emerging and re-emerging diseases (1).

In Uganda, laboratory services are a key driver for effective delivery of the Uganda National Minimum Health Care Package (UNMHCP) (2). However, most of the laboratories in Uganda function below capacity and are characterized by unavailability of vital tests, tests of low quality and clinically unreliable results (3). The quality of laboratory services has been hindered by a number of factors including lack of standardized laboratory test menus, equipment, techniques, supplies list for the various levels of healthcare delivery and among others (4, 5). In order for laboratories to operate efficiently and cost-effectively, they need uninterrupted supply of reagents, functioning equipment, supplies and personnel. The inability to conduct tests delays and disrupts clinical care, prevention activities and public health programs (6).

A number of initiatives have been implemented to improve the quality of testing service in African laboratories (7, 8). Some of these include the establishment of the East Africa Public Health Laboratory Network Project, World Health Organization (WHO) which is reported to have led to the establishment of initiatives like Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), Strengthening Laboratory Management Toward Accreditation (SLMTA) (9). In 2013, Uganda embarked on the process of standardizing the laboratory test menus and supplies for the various tiers of laboratories in the laboratory network with the aim of improving quality of testing services (10). Despite these advances most of the laboratories in the country are still not performing to the set standards. Therefore, we established the functionality of the laboratories based on availability of test menus and supplies across the different laboratory levels in Uganda.

Laboratory service testing menus in Uganda: Laboratory testing menus are intended to define the minimum testing services expected at the various levels in the tiered laboratory network (10). Uganda has a well-defined laboratory tiered network that is aligned with the public health service delivery. At the lowest level, closest to the community, Health centre two (HCII) the basic laboratory tests are offered and subsequently at each higher levels of service delivery those tests which are not available at the lower levels are offered.

Laboratory Hubs: In order to increase access to quality laboratory services and improve accuracy, efficiency and immediacy in disease diagnosis, laboratory hubs were established in Uganda in 2006. Laboratory hubs provide enhanced services on-site or refer to a higher-level facility that has capacity to perform the test (11). The laboratory test menus for laboratory at each level of service delivery are summarized in Figure 1.

The functionality of the laboratories based on test menus and availability of supplies remains unknown in Uganda (3). This information deficit is a detriment to public health because it undermines service delivery and quality improvement efforts. This study therefore sought to assess laboratory

functionality based on test menus and supplies availability in Uganda. This study presents policy makers and public health authorities in Uganda, with viable information for strengthening laboratory testing services.

Methods

Study design and setting

This cross-sectional study was conducted in the four regions (Northern, Western, West Nile, and Eastern) of Uganda.

Study population and sampling

A total of 100 laboratory managers and in-charges from 100 randomly selected laboratories participated in the study. This sample of 100 laboratories, considered to be representative of the four regions of the country was obtained by including five laboratories selected from each of the five districts randomly selected from each region. These included 57 HC IIIs, 18 HC IVs, 19 Hospitals and 6 regional referral hospital laboratories. Of all the 100 laboratories assessed, 16 were hub laboratories while 84 were non hub laboratories.

Data collection procedures

The data was collected between December 2015 and January 2016. Data on availability of testing services, and diagnostic capacities were assessed using a laboratory assessment tool adapted from the WHO and USAID assessment tool for laboratory services and supply chain (ATLAS), 2006. A checklist for laboratory supplies adapted from the Essential Medicines and Health supplies list for Uganda, (2012) was used to assess availability of testing supplies. Survey questions were administered in person to the laboratory managers or in charges at each laboratory facility. Test menus, specimen and test referrals, availability of supplies and reasons for lack of tests were documented at each laboratory level.

Data management and analysis

Quantitative data were entered in EPI Info version 7 software, cleaned and analyzed using Excel and STATA. Test and supplies availability were obtained by comparing the available test and supplies with standard testing menus (WHO, 2017) and standard essential lists for supplies respectively based on the level of health facilities (WHO, 2012). Proportions of facilities offering a given tests based on the standard testing menus and availability of supplies were obtained.

