



<b>Study Specific Procedure</b>	<b>SSP No: LAP01</b> <b>Version No: 2.0</b> <b>Supersedes: 1</b> <b>Effective Date:</b> <b>4<sup>th</sup> June 2022</b>
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**Title: PB SAM Laboratory Analytical Plan**

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**APPROVED**

## Study/Protocol Details

<b>Protocol Number / Protocol Title</b>	PB-SAM	
<b>Protocol Version</b>	1.0	
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## Abbreviations

Abbreviation	Term
PB	Pancreatic Enzymes and Bile Acids
SAM	Severely Malnourished Children
CBC	Full blood count
LFT	Liver function tests
UKNEQAS	United Kingdom National External Quality Assurance Services
RCPA	Royal College of Pathologists of Australasia
MLW	Malawi Liverpool Wellcome-Trust

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## Introduction

The **CHAIN Network** is focused on optimizing the management and care of the sick and undernourished child in resource-limited settings to improve survival, growth and development. We also aim to identify the biological mechanisms and the socio-economic factors that determine a child's risk of mortality in the six months following presentation to medical care with an acute illness.

### 1. Study Background

Children with severe malnutrition who are sick and admitted to hospitals have high mortality, usually because of infection. Malnourished children have more potentially harmful bacteria in their upper intestines than well-nourished children and this may contribute to inflammation in the gut and whole body. These bacteria may cross from the intestines to the bloodstream causing life-threatening infection. Another abnormality among malnourished children is reduction in the digestive enzymes made by the pancreas and the liver. Apart from helping with digestion of food, these enzymes are important in controlling bacteria in the intestines. It is therefore possible that treatment with digestive enzymes could help reduce the burden of harmful bacteria and thus lower inflammation and risk of serious infection. One study conducted in Malawi has shown that children with severe malnutrition

who were supplemented with pancreatic enzymes had a lower risk of dying. However, this was a small study and although promising, requires validation. No studies of supplementation with bile acids have been done among severely malnourished children. However, bile acids are commonly used to manage patients with cholestatic liver diseases, something that malnourished children suffer from as well.

## 2. Purpose of the study

We want to find out if giving special salts that help in digestion (pancreatic enzymes and bile acids) for ill children with severe acute malnutrition is safe and reduces the risk of death, deterioration or readmission to hospital. We will also assess the costs associated with the interventions to patients and health providers.

## 3. Study/Project Tasks Organization

Site/Laboratory	Name	Project Title/Responsibility	Contact
KEMRI/Wellcome Trust Research Programme-Nairobi	Caroline Tigoï	Lab Coordinator	<a href="mailto:ctigoï@kemri-wellcome.org">ctigoï@kemri-wellcome.org</a>
KEMRI/Wellcome Trust Research Programme-Kilifi	Johnstone Thitiri	Trial Coordinator	<a href="mailto:jthitiri@kemri-wellcome.org">jthitiri@kemri-wellcome.org</a>
KEMRI/Wellcome Trust Research Programme-Kilifi	Robert Musyimi	Bio-repository	<a href="mailto:rmusyimi@kemri-wellcome.org">rmusyimi@kemri-wellcome.org</a>
Queen Elizabeth Central Hospital, P Bag 360, Blantyre, Malawi	Dr Emmie Mbale	Clinical Lead-Malawi	<a href="mailto:emmiembale@gmail.com">emmiembale@gmail.com</a>
Makerere University College of Health Sciences: Kampala, Uganda	Dr Ezekiel Mupere	Clinical Lead-Uganda	<a href="mailto:mupez@yahoo.com">mupez@yahoo.com</a>

KEMRI/Wellcome Trust Research Programme	Dr Caroline Ogwang	Clinical Lead-Kenya	<a href="mailto:cogwang@kemri-wellcome.org">cogwang@kemri-wellcome.org</a>
Dhaka Hospital, icddr,b; 68 Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka 1212, Bangladesh	Dr. Mohammad Jobayer Chisti	Clinical Lead-Bangladesh	<a href="mailto:chisti@icddr.org">chisti@icddr.org</a>
Queen Elizabeth Central Hospital, Blantyre, Malawi	Dr. Robert Bandsma	PI	<a href="mailto:robert.bandsma@sickkids.ca">robert.bandsma@sickkids.ca</a>
Queen Elizabeth Central Hospital, Blantyre, Malawi	Dr. Wieger Voskujl	Co-PI	<a href="mailto:w.p.voskujl@amsterdamumc.nl">w.p.voskujl@amsterdamumc.nl</a>
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Queen Elizabeth Central Hospital, Blantyre, Malawi	Isabel Potani	Trial Coordinator	<a href="mailto:isabelpotani@gmail.com">isabelpotani@gmail.com</a> +265992319586
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Queen Elizabeth Central Hospital, Blantyre, Malawi	Stanley Khoswe	Laboratory Manager	<a href="mailto:skhoswe@medcol.mw">skhoswe@medcol.mw</a> +265888055937
Queen Elizabeth Central Hospital, Blantyre, Malawi	Chikondi Makwinja	Data Officer	<a href="mailto:chicomakwinja@gmail.com">chicomakwinja@gmail.com</a> +265881767347
Queen Elizabeth Central Hospital, Blantyre, Malawi	Chisomo Phiri	Laboratory technician	<a href="mailto:griffinchisomophiri@gmail.com">griffinchisomophiri@gmail.com</a> +265888435244
Kemri-WT Mbagathi County Hospital-	Molly Timbwa	Site Lead/Clinical Coordinator	<a href="mailto:mtimbwa@kemri-wellcome.org">mtimbwa@kemri-wellcome.org</a> +254710257675

#### 4. Laboratory study roles and tasks

Site	Laboratory Section	Roles and Tasks	Responsibility
Kilifi	KEMRI-CGMRC, Top Lab, Kilifi	<ul style="list-style-type: none"> <li>- Sample reception</li> <li>- CBC</li> <li>- LFT</li> <li>- Biochemistry.</li> </ul>	Robert Musyimi
	KEMRI-CGMRC, Microbiology Lab, Kilifi	<ul style="list-style-type: none"> <li>- Bactec FX incubation</li> <li>- Subculture, isolation of pathogens, AST and storage.</li> <li>- EDTA plasma separation and storage.</li> </ul>	Robert Musyimi
Malawi	Queen Elizabeth Central Hospital, Blantyre, Malawi	<ul style="list-style-type: none"> <li>- Sample reception</li> <li>- EDTA plasma separation and storage</li> <li>- Stool processing and storage</li> <li>- Rectal swab storage</li> </ul>	Chisomo Phiri
Uganda	Integrated Biorepository of H3Africa Uganda – IBRH3AU	- c	Sharley Aloyo Rogers Kamulegeya Victor
	Uganda Cancer Institute Laboratories	<ul style="list-style-type: none"> <li>- CBC</li> <li>- LFT</li> <li>- RFT</li> </ul>	Wannume Henry
Bangladesh	Specimen reception unit (SRU)	- Sample reception	Shahriar Bin Elahi
	Clinical Chemistry Laboratory	<ul style="list-style-type: none"> <li>- LFT</li> <li>- Biochemistry</li> </ul>	Dr. Syeda Momena Afsana
	Haematology and Clinical Pathology Laboratory	<ul style="list-style-type: none"> <li>- CBC</li> </ul>	Dr. Md. Hafizur Rahman
	Clinical Microbiology and Immunology Laboratory	<ul style="list-style-type: none"> <li>- Bactec FX incubation</li> <li>- Subculture, isolation of pathogens, AST and storage</li> <li>- EDTA plasma separation and storage</li> </ul>	Dr. Dilruba Ahmed
	Dhaka Hospital	- Blood gas and lactate through i-STAT	Dr. Md. Jobayer Chisti
Nairobi	Kemri-WT Mbagathi County Hospital-Mbagathi STAT lab	<ul style="list-style-type: none"> <li>- Sample reception</li> <li>- EDTA plasma separation and storage</li> <li>- Stool processing and storage</li> <li>- Rectal swab storage</li> </ul>	Anthony Waithaka

## 5. Laboratory Assays and their associated procedures

The assays noted in the table below will be used for performing the study specific laboratory tests:

Site	Test/Assay	Assay Kit	Type of Sample Tested	Clinic/Laboratory Location	SOP (Indicate SOP No)
Kilifi	CBC	EDTA 0.5ml 450530	Whole blood in EDTA	KEMRI - Wellcome trust STAT lab	LHEME-013
	Biochemistry and LFT	H3130/10001B	Plasma in Lithium heparin	KEMRI - Wellcome trust STAT lab	LSTAT-037
Malawi	NA	NA	NA	NA	NA
Uganda					
	CBC	BD vacutainer K2EDTA 2ml, Ref 367842	Whole blood in EDTA	Uganda Cancer Institute Laboratories	UCILAB-TCE 012
	LFTs and RFTs	BD vacutainer (Clot activator tube)	Serum	Uganda Cancer Institute Laboratories	UCILAB-TCE 013
Bangladesh	CBC	BD Vacutainer K2EDTA 3mL Ref 367856	Whole blood in EDTA	Haematology and Clinical Pathology Laboratory, LSSD, icddr,b	HE.TP.54
	Biochemistry and LFT	BD Vacutainer Lithium heparin PST 4.5 mL Ref 367375	Plasma in Lithium heparin	Clinical Biochemistry Laboratory, LSSD, icddr,b	BC.WI.015
All sites	Plasma for storage	EDTA 2.0 ml 368841	Whole blood in EDTA	KEMRI - Wellcome trust Immunology lab	CHAIN sample storage SOP
	Rectal swabs	Ref 4C028S and 5U002S	Storage	KEMRI - Wellcome trust Micro lab	CHAIN sample storage SOP
	Stool	LAB0327	Storage	KEMRI - Wellcome trust Immunology lab	CHAIN sample storage SOP



## **6. Sampling Strategy/Planning**

### **6.1 Sample collection**

- Sample collection will be done by the clinical team under aseptic conditions as described in CHAIN sample collection SOP

### **6.2 Laboratory Requisition Form**

- PB-SAM sample storage CRF forms will be filled for sample storage

### **6.3 Sample information and Labelling**

#### **6.3.1 General information on Labels and Barcode Printing**

Barcode labels will be generated to all specimen freezing vials. The following barcode variables will be generated:

##### **6.3.1.1 Country code**

10– Kenya  
20 – Uganda  
30 – Malawi  
50 –Bangladesh

##### **6.3.1.2 Collection time point**

A0- Admission  
D7 – Day seven (applicable for Uganda)  
RLL – Rolling stool  
D0 - Discharge  
D21 - Day 21  
D60 - Day 60  
RA - Readmission

##### **6.3.1.3 Specimen type**

P – Plasma (P1 or P2) –depicting aliquot numbers  
R1 – Rectal Swab 1 (Dry)  
R2 – Rectal Swab 2 (Wet)  
F– Stool/Faeces aliquots  
F2– Stool/Faeces aliquot 2

##### **6.3.1.4 Patient ID**

001  
002  
003 etc.

##### **6.3.1.5 Collection date/Date collection**

12/10/2021 – DD/MM/YYYY

#### **6.3.2 Sample Labelling**

- 6.3.2.1 Rectal swab tubes should be labelled with Country code, collection time-point, specimen type (R1 or R2), Participant ID and date of collection. For example, 10-A0-R1-XXX-12/10/2021 or 10XXX, Rectal swab for PCR or Rectal swab for culture, specimen abbreviation R1 or R2 and date collect.

- 6.3.2.2 Samples should be labelled by Country code, collection time-points specimen type (F1, F2, F3 and F4), Participant ID and date of collection. For example, 10-A0-F1-XXX-12/10/2021 or 10XXX, stool, specimen abbreviation F1, F2, F3 or F4 and date collect.
- 6.3.2.3 Blood tubes should be labelled with the Country code, collection time-point, specimen type, Participant ID and date of collection. P= plasma from EDTA tube. For example, 10-A0-P1-XXX-12/10/2021 or 10XXX, EDTA plasma, specimen abbreviation P1, P2, P3 or P4 and date collect.

	ADMISSION (and within 72 hours)	DAILY IN HOSPITAL	DISCHARGE	Day 21	Day 60	READMISSION
<b>Blood sample</b>	X			X		X
<b>Rectal swab/stool</b>	X		X	X	X	X
<b>12 hourly capillary blood gas &amp; lactate (days 1-5 only) *</b>		X				
<b>Hydrogen breath test**</b>	X			X		

#### 6.4 Sample Reception and data management

The samples shall be received in **Clinical Trials Laboratory** (CTL and Microbiology) via Kilifi Integrated Data Management System (KIDMS) through which the samples shall be entered and acknowledged.

Samples will be registered using <https://rss.kemri-wellcome.org/site/login>.

After registration, sample management will be done under <https://kidms.kemri-wellcome.org/index.php?r=site/login>.

Sample storage will be done using <https://lims.kemri-wellcome.org/site/login>.

#### 6.5 Sample Processing

##### 6.5.1 Haematology and Biochemistry Labs

Blood samples for CBC and Biochemistry will be processed using the following methods and results will be recorded on individual request forms and updated in KIDMS database.

Site	Biochemistry analyzer	Haematology analyzer	SOP No.
Kilifi	ILAB Aries analyzer	AcT5 diff blood coulter analyzer	SOPs LSTAT 042 and LSTAT 048
Malawi	NA	NA	NA
Uganda	Cobas 6000 chemistry Analyzer. (c501/c601)	Sysmex XN20 (XN 1000)	UCILAB-TCE 013 and UCILAB-TCE 012
Bangladesh	Beckman Coulter AU series	Sysmex XN1000	BC.WI.015 BC.WI.001 BC.WI.020 BC.WI.025 HE.TP.054

## 6.5.2 Microbiology

### 6.5.2.1

Site	Blood cultures machine	Identification system	SOP
Kilifi	Bactec FX, Bactec 9050	MALDI-TOF	LMIC-015 and LMIC-085
Malawi	NA	NA	NA
Uganda	NA	NA	NA
Bangladesh	BacTAlert 3D	Vitek 2	MI.TP.060 MI.TP.002

6.5.2.2 EDTA plasma will be centrifuged and stored at  $-80^{\circ}\text{C}$  using plasma storage CHAIN sample storage SOP

6.5.2.3 Rectal swabs will be snipped and stored at  $-80^{\circ}\text{C}$  using CHAIN sample storage SOP

6.5.2.4 Stool will be aliquoted and stored at  $-80^{\circ}\text{C}$  using CHAIN sample storage SOP

## 6.6 Sample Chain of custody

Sample chain of custody will be maintained at all stages in the lab using sample transport log or reception logbooks

## 7. Sample Storage and Shipment

Plasma, Stool and Rectal swab will be stored according to CHAIN bio repository SOP and Sample shipment will be done at end of the study as per CHAIN sample shipment SOP. RSS systems will be used for participant and sample registration. KIDMS will be used for sample management while LIMS will be used for sample storage across all sites.