Results

In this section, we present the tests performed at the different laboratory levels based on the standard menus, reasons for the lack of tests, specimen and test referral and availability of vital and essential supplies.

Background characteristics

A total of 57 HCIIIs, 18 HCVs, 19 hospital laboratories and 6 regional referral hospital laboratories were assessed. Sixteen of these laboratories were hubs and 84 were non hubs. The laboratories had been in operation for an average of 15 years (Table 2).

Table 1: Levels of Laboratories assessed

Level of Laboratory	Frequency (N=100)
HC III	57
HC IV	18
Hospital	19
Regional Referral	6
Hub laboratories	16
Non Hub laboratories	84

Tests performed at facility level according to Test menus

Health center III laboratories: Most health center III laboratories can conduct basic urine/stool analysis with a few exceptions due to non-functioning equipment and lack of reagents. All conducted HIV tests, malaria and pregnancy tests. None of the HC III laboratories performed blood grouping, sickle cell screening due to non-functioning equipment, lack of equipment and reagents. Full blood count and basic chemistry tests were grossly lacking due to non-functioning equipment, lack of equipment, reagents and skilled staff (Table 3).

Health center IV laboratories: All the Health center IV laboratories conducted HIV tests, malaria and pregnancy tests. None of the pneumonia and ulcer tests, electrolytes and chemistry tests was performed at Health center IV laboratories due to non-functioning equipment, lack of equipment, reagents and limited staff skills. The majority of the diabetes (83.3%), Hepatitis (76.5%) and CBC (60.0%) tests were referred mainly due to broken down equipment and lack of reagents (Table 3).

Table 2: Tests performed at Health Center IIIs and Health center IV according to test menus

Test Menus	HC III 57(%)	Reasons for unavailability of tests
Bacteriology tests		
Stool analysis	36 (63.2)	*&
Urine Analysis	48 (84.2)	*&
AFB (TB screening)	40 (70.2)	*#&
Serology		
Syphilis test	52 (91.2)	*#&
HIV test	57(100.0)	-
Pregnancy test	57(100.0)	-
Rapid Blood Sugar	44(77.2)	&
Parasitology		
Malaria test	57 (100.0)	-
Hematology		
Full blood count	5 (8.8)	*#&
Blood grouping	0(0.0)	*#&
Sickle cell screening test	0(0.0)	*#&
Chemistry test	5 (8.8)	\$*#&
<i>Test Menus for HCIV</i>	<i>HCIV 18 (%)</i>	
Bacteriology		
Stool analysis	16 (88.9)	&
Urine Analysis	17 (94.4)	#
AFB (TB screening)	17 (94.4)	&
Serology		
Syphilis test	16 (88.9)	*#
HIV test	18(100.0)	-
Pregnancy test	18(100.0)	-
Rapid Blood Sugar	3(16.7)	&
Parasitology		
Malaria test	18 (100.0)	-

Electrolytes	0 (0.0)	\$*#&
Hematology		
Full blood count	6 (33.3)	*#&
Blood grouping	9(50.0)	&
Sickle cell screening test	7(38.9)	&
Chemistry test	1 (5.6)	\$*#&

*\$-Staff not trained, *-nonfunctioning equipment, #-No equipment, &-No reagents, bold-weak areas*

Tests performed at Hospital laboratories

Almost all tests supposed to be conducted at hospital level laboratories, were conducted except for chemistry and electrolytes tests. Majority (52.6%) of laboratories did not conduct electrolytes tests due nonfunctioning equipment, lack of equipment, reagents and skilled staffs. A few laboratories did not conduct chemistry tests (26.3%) due to nonfunctioning equipment and lack of equipment. BAT tests (12.8%), TB tests (16.7%) and Ulcer tests (25.0) were also not available at the time of assessment due to lack of reagents and equipment (Table 4).