**8. Equipment/Materials and Reagents**  
**8.3 Laboratory Equipment, Reagents and Kits**

<b>CLINICAL CHEMISTRY AND HAEMATOLOGY</b>		
<b>SITE</b>	<b>EQUIPMENT/ANALYSERS</b>	<b>LABORATORY REAGENTS &amp; KITS</b>
Kilifi	a) Laboratory Equipment for CTL b) Coulter Act 5Diff AL sn.AX38090 c) Coulter AcT 5Diff CP sn. AI0402 d) Coulter AcT 5Diff CP sn. AM12023 e) Coulter AcT 5Diff f) Coulter AcT 5Diff g) ILab Aries sn. 1107106	<b><u>Haematology Kits</u></b> - Coulter AcT 5diff Ref. 8547171 - Coulter AcT 5diff WBC Lyse Ref. 854-7170 - Coulter AcT 5diff Hgb Lyse Ref 854-7168 - Coulter AcT 5diff Rinse Ref. 854-7167 - Coulter AcT 5diff Diluent Ref. 854- <b><u>Chemistry Kits</u></b> - ALT reagent cat no. 0018257440 - Bilirubin reagent cat no. 0018258340 - Creatinine reagent cat no. 0018255540 - Urea reagent cat no. 0018255440 - Albumin reagent cat no. 0018481800 - Potassium reagent cat no. ISE CAL A-0018469700 - Sodium reagent cat no. ISE CAL B-0018469800
Malawi	NA	NA
Uganda	1. Sysmex XN20 (XN 1000) Haematology Analyzer 2. Cobas 6000 chemistry Analyzer. (c501/c601)	Haematology kits - Cell pack DCL - Cell pack DFL - Lysercell WNR - Lysercell WDF - Fluorocell WNR - Fluorocell WDF - Fluorocell WPC - Fluorocell RET - Fluorocell PLT - Cell clean - Commercial IQCs (Level 1,2 &3) <b>Chemistry kits</b> - ALB BCG - Cobas Integra ALP IFCC Gen2 S - CREAJ Gen.2 - TP Gen.2, cobas c, Integra - BIL-D Gen.2, cobas c, Integra

		<ul style="list-style-type: none"> <li>- ALTL, cobas c, Integra</li> <li>- BIL-T Gen.3</li> <li>- GGT Gen.2</li> <li>- UREAL</li> <li>- ASTL</li> <li>- Cartridge CL (Chloride)</li> <li>- Cartridge NA (Sodium)</li> <li>- Cartridge K (Potassium)</li> <li>- Pericontrol clinichem - Normal</li> <li>- Pericontrol clinichem - Pathological</li> <li>- C.f.a.s Calibrator</li> <li>- Cell wash NAOHD</li> <li>- Cell wash Acid wash</li> <li>- ECO-D</li> <li>- ISE Standard</li> <li>- ISE reference electrolyte</li> <li>- ISE Diluent</li> <li>- Probe wash 1 &amp; 2</li> <li>- Sample cleaner 1 &amp; 2</li> <li>- Sample cups</li> </ul>
Bangladesh	Beckman Coulter AU680 Beckman Coulter AU480 Olympus AU640 Sysmex XN1000	<p><b>Bio Chemistry Kits</b></p> <ol style="list-style-type: none"> <li>1. For Electrolyte (Sodium, Potassium):              ISE Buffer (66320).              ISE Mid Standard (66319).              ISE Reference (66318).              ISE Low Serum Standard (66317)              ISE High Serum Standard (66316)              ISE Low/High Urine Standard (66315)</li> <li>2. For ALT: OSR6007</li> <li>3. For Total Bilirubin: OSR6112</li> <li>4. For Creatinine: OSR61204</li> <li>5. For Urea: OSR6134</li> <li>6. For Albumin: OSR6102</li> <li>7. For Total Calcium: OSR60117</li> <li>8. For Total Magnesium: OSR6189</li> <li>9. For inorganic Phosphorus: OSR6122</li> <li>10. For Alkaline Phosphatase: OSR6004</li> </ol> <p><b>Haematology Kits</b>            Cell Pack DCL CT661628            Lysercell WNR ZPPBL121531            Flurocell WNR CP066715</p>

		Lysercel WDF ZPPAL337564 Flurocell WDF CV377552 Sulfolyser P90411414 Flurocell RET BN337547 Cellpack DFL BT96591O Cell clean ayto CF-579-595
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MICROBIOLOGY LAB		
SITE	EQUIPMENT/ANALYSERS	LABORATORY REAGENTS & KITS
Kilifi	a) Aerobic 37 <sup>0</sup> C incubator b) CO <sub>2</sub> 37 <sup>0</sup> C incubator c) Bactec FX d) MALDI-TOF e) Eppendorf refrigerated centrifuge f) -800C freezer of Sanyo or Panasonic model	1. Mueller Hinton Agar Cm0337 2. Tyryptone Soya Broth Cm029 3. Columbia Agar Base Cm0331 4. Carry Blair Cm0519  <b>MALDI-TOF REAGENTS</b> 1. BTS - #8255343 2. HCCA Matrix - #8255344 3. Bruker standard solvent - #SHBJ5445  <b>ANTIBIOTICS REAGENTS</b> 1. AMPICILLIN (3) 10µg CT0003B 2. AMIKACIN 30µg CT0107B 3. AUGMENTIN 30µg CT02223 4. CEFOTAXIME 30µg CT0166B 5. COTRIMOXAZOLE 1.25/23.75 µg CT0052B 6. CEFTAZIDIME 30µg CT0412B 7. CEFTRIAZONE 30µg CT0417B 8. CEFOXITIN 30µg CT0119B 9. CAZ/CLA 30/10µg 231754 10. CTX/CLA 30/10µg 231752 11. CHLORAMPHENICAL 30µg CT0013B 12. CIPROFLOXACIN 5µg CT0425B 13. GENTAMYCIN 10µg CT0024B 14. IMEPINEM 10µg CT0455B
Malawi	NA	NA
Uganda	NA	NA
Bangladesh	a) Aerobic 37 <sup>0</sup> C incubator b) CO <sub>2</sub> 37 <sup>0</sup> C incubator c) BacAlert 3D d) Eppendorf refrigerated	1. MacConkey agar 2. Mueller Hinton Agar 3. Salmonella-Shigella Agar 4. Cary Blair

	centrifuge e) -80° C So-Low,USA NU80-28	5. Brucella Agar 6. VITEK 2 Reagents <ul style="list-style-type: none"> <li>• Sterile Saline</li> <li>• Disposable Sterile tube</li> <li>• Sterile Volume SalineDispensor</li> <li>• DensiCheck</li> <li>• GP &amp; GN ID Card</li> <li>• GP &amp; GN AST Card</li> </ul> <b>ANTIBIOTICS REAGENTS</b> <ol style="list-style-type: none"> <li>1. AMPICILLIN 10µg</li> <li>2. AMIKACIN 30µg</li> <li>3. AMOXICLAV20/10 µg</li> <li>4. COTRIMOXAZOLE 1.25/23.75 µg</li> <li>5. CEFTAZIDIME 30µg</li> <li>6. CEFTRIAZONE 30µg</li> <li>7. CEFIXIME5µg</li> <li>8. TZP 100/10 µg</li> <li>9. CIPROFLOXACIN 5µg</li> <li>10. GENTAMYCIN 10µg</li> <li>11. IMEPINEM 10µg</li> <li>12. CEFEPIME 30 µg</li> <li>13. CEFUROXIME 30 µg</li> <li>14. MEROPENEM 10µg</li> <li>15. ETRAPENEM 10µg</li> <li>16. COLISTIN 10 µg</li> <li>17. TIGECYCLINE 15 µg</li> <li>18. NALIDIXIC ACID 30 µg</li> </ol>
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### 9.1 Equipment Calibration and Maintenance