Tests performed at Regional Referral hospital laboratories

Almost all tests supposed to be conducted at regional referral laboratories were available at the time of the assessment. However, half of the laboratories did not conduct electrolyte tests due to lack of reagents and equipment. One lab did not conduct full blood count due to lack of reagents (Table 4).

Table 3: Tests Performed at Hospital and Regional Referral hospital laboratories according to testing menus

Test Menus	Hospital 19(%)	Reasons for unavailability of Tests
Bacteriology		
Stool analysis	19 (100.0)	-
Urine Analysis	19 (100.0)	-
AFB (TB screening)	19 (100.0)	-
Serology		
Syphilis test	18 (94.7)	#
HIV test	19 (100.0)	-
Pregnancy test	19 (100.0)	-
Rapid Blood Sugar	19 (100.0)	-
Parasitology		
Malaria test	19 (100.0)	-
Electrolytes	9 (47.4)	*#\$&
Hematology		
Full blood count	16 (84.2)	*#
Blood grouping	18 (94.7)	&
Sickle cell screening test	18 (94.7)	&
Chemistry test	14 (73.7)	*#
Test Menus	RRH 6(%)	Reasons for unavailability of Tests
Bacteriology		
Stool analysis	5 (83.3)	&
Urine Analysis	5 (83.3)	#
AFB (TB screening)	6 (100.0)	-
Serology		
Syphilis test	5 (83.3)	#
HIV test	6 (100.0)	-
Pregnancy test	6 (100.0)	-
Rapid Blood Sugar	6 (100.0)	-
Parasitology		

Malaria test	6 (100.0)	-
Electrolytes	3 (50.0)	#&
Hematology		
Full blood count	5 (83.3)	&
Blood grouping	6 (100.0)	-
Sickle cell screening test	6 (100.0)	-
Chemistry test	6(100.0)	-

*§-Staff not trained, *-nonfunctioning equipment, #-No equipment, &-No reagents, bold-weak areas*

Tests performed at hub laboratories according to test menus and reasons for non-availability of tests

Almost all tests could be performed at hub laboratories. All the hub laboratories had malaria tests and TB screening. Less than half(43.8%) of the hub laboratories were able to perform electrolytes tests due to lack of equipment, non-functioning equipment and lack of reagents, ¼ of the hub laboratories could not conduct Full blood count due to lack of equipment. A few 3/16 hub laboratories were not able to conduct chemistry tests due to lack of equipment and nonfunctioning equipment (Table 5).

Table 4: Tests available at Hub laboratories according to Test menus

Test Menus	N16 (%)	Reasons for unavailability of tests
Bacteriology		
Stool analysis	14(87.5)	&
Urine analysis	14(87.5)	#&
AFB (TB screening)	16(100.0)	-
Serology		
Syphilis test	14(87.5)	#
Parasitology		
Malaria test	16(100.0)	-
Electrolytes	7(43.8)	*#&
Hematology		
Full blood count	12(75.0)	#
Chemistry	13(81.2)	*#

*§-Staff not trained, *-nonfunctioning equipment, #-No equipment, &-No reagents, bold-weak areas*

Tests and specimen routinely referred

Generally, 48.4% of the laboratories referred specimen for tests that could be performed in the laboratories. This was mainly due to lack of reagents (44.1%) and lack of equipment (39.8%). More than half of laboratories at all levels received referred results more than a week from the time the specimens were referred, with HCIVs having the highest number (68.8%) of laboratories receiving results after a week.

Health center III laboratories: Slightly less than half (42.1%) of the health center III laboratories routinely referred tests for which they are mandated to perform. These included BAT Test (33.3%), diabetes tests (25.0%). The main reason for routine referral of these tests was lack of reagents.