Site	Equipment/analyzers	SOP
Kilifi	Coulter AcT 5Diff calibration and maintenance	LSTAT 042
	ILab Aries calibration and maintenance	LSTAT 048
	Bactec FX calibration and maintenance	LMIC 071
	MALDI-TOF calibration and maintenance	LMIC 082 and LMIC 086
Malawi	NA	NA
Uganda	-80°C IBRH3AU Freezer	IBRH3AU-EQP-007
	Gilson 200µl Pipette	IBRH3AU-EQP-002
	Gilson 1000µl Pipette	IBRH3AU-EQP-002
	Thermo Scientific Refrigerated Centrifuge	IBRH3AU-EQP-006
	Class II biosafety cabinet	IBRH3AU-EQP-003
Bangladesh	Beckman Coulter AU680 Operation and maintenance work instruction	BC.WI.020
	Beckman Coulter AU 480 Operation and	BC.WI.025

	maintenance work instruction	
	Olympus AU640 Operation and maintenance work instruction	BC.WI.001
	Sysmex operation and maintenance work Instruction BACTALERT calibration and maintenance VITEK2 calibration and maintenance CENTRIFUGE calibration and maintenance	HE.WI.015 AL.FM.005
Nairobi-Mbagathi	Centrifuge Calibration and Maintenance	LGEQ-008

## 9.2 Reagent validation/Parallel testing

Site	Procedure	SOP
Kilifi	CBC	SOP LHEME-037
	Biochemistry/LFT	LSTAT-052
Malawi	NA	NA
Uganda	CBC	UCILAB-TCE 012
	Chemistry	UCI LAB MGT 022, UCILAB-TCE 012
Bangladesh	CBC	AL.PR.019
	Biochemistry/LFT	AL.PR.021

## 10. Reporting of Test Results

See Appendix A for study/trial reference ranges.

### 10.1 Result reporting, Release and Approval of Reports

Site	Procedure of reporting results
Kilifi	LMIC 035
	LHEME-041
	i-STAT will be filled in i-STAT CRF
Malawi	NA
Uganda	UCI LAB MGT 020
Bangladesh	SR.PR.003
	i-STAT will be filled in i-STAT CRF

### 10.2 Results from External Laboratories

There are currently no samples indicated to be analysed to external labs



## 11.External Quality Assurance

### 11.1 Proficiency Testing

#### Proficiency testing

Site	Test	EQA Program/Provider	Frequency (cycles per year)
Kilifi	Identification of bacteria and AST	UKNEQAS	Monthly
	Biochemistry	RCPA	Monthly
	CBC	UKNEQAS and RCPA	Monthly
	i-STAT	To be identified	Monthly
Malawi	NA	NA	NA
Uganda	Biorepository Proficiency Testing	Integrated Biobank of Luxembourg (IBBL)	Annually
	CBC	UKNEQAS	Monthly
	Serum LFTs and RFTs	UKNEQAS	Monthly
Bangladesh	Identification of bacteria and AST	College of American Pathologists	3 cycles/year
	Biochemistry	College of American Pathologists	3 cycles/year
	CBC	College of American Pathologists	3 cycles/year
	i-STAT	To be identified	Monthly

## 11.2 Audit/Monitoring Program

### Audit/monitoring Program

site	Laboratory Name	Auditors/Monitors	Frequency
Kilifi	KEMRI-Wellcome trust Haematology Laboratory	Qualogy CLS	1 x annually 2 x annually
	KEMRI-Wellcome trust microbiology Laboratory	Qualogy	1 x annually
Malawi			
Uganda	Integrated Biorepositor y of H3Africa Uganda – IBRH3AU	N/A	N/A
	Uganda Cancer Institute Laboratories	East Africa Public Health Laboratory Networking Project (EAPHLNP)/MoH	Annually
Bangladesh	Clinical Biochemistry laboratory, Clinical Microbiology Laboratory, Haematology and Clinical Pathology Laboratory	<ol style="list-style-type: none"> <li>1. QMS Audit (Internal audit)</li> <li>2. External Assessment (Accreditation audit) by BLQS, Thailand</li> </ol>	<ol style="list-style-type: none"> <li>1. Annually</li> <li>2. Biannual on-site assessment</li> </ol>

**11.3 Appendices (Provide all the tables and list of information relevant to the project)**

**Appendix A: Reference Ranges: KILIFI HAEMATOLOGY REFERENCE VALUES**

**Kilifi Paediatric Community Reference Values for Haematology:  
Table 1a: Age: 1-5 Months 95% CI**

<b>HEMATOLOGY COMPLETE BLOOD COUNT</b>	<b>Sample Size (N)</b>	<b>LOWER RANGE</b>	<b>UPPER RANGE</b>	<b>S.I UNITS</b>
<b>RBC (Total count)</b>	<b>428</b>	<b>2.85</b>	<b>5.34</b>	<b>(x10<sup>6</sup>) cells/μL</b>
<b>Haemoglobin (Hb)</b>	<b>499</b>	<b>8.1</b>	<b>14.0</b>	<b>g/dL</b>
<b>Haematocrit (HCT)</b>	<b>423</b>	<b>24.6</b>	<b>42.1</b>	<b>%</b>
<b>Mean Cell Volume (MCV)</b>	<b>431</b>	<b>57</b>	<b>100</b>	<b>fL</b>
<b>Mean Cell Haemoglobin (MCH)</b>	<b>62</b>	<b>15.9</b>	<b>33.6</b>	<b>pg</b>
<b>Mean Cell Haemoglobin Concentration (MCHC)</b>	<b>62</b>	<b>30.0</b>	<b>34.2</b>	<b>g/dL</b>
<b>Platelets (PLT)</b>	<b>427</b>	<b>52</b>	<b>752</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>WBC (Total count)</b>	<b>414</b>	<b>5.1</b>	<b>14.9</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Neutrophils: (ABS)</b>	<b>313</b>	<b>0.57</b>	<b>4.03</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Neutrophils %</b>	<b>313</b>	<b>9.1</b>	<b>35.1</b>	<b>%</b>
<b>Lymphocytes (ABS)</b>	<b>331</b>	<b>3.12</b>	<b>9.44</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Lymphocytes (%)</b>	<b>331</b>	<b>44.2</b>	<b>78.0</b>	<b>%</b>
<b>Monocytes (ABS)</b>	<b>317</b>	<b>0.29</b>	<b>1.90</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Monocytes (%)</b>	<b>317</b>	<b>4.0</b>	<b>18.9</b>	<b>%</b>
<b>Eosinophils (ABS)</b>	<b>307</b>	<b>0.07</b>	<b>0.71</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Eosinophils (%)</b>	<b>307</b>	<b>0.8</b>	<b>6.9</b>	<b>%</b>
<b>Basophil (ABS)</b>	<b>289</b>	<b>0.01</b>	<b>0.13</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Basophil (%)</b>	<b>289</b>	<b>0.1</b>	<b>1.9</b>	<b>%</b>

## Kilifi Paediatric Community Reference Values for Haematology:

**Table 1b: Age: 6-11 Months 95% CI**

HEMATOLOGY COMPLETE BLOOD COUNT	Sample Size (N)	LOWER RANGE	UPPER RANGE	S.I UNITS
RBC (Total count)	757	3.80	5.78	(x10 <sup>6</sup> ) cells/μL
Haemoglobin (HGB)	836	7.2	11.5	g/dL
Haematocrit (HCT)	755	23.7	35.8	%
Mean Cell Volume (MCV)	764	52	78	fL
Mean Cell Haemoglobin (MCH)	400	15.3	25.6	pg
Mean Cell Haemoglobin Concentration (MCHC)	395	29.0	33.5	g/dL
Platelets (PLT)	753	89	789	(x10 <sup>3</sup> ) cells/μL
WBC (Total count)	746	6.0	17.2	(x10 <sup>3</sup> ) cells/μL
Neutrophils: (ABS)	642	0.98	4.38	(x10 <sup>3</sup> ) cells/μL
Neutrophils %	642	10.2	38.5	%
Lymphocytes (ABS)	650	3.39	11.00	(x10 <sup>3</sup> ) cells/μL
Lymphocytes (%)	650	44.2	77.6	%
Monocytes (ABS)	646	0.30	1.86	(x10 <sup>3</sup> ) cells/μL
Monocytes (%)	646	3.2	15.7	%
Eosinophils (ABS)	634	0.06	1.11	(x10 <sup>3</sup> ) cells/μL
Eosinophils (%)	634	0.7	10.7	%
Basophil (ABS)	649	0.01	0.30	(x10 <sup>3</sup> ) cells/μL
Basophil (%)	649	0.1	2.4	%

## Kilifi Paediatric Community Reference Values for Haematology:

**Table1c: Age:     12-59    Months 95% CI**

HEMATOLOGY COMPLETE BLOOD COUNT	Sample Size (N)	LOWER RANGE	UPPER RANGE	S.I UNITS
<b>RBC (Total count)</b>	<b>988</b>	<b>3.84</b>	<b>5.92</b>	<b>(x10<sup>6</sup>) cells/μL</b>
<b>Haemoglobin (HGB)</b>	<b>1094</b>	<b>7.6</b>	<b>12.2</b>	<b>g/dL</b>
<b>Haematocrit (HCT)</b>	<b>982</b>	<b>25.7</b>	<b>37.3</b>	<b>%</b>
<b>Mean Cell Volume (MCV)</b>	<b>992</b>	<b>52</b>	<b>82</b>	<b>fL</b>
<b>Mean Cell Haemoglobin (MCH)</b>	<b>714</b>	<b>16.1</b>	<b>28.3</b>	<b>pg</b>
<b>Mean Cell Haemoglobin Concentration (MCHC)</b>	<b>706</b>	<b>29.5</b>	<b>34.1</b>	<b>g/dL</b>
<b>Platelets (PLT)</b>	<b>968</b>	<b>139</b>	<b>730</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>WBC (Total count)</b>	<b>966</b>	<b>5.1</b>	<b>16.3</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Neutrophils: (ABS)</b>	<b>851</b>	<b>1.12</b>	<b>5.27</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Neutrophils %</b>	<b>851</b>	<b>12.8</b>	<b>51.8</b>	<b>%</b>
<b>Lymphocytes (ABS)</b>	<b>858</b>	<b>2.50</b>	<b>10.39</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Lymphocytes (%)</b>	<b>858</b>	<b>36.9</b>	<b>74.8</b>	<b>%</b>
<b>Monocytes (ABS)</b>	<b>854</b>	<b>0.21</b>	<b>1.42</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Monocytes (%)</b>	<b>854</b>	<b>2.8</b>	<b>12.6</b>	<b>%</b>
<b>Eosinophils (ABS)</b>	<b>836</b>	<b>0.07</b>	<b>1.07</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Eosinophils (%)</b>	<b>836</b>	<b>0.7</b>	<b>10.2</b>	<b>%</b>
<b>Basophil (ABS)</b>	<b>823</b>	<b>0.01</b>	<b>0.25</b>	<b>(x10<sup>3</sup>) cells/μL</b>
<b>Basophil (%)</b>	<b>823</b>	<b>0.1</b>	<b>2.0</b>	<b>%</b>

**Kilifi Paediatric Community Reference Values for Clinical Chemistry:  
Table 2a: Age: 1 - 5 Months.95% CI**

PARAMETERS	Sample Size (N)	LOWER RANGE	UPPER RANGE	S.I UNITS
ALANINE AMINOTRANSFERASE ALT (SGPT)	86	7	35	IU/L
ASPARTATE AMINOTRANSFERASE AST (SGOT) †	352	31	63	IU/L
TOTAL BILIRUBIN(T.Bil) †	292	2	9	µmol/L
DIRECT BILIRUBIN †	276	0	3	µmol/L
CREATININE	91	26	43	µmol/L
TOTAL PROTEIN ‡	220	63	83	g/L
ALBUMIN	297	36.0	51.3	g/L
OSMOLALITY ‡	220	269	288	Mosmol/L
CHLORIDE (CL) ‡	220	100	111	mmol/L
GAMMA GLUTAMYL TRANSFERASE (GGT)	294	9	33	IU/L
INORGANIC PHOSPHATE (IN. PHOS) ‡	220	1.27	2.63	mmol/L
UREA *	51	0.6	2.4	mmol/L
SODIUM (Na) *	55	133	139	mmol/L
POTASSIUM (K) *	53	3.9	5.4	mmol/L
CALCIUM (Ca) ‡	220	1.93	2.58	mmol/L
MAGNESIUM (Mg) ‡	220	0.55	1.04	mmol/L
BLOOD GLUCOSE §	507	3.9	6.4	mmol/L

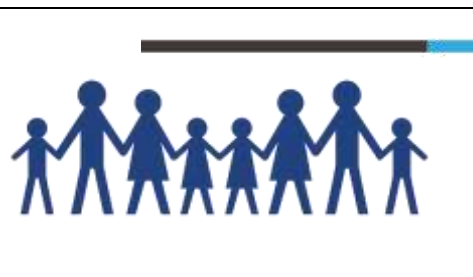
KEY: †Picked from 12-59 months table 2c, ‡ Picked from Kilifi Paediatric Community Reference Values for Clinical Chemistry V2: November 2005, \*Picked from 6-11 months table 2b, §Picked from 60-215 months table 2d