Health center IV laboratories: Half 9/18 (50.0%) of the health center IV laboratories routinely referred specimen for tests that could be carried out in the laboratory. These mainly included TB culture (9/9), CD4 (7/9), Viral load (9/13), chemistry (4/9) and hematology (3/9). The main reasons for referral included lack of reagents (88.8%) and broken equipment (55.6%).

Hospital level laboratories: More than half 11/19 (57.9%) of the general hospital laboratories routinely referred specimen for tests that could be carried out in the laboratory. These mainly included PCR (11/11), Histology (7/11), TB culture (8/11) and Viral load (8/11). The main reasons for referral of tests included lack of reagents (72.7%), broken equipment (72.7%) and lack of staff (9.1%).

Regional referral hospital laboratories: Less than half (2/6) of the regional referral hospital laboratories routinely referred specimen for tests that could be carried out in the laboratory. These were mainly PCR, TB culture and viral load. The main reason for referral of specimens was lack of reagents.

Hub Laboratories: The majority 10/16 of the hubs routinely referred specimens for tests that are supposed to be carried out in their laboratories. These tests included PCR (9/10), Histology (4/10), TB culture (10/10), chemistry (4/10), CD4 (6/10) and Viral load (10/10). The main reason for specimen referral in the hub laboratories included lack of reagents (66.7%) and nonfunctional equipment (58.3%).

Availability of essential and vital laboratory supplies at different laboratory levels

Overall: HIV testing kits, Malaria rapid tests strips, urine strips, were well stocked at all laboratory levels with over 95% of the laboratories having those supplies. At all levels, there was a general shortage of Igm (tubex), reconstituted laboratory reagents for malaria CBC, TB and opportunistic infections which were found in less than half of the laboratories.

Health center III laboratories: Of the supplies mandated to be available at this level, majority (94.7%) of the HC III laboratories were stocked with HIV testing kits (94.7%), malaria rapid diagnostic tests (92.9%) and about half (50.9%) were stocked with blood glucose test strips. There were critical shortages in the availability of IgM tubex (8.8%), reconstituted laboratory reagents for malaria, CBC, tuberculosis and

opportunistic infections (28.5%), chemicals (25.2%), blood grouping anti sera (42.8%) and about 39.8% had glass ware and apparatus (Table 6).

Health center IV laboratories: For the supplies supposed to be available at Health center IV laboratories, all of them had HIV testing kits and malaria rapid test strips. None of the laboratories had CD4 Reagents, EasyCD4 (GUAVA), Sysmex 3-part reagent kit, Cobas C 111 equipment reagents, Cobas c 311 liver profile test kits, reagents for Selectra, and blood collection sets and only 35.3% had been stocked with glassware (Table 7).

Hospital level laboratories: All hospital laboratories were stocked with HIV, malaria and urine test strips. There were critical shortages of CD4 reagents (20.0%), Anti-microbial sensitivity disc kit (20.0%), culture media (16.0%), and coagulation reagents (15.0%) Less than half of the laboratories were stocked with human liver function test kits (48%), Blood grouping anti sera (48%) and blood collection supplies (44.0%) while none of them were stocked with reagents for selectra and biochemistry reflotron reagents (Table 6).

Hub level laboratories: Availability of supplies according to supplies menus at Hub laboratories level could not be assessed due to lack of a supplies list for these hub laboratories.

Table 5: Availability of selected Essential and Vital Supplies according to the menus at the time of assessment