**Kilifi Paediatric Community Reference Values for Clinical Chemistry:**

**Table 2b: Age: 6 - 11 Months.95% CI**

<b>PARAMETERS</b>	<b>Sample Size (N)</b>	<b>LOWER RANGE</b>	<b>UPPER RANGE</b>	<b>S.I UNITS</b>
<b>ALANINE AMINOTRANSFERASE ALT (SGPT)</b>	<b>278</b>	<b>10</b>	<b>33</b>	<b>IU/L</b>
<b>ASPARTATE AMINOTRANSFERASE AST (SGOT)<sup>†</sup></b>	<b>352</b>	<b>31</b>	<b>63</b>	<b>IU/L</b>
<b>TOTAL BILIRUBIN (T. Bil)<sup>†</sup></b>	<b>292</b>	<b>2</b>	<b>9</b>	<b>µmol/L</b>
<b>DIRECT BILIRUBIN<sup>†</sup></b>	<b>276</b>	<b>0</b>	<b>3</b>	<b>µmol/L</b>
<b>CREATININE</b>	<b>279</b>	<b>25</b>	<b>45</b>	<b>µmol/L</b>
<b>TOTAL PROTEIN<sup>‡</sup></b>	<b>220</b>	<b>63</b>	<b>83</b>	<b>g/L</b>
<b>ALBUMIN<sup>†</sup></b>	<b>297</b>	<b>36.0</b>	<b>51.3</b>	<b>g/L</b>
<b>OSMOLALITY<sup>‡</sup></b>	<b>220</b>	<b>269</b>	<b>288</b>	<b>Mosmol/L</b>
<b>CHLORIDE (CL)<sup>‡</sup></b>	<b>220</b>	<b>100</b>	<b>111</b>	<b>mmol/L</b>
<b>GAMMA GLUTAMYL TRANSFERASE (GGT)<sup>†</sup></b>	<b>294</b>	<b>9</b>	<b>33</b>	<b>IU/L</b>
<b>INORGANIC PHOSPHATE (IN. PHOS)<sup>‡</sup></b>	<b>220</b>	<b>1.27</b>	<b>2.63</b>	<b>mmol/L</b>
<b>UREA</b>	<b>51</b>	<b>0.6</b>	<b>2.4</b>	<b>mmol/L</b>
<b>SODIUM (Na)</b>	<b>55</b>	<b>133</b>	<b>139</b>	<b>mmol/L</b>
<b>POTASSIUM (K)</b>	<b>53</b>	<b>3.9</b>	<b>5.4</b>	<b>mmol/L</b>
<b>CALCIUM (Ca)<sup>‡</sup></b>	<b>220</b>	<b>1.93</b>	<b>2.58</b>	<b>mmol/L</b>
<b>MAGNESIUM (Mg)<sup>‡</sup></b>	<b>220</b>	<b>0.55</b>	<b>1.04</b>	<b>mmol/L</b>
<b>BLOOD GLUCOSE<sup>§</sup></b>	<b>507</b>	<b>3.9</b>	<b>6.4</b>	<b>mmol/L</b>

**KEY:** <sup>†</sup>Picked from 12-59 months table 2c, <sup>‡</sup> Picked from Kilifi Paediatric Community Reference Values for Clinical Chemistry V2: November 2005, <sup>§</sup> Picked from 60-215 months table 2d

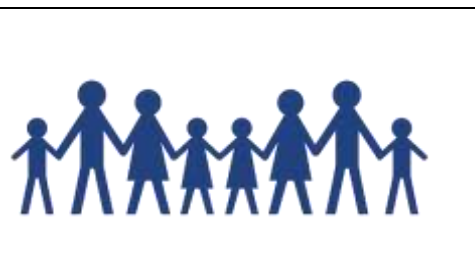


**Kilifi Paediatric Community Reference Values for Clinical Chemistry:  
Table 2c: Age: 12- 59 Months.95% CI**

PARAMETERS	Sample Size (N)	LOWER RANGE	UPPER RANGE	S.I UNITS
ALANINE AMINOTRANSFERASE ALT (SGPT)	513	11	35	IU/L
ASPARTATE AMINOTRANSFERASE AST (SGOT)	352	31	63	IU/L
TOTAL BILIRUBIN (T. Bil)	292	2	9	µmol/L
DIRECT BILIRUBIN	276	0	3	µmol/L
CREATININE	517	25	48	µmol/L
TOTAL PROTEIN <sup>‡</sup>	220	63	83	g/L
ALBUMIN	297	36.0	51.3	g/L
OSMOLALITY <sup>‡</sup>	220	269	288	Mosmol/L
CHLORIDE (CL) <sup>‡</sup>	220	100	111	mmol/L
GAMMA GLUTAMYL TRANSFERASE (GGT)	294	9	33	IU/L
INORGANIC PHOSPHATE (IN. PHOS) <sup>‡</sup>	220	1.27	2.63	mmol/L
UREA	53	0.9	4.4	mmol/L
SODIUM (Na)	52	135	140	mmol/L
POTASSIUM (K)	52	3.68	5.07	mmol/L
CALCIUM (Ca) <sup>‡</sup>	220	1.93	2.58	mmol/L
MAGNESIUM (Mg) <sup>‡</sup>	220	0.55	1.04	mmol/L
BLOOD GLUCOSE <sup>§</sup>	507	3.9	6.4	mmol/L

**KEY:** <sup>‡</sup> Picked from Kilifi Paediatric Community Reference Values for Clinical Chemistry V2:  
November 2005, <sup>§</sup> Picked from 60-215 months table 2d





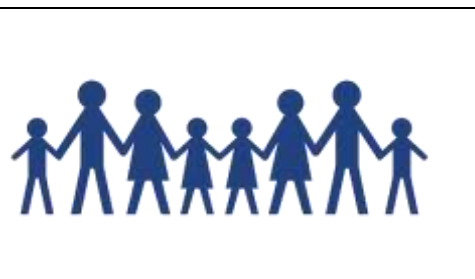
# Childhood Acute Illness & Nutrition Network

**Pancreatic Enzymes and Bile Acids:  
A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill  
Severely Malnourished Children**

**DOCUMENT TITLE: Laboratory Analytical Plan Template**

## BANGLADESH HAEMATOLOGY REFERENCE VALUES

HEMATOLOGY COMPLETE BLOOD COUNT	Children (6 months-6 years)	UNIT
RBC (Total count)	3.81-4.74	$\times 10^{12}/L$
Haemoglobin (HGB)	11.0-14.0	g/dL
Haematocrit (HCT)	30.5-37.0	%
Mean Cell Volume (MCV)	75.6-84.1	fL
Platelets (PLT)	150-400	$\times 10^9/L$
WBC (Total count)	6.0-17.5	$\times 10^9/L$
Neutrophils: %	22.7-77.5	%
Neutrophils (Abs)	1.0-8.5	$\times 10^9/L$
Lymphocytes %	11.0-70.0	%
Lymphocytes (Abs.)	4.0-12.0	$\times 10^9/L$
Monocytes %	4.0-10.0	%
Monocytes (Abs.)	0.2-1.0	$\times 10^9/L$
Eosinophils %	1.0 - 5.0	%
Eosinophils (Abs.)	.81	$\times 10^9/L$
Basophil %	0.0 - 1.0	%
Basophil (Abs.)	0.21	$\times 10^9/L$
CD4 T Cell count (Abs)	500-1500	$\times 10^3/\mu L$
CD8 T Cell count(Abs.)	220-1400	$\times 10^3/\mu L$



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### Chemistry Reference Values

PARAMETERS	Unit	Reference Range			
		MALE (N = 167)			
		General	Children, age specific reference range (Male)	General	Children, age specific reference range (Female)
<b>Albumin</b>	<b>g/L</b>	<b>35-52</b>	28-44 (0-4 day),	<b>35-52</b>	28-44 (0-4 day),
<b>T. Protein (Blood)</b>	<b>g/L</b>	<b>66-83</b>	57-80 (Child, 1-18 y), 41-63(1-30day))	<b>66-83</b>	57-80 (Child, 1-18 y), 41-63(1-30day))
<b>BUN</b>	<b>mg/dl</b>	<b>6-20</b>	<b>6-12</b>	<b>6-20</b>	<b>6-12</b>
<b>CRP (Quantitative)</b>	<b>mg/dl</b>	<0.5	<0.5	<0.5	<0.5
<b>S. Inorg. Phosphorous</b>	<b>mmol/L</b>	<b>0.81-1.45</b>	0.81-1.45 (Adult) 1.29 – 2.26 (Child)	<b>0.81-1.45</b>	0.81-1.45 (Adult) 1.29 – 2.26 (Child)
<b>T. Calcium</b>	<b>mmol/L</b>	<b>2.2-2.65</b>	1.9-2.60 (0-1day) 2.25-2.75 (10d-24m) 2.2-2.7 (2y-12y),	<b>2.2-2.65</b>	1.9-2.60 (0-1day), 2.25-2.75 (10d-24m), 2.2-2.7 (2y-12y),
<b>T. Magnesium</b>	<b>mmol/L</b>	<b>0.73-1.06</b>	0.70-0.95 (5 mo-6 y), 0.70-0.86 (6 y-12 y).	<b>0.77-1.03</b>	0.70-0.95 (5 mo-6 y), 0.70-0.86 (6 y-12 y).
<b>Urea</b>	<b>mmol/L</b>	<b>2.8-7.2</b>	1.4-4.3 (newborn), 1.8-6.4 (infant/ children),	<b>2.8-7.2</b>	1.4-4.3 (newborn), 1.8-6.4 (infant/ children),