Supplies Menus	HC III	HC IV	Hospitals N=25
HIV testing kits	54(94.7)	17(100.0)	25(100.0)
Specimen containers	42(73.7)	13(76.5)	20 (79.4)
Blood glucose test strips	29 (50.9)	7(41.2)	21(84.0)
Brucella abortus Ag	*	5(29.4)	14(56.0)
HCG pregnancy test strips	45(79.0)	12(70.6)	24(86.0)
IgM (tubex)	5 (8.8)	1(5.9)	1(4.0)
Malaria rapid	53(92.9)	17(100.0)	25(100.0)
RPR test strips	48 (84.2)	13(76.5)	19(76.0)
Treponema	15(26.3)	6(35.3)	15(60.0)
Urine test strips	51(91.1)	16(94.11)	25(100.0)
Reconstituted lab reagents for malaria, CBC, TB	16(28.5)	7(41.2)	11 (43.3)
Tuberculosis reagents kit	48(84.2)	15(88.2)	25 (100.0)
Malaria fields stain reagents kit	29(48.9)	7(41.2)	15 (60.0)
Gram stain kit	32(55.7)	12(70.6)	24 (95.0)
Chemicals	18(25.2)	5(29.4)	16 (62.2)
CD4 Reagents	*	0(0.0)	5 (20.0)
BD FACS Count reagents	*	1(5.9)	10 (40)
CD4 point of care machine	*	12(70.6)	9 (36.0)
PointCare Now	*	2(11.8)	1 (4.0)
HUMAN liver function test	*	1(5.9)	13(52.0)
Blood grouping anti sera	24(42.8)	12(70.6)	16(64.0)
Blood collection sets	*	0(0.0)	7(28.0)
Blood giving sets	*	5(29.4)	20(80.0)
Anti-microbial sensitivity disc kit	*	*	5(20.0)

* Supplies not in test menus for that level of health facility

Discussion

The functionality of the laboratories in terms of test menus is critical in guiding clinicians in diagnosing and giving the appropriate course of treatment to patients and also guiding public health workers on the effectiveness of health intervention and health programs (12). Therefore, the main purpose of this study was to establish the functionality of the laboratories based on availability of test menus and supplies across the different laboratory levels in Uganda. In this study, we found that many laboratories performed well regarding the common tests of malaria, HIV, urine and stool analysis, with low performance of advanced tests like chemistry, electrolytes and full blood counts in laboratories mandated to perform such tests. The main reasons for unavailability of tests was non-functioning equipment, lack of equipment and reagents.

The study indicated that generally, most basic tests were available at the time of assessment across the different laboratory levels. The most frequently done tests included malaria test, stool and urine analysis, Syphilis and TB screening. This finding concurs with the results of a survey in Kampala which revealed that stool analysis, urinalysis, syphilis and malaria tests were among the high availability tests in the city (13). However, many laboratories did not meet testing requirements especially for the advanced test according to standard testing menus for Uganda. A few HC III laboratories performed advanced tests which were not in their mandate. These could have been privately owned laboratories with the capacity to perform such tests.

It is indicated in this study that there was a dismal performance on the full blood count, Electrolytes and Chemistry tests at HC IV, hospital and regional referral levels where these tests are actually supposed to be conducted. The poor performance in these tests was highest at HCIV, which is the first point of referral. This dismal performance is attributed to mainly the lack of functional equipment for these tests. This underscores the need for regular maintenance of the equipment. Similar observations were reported in south western Ethiopia where clinical chemistry performance was very low and the quality of clinical chemistry test services were under standard (14). The most common reason for not having these tests was the lack of equipment followed by lack of reagents to run the tests. This is consistent with the findings of a study by (15) in Kampala, Uganda which revealed that 92% of the laboratories in reported that tests were not carried out due to lack of equipment and reagents. Thus, to improve the quality and availability of clinical chemistry, electrolytes and full blood count tests, there is need for measures to boost laboratories with essential and vital supplies and the key equipment.

Regarding functionality of hub laboratories, Although hub laboratories were equipped to perform full blood count, chemistry tests and electrolytes tests to service a wider area and act as referral lab for the region, $\frac{1}{4}$ of the hub laboratories could not perform FBC due to lack of equipment. Only less than half were able to conduct electrolytes due to non-functioning equipment, lack of equipment and reagents. Since these hub laboratories are intended to bridge gaps in service availability more, therefore efforts need to be made to ensure that the ability of hubs to conduct electrolyte and chemistry tests is not constrained by are equipped with chemistry equipment, repair non-functioning equipment and the lack of ensure reagents are available.

The study revealed that about half of the laboratories routinely referred specimen for tests that they should be performing according to standard menus. These gaps were more pronounced in HCIV and hospitals laboratories experienced in over 56.0% of the laboratories. Furthermore, unexpectedly, a high number of hub laboratories routinely referred specimen for tests that they should be conducting compared to non-hub laboratories. The main reasons for referral of specimen was lack of reagents and functional equipment. According to the National laboratory strategic plan (2010–2015), lack of or frequent break down of equipment and frequent stock out of supplies were the reasons many laboratories did not fulfill the testing requirement. Hub laboratories offer a prime opportunity to further improve access and quality of services. These hubs should be further supported to by MOH to mitigate their persisting challenges of equipment breakdown and stock outs of reagents. Upgrading of some of these hub facilities would reduce the need to referral samples even further away from the requesting facilities and thereby reduce waiting times regionally. Quality improvement initiatives are still needed especially at hub, HC IV and hospital level laboratories so that they are able to perform tests according to standard.

Regarding availability of supplies, most of the laboratories, were well stocked with HIV testing kits, Malaria RDTs, TB reagents kits and gram stain kits. This was probably because of an additional source of funding both from donors and implementing partners in most of the laboratories. However, laboratories were less stocked with blood glucose test strips which are critical for detection of diabetes which is contributing to the increased non communicable diseases in Uganda. There were also less stock of chemicals, blood grouping anti sera, IgM tubex and glassware. It was further observed that stock outs of chemistry reagents were a critical challenge for the high-level laboratories. This was probably because government was the sole source of funding for most of the chemistry reagents. Similar observations were noted in Ethiopia where most of the laboratories did not have adequate chemistry reagents and chemicals to do all the necessary tests and thus health decisions could be possibly made based on incomplete laboratory test results (14). Therefore, there is need to ensure that high level laboratories are equipped with adequate vital and essential supplies especially for the advanced tests since these constitute the main referrals. Hub laboratories are officially recognized in the laboratory service delivery structure, however, there is no specified list/menus for essential and vital supplies for hubs. This makes these laboratories vulnerable to missing out on the most critical supplies and hence compromises their ability not be able to perform some tests. Therefore, there is need to develop and institute an essential supplies list of supplies menus for hub laboratories to ensure that the most vital and essential supplies are supplied to boost functionality.

Conclusion

In this study it was revealed that many laboratories performed well regarding the basic tests of malaria, HIV, urine and stool analysis but poorly with regard to availing advanced tests like chemistry, electrolytes and full blood counts in laboratories which are mandated to perform such tests including some of the hub laboratories and high-level laboratories. To mitigate wastage and improve the quality of services provided by laboratories harmonized efforts to be made to repair existing equipment, train staff where

needed and to provide necessary supplies for functionality. The goal should be to make Hub laboratories fully functional while addressing supplies and capacity gaps where equipment exist at lower levels of care.

List Of Abbreviations

HC Health Center

HIV Human Immunodeficiency Virus

TB Tuberculosis

PCR Polymerase Chain Reaction

MoH Ministry of Health

CBC Complete blood Count

RRH Regional Referral Hospital

Declarations

Ethics approval and consent to participate

We obtained ethical approval from Makerere University School of Public Health Higher Degrees Research and Ethics committee (protocol number HDREC 364). All the participants consented before being interviewed.

Consent for publication

Not Applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare no competing interests

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Authors' contributions

SNK and ANK wrote the protocol of the study. NN and MA analyzed and interpreted the data. NN drafted the initial manuscript, all authors contributed to the first draft and all authors read and approved the final manuscript.

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1\$ua = 1.