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<b>ALKALINE PHOSPHATASE (ALP)</b>	<b>U/L</b>	<b>30-120 (&gt;17yrs)</b>	75-316 (1-30 days), 82-383 (30d-1y), 104-345 (1y-3y), 93-309(4y-6y), 86-315 (7y-9y), 42-362 (10y-12y), 74-390 (13y-15y), 52-171(15y-18y)	<b>30-120 (&gt;17yrs)</b>	48-406 (1-30 days), 124-341 (30d-1y), 107-317 (1y-3y), 96-297 (4y-6y), 69-325(7y-9y), 21-332 (10y-12y), 50-162 (13y-15y), 47-119(15y-18y)
<b>ALANINE AMINOTRANSFERASE ALT (SGPT)</b>	<b>U/L</b>	<b>&lt;50</b>	13-45 (newborn/infant)	<b>&lt;35</b>	13-45 (newborn/infant)
<b>ASPARTATE AMINOTRANSFERASE AST (SGOT)</b>	<b>U/L</b>	<b>&lt;50</b>	25-75 (newborn), 15-60(infant)	<b>&lt;35</b>	25-75 (newborn), 15-60(infant)
<b>TOTAL BILIRUBIN(T.Bil)</b>	<b>µmol/l</b>	<b>5.0-21.0</b>	24-149 (0-1d), 58-179(1-2day), 26-205(3-5day), 17-240 (premature 0-5day)	<b>5.0-21.0</b>	24-149 (0-1d), 58-179(1-2day), 26-205(3-5day), 17-240 (premature 0-5day)
<b>DIRECT BILIRUBIN</b>	<b>µmol/l</b>	<b>&lt; 3.4</b>		<b>&lt; 3.4</b>	
<b>Sodium</b>	<b>mmol/L</b>	136.0-145.0		136.0-145.0	
<b>Potassium</b>	<b>mmol/L</b>	3.5-5.1 (Serum), 3.5-4.5 (Plasma)		3.5-5.1 (Serum), 3.5-4.5 (Plasma)	
<b>Chloride</b>	<b>mmol/L</b>	98.0-107.0		98.0-107.0	

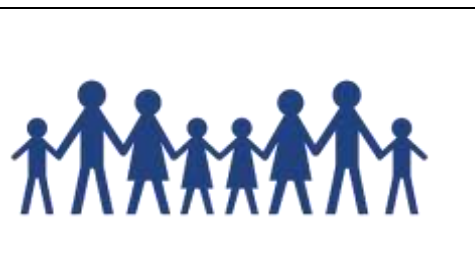


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<b>TCO2/Bicarbonate</b>	<b>mmol/L</b>	<b>23.0-29.0</b>	20.0-28.0 (Child), 16-24 (2m-2Y), 19-24 (infant)	<b>23.0-29.0</b>	20.0-28.0 (Child), 16-24 (2m-2Y), 19-24 (infant)
<b>CREATININE</b>	<b>μmol/l</b>	<b>64 - 104</b>	22-90 (neonate), 11 - 34 (Infant), 21 - 65 (Child)	<b>49 - 90</b>	22-90 (neonate), 11 - 34 (Infant), 21 - 65 (Child)
<b>IgG</b>	<b>mg/dl</b>	<b>700-1600</b>		<b>700-1600</b>	
<b>LDH</b>	<b>U/L</b>	<b>&lt;248 U/L</b>	110-295 (2-12 y) 180-430 (10 d-2 y) 545-2000 (4-10 day) 290-775 (0-4day)	<b>&lt;247 U/L</b>	110-295 (2-12 y) 180-430 (10 d-2 y) 545-2000 (4-10 day) 290-775 (0-4day)
<b>S. Amylase</b>	<b>U/L</b>	22-80		22-80	
<b>CK / CPK</b>	<b>U/L</b>	<b>≤171</b>		<b>≤145</b>	



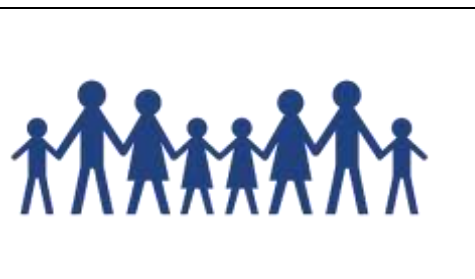
## Childhood Acute Illness & Nutrition Network

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Uganda Haematology reference ranges:

HEMATOLOGY COMPLETE BLOOD COUNT	Children (2 months-6 years)	Reference ranges	UNIT
<b>RBC (Total count)</b>	61-730 days	3.4-5.2	x10 <sup>12</sup> /L
	2-6 years	3.3-4.9	x10 <sup>12</sup> /L
<b>Haemoglobin (HGB)</b>	61-730 days	7.2-12.7	g/dL
	2-6 years	11.5-13.5	g/dL
<b>Haematocrit (HCT)</b>	181-730 days	33-39	%
	2-6 years	34-40	%
<b>Mean Cell Volume (MCV)</b>	181-730 days	70-86	fL
	2-6 years	75-87	fL
<b>MCH</b>	61-730 days	24.2-30.0	pg
	2-12 years	24.6-30.9	pg
<b>MCHC</b>	181-730 days	30.0-36.0	g/dL
	2-6 years	31.0-37.0	g/dL
<b>RDW</b>	61-730 days	12.1-16.2	%
	2-12 years	11.8-14.9	%
<b>Platelets (PLT)</b>	91-730 days	140-635	x10 <sup>9</sup> /L
	2-6 years	150-350	x10 <sup>9</sup> /L
<b>WBC (Total count)</b>	366-730 days	3.6-16.4	x10 <sup>9</sup> /L