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Figures

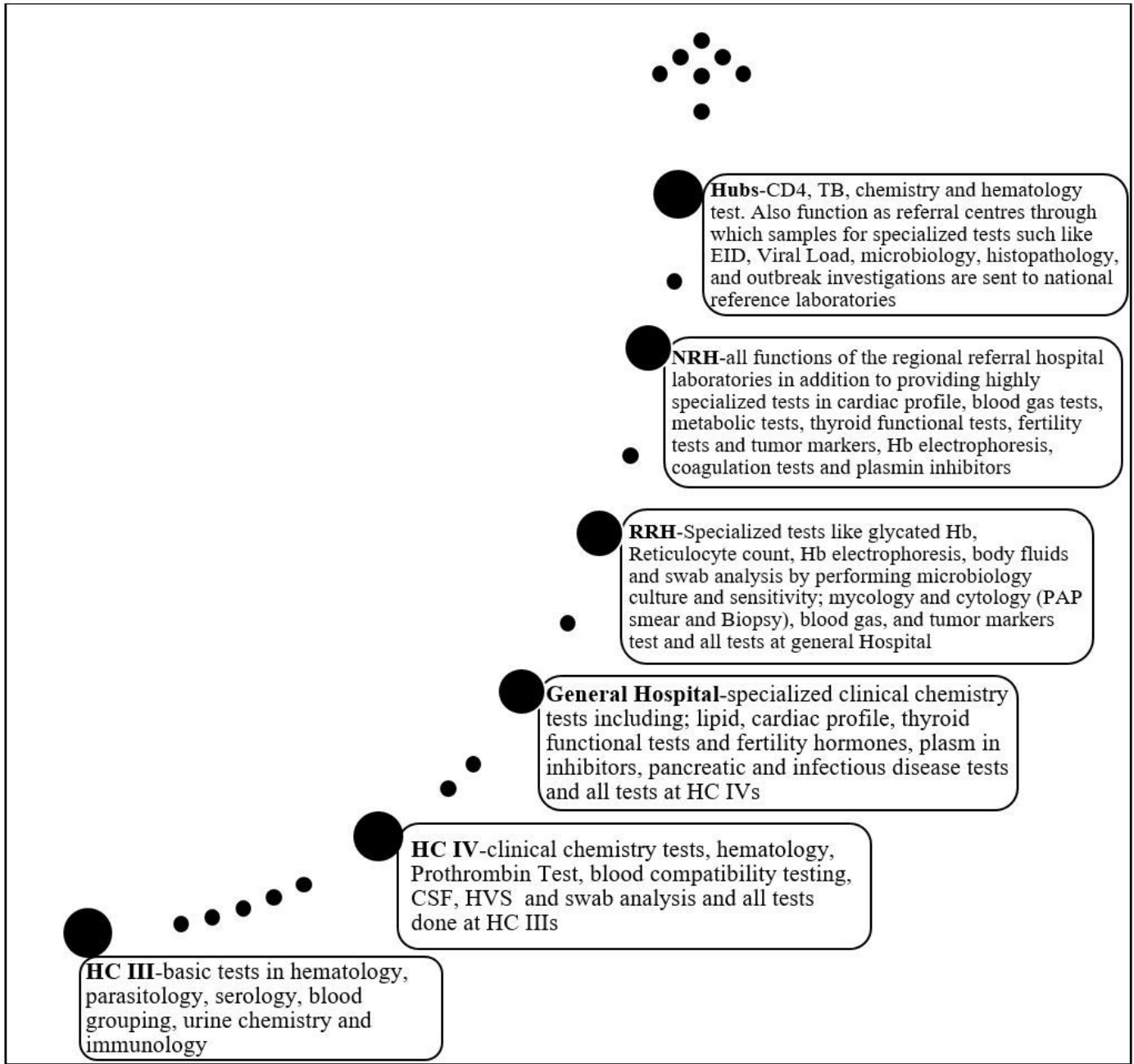


Figure 1

Laboratory test menus for Uganda (MOH, 2017)