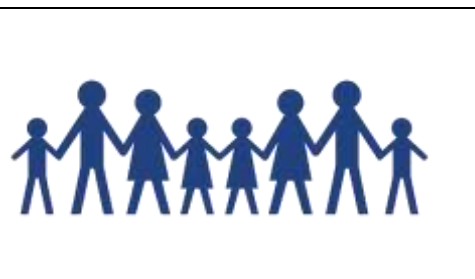


# Childhood Acute Illness & Nutrition Network

## Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children

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	2-6 years	5.0-15.5	x10 <sup>9</sup> /L
<b>Neutrophils: %</b>	61-730 days	20.7-61.8	%
	2-12 years	32.3-76.9	%
<b>Neutrophils (Abs)</b>	61-730 days	1.5-8.5	x10 <sup>9</sup> /L
	2-6 years	1.5-8.0	x10 <sup>9</sup> /L
<b>Lymphocytes %</b>	366-730 days	28-70	%
	2-6 years	14.3-50.6	%
<b>Lymphocytes (Abs.)</b>	366-730 days	1.1-8.6	x10 <sup>9</sup> /L
	2-6 years	1.5-7.0	x10 <sup>9</sup> /L
<b>Monocytes %</b>	61-730 days	3.3-18.1	%
	2-12 years	4.2-13.3	%
<b>Monocytes (Abs.)</b>	61-730 days	0.3-1.9	x10 <sup>9</sup> /L
	2-12 years	0.4-1.1	x10 <sup>9</sup> /L
<b>Eosinophils %</b>	61-730 days	0-3.1	%
	2-12 years	0-4.0	%
<b>Eosinophils (Abs.)</b>	61-730 days	0-0.2	x10 <sup>9</sup> /L
	2-12 years	0-0.2	x10 <sup>9</sup> /L
<b>Basophil %</b>	61-730 days	0-1.1	%
	2-12 years	0-1.1	%
<b>Basophil (Abs.)</b>	61-730 days	0-0.2	x10 <sup>9</sup> /L
	2-12 years	0-0.2	x10 <sup>9</sup> /L



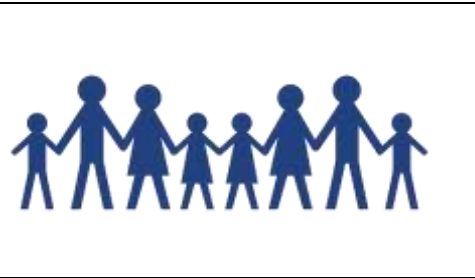
## Childhood Acute Illness & Nutrition Network

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Uganda Chemistry reference ranges:

<b>BIOCHEMISTRY PEADIATRIC PANEL REFERENCE RANGES</b>			
<b>Test</b>	<b>Age</b>	<b>Reference Ranges</b>	<b>Units</b>
ALB	5 days -14 yr.	38 – 54	g/L
ALP	6 – 180 days	0- 449	U/L
	7-12 months	0- 462	U/L
	1-3yr	0- 281	U/L
	4-6yr	0- 269	U/L
ALT	31- 60days	5 - 55	U/L
	61 – 180 days	0- 60	U/L
	7-12 months	0- 57	U/L
	1-3yr	0 - 39	U/L
	4-6yr	0 - 39	U/L
AST	6 – 180 days	0- 84	U/L
	7-12 months	0- 89	U/L
	1-3yr	0- 56	U/L
	4-6yr	0- 52	U/L
Total Bilirubin	8- 60 days	0 – 3.59	µmol/L
	61days- 18 days	0-17.1	µmol/L
Direct Bilirubin	Infants/children	< 5.13	µmol/L
GGT	6 – 180 days	0 -204	U/L
	7-12 months	0-34	U/L
	1-3yr	0 – 18	U/L
	4-6yr	0-23	U/L
TP	2-12months	48-76	g/L
	>1yr	60-80	g/L
CREATININE	2-12months	0 – 34.48	µmol/L
	1-3yr	0- 30.95	µmol/L
	4-5yr	37.14	µmol/L



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UREA	0-6months	0 – 15	mmol/L
	0.5-18yrs	0 – 17.14	mmol/L
Cl <sup>-</sup>	1-12months	93 - 112	mmol/L
	1-18 yrs	96 - 111	mmol/L
K <sup>+</sup>	1-12months	3.6 – 5.8	mmol/L
	1-18 yrs	3.1 – 5.1	mmol/L
Na <sup>+</sup>	1-12months	129 - 143	mmol/L
	1-18 yrs	132 - 145	mmol/L

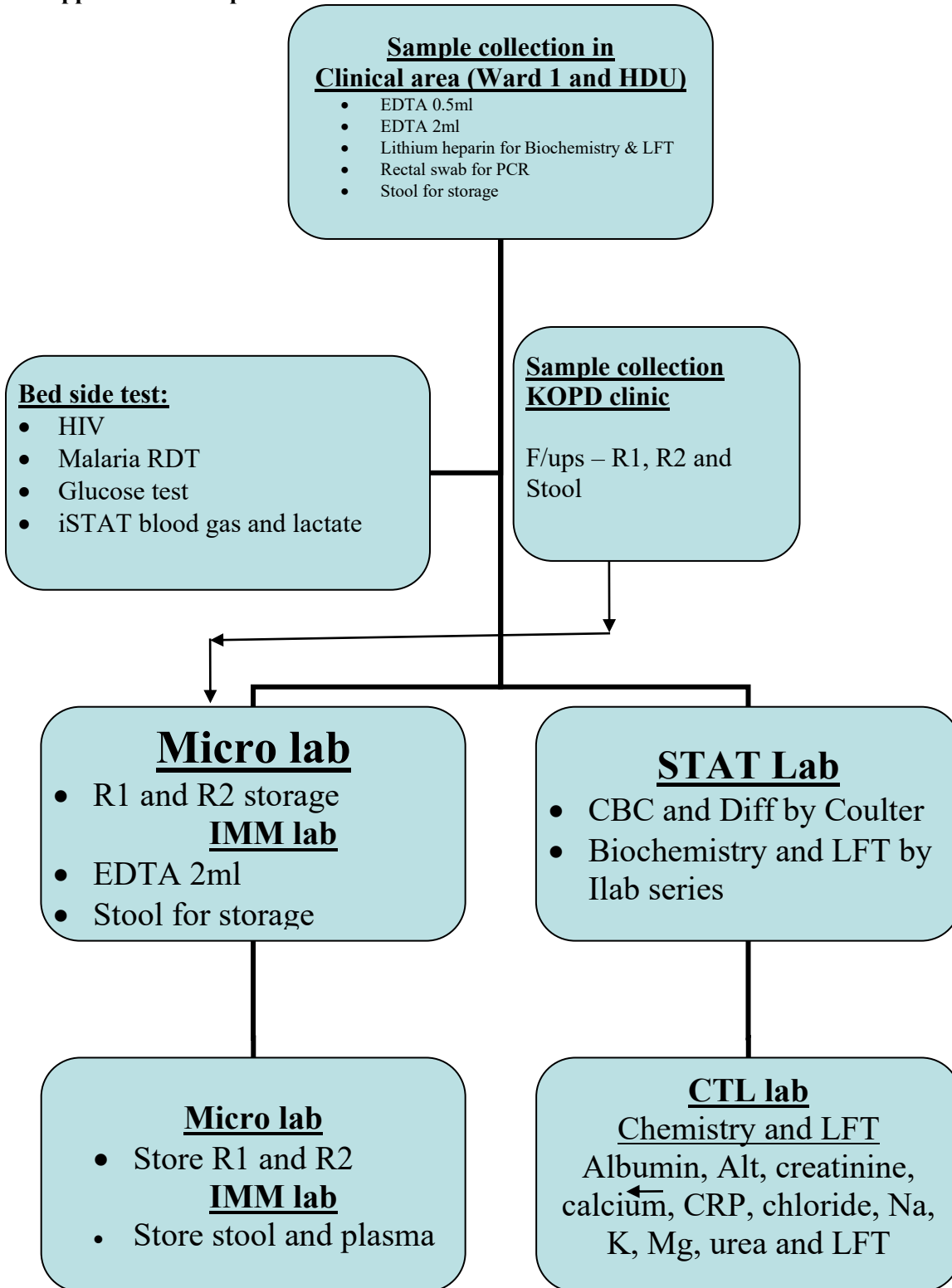
**Appendix B: Laboratory Accreditation certificates**

This is a place holder for the accreditation certificates.





**Appendix C: Sample Flow Charts for kilifi**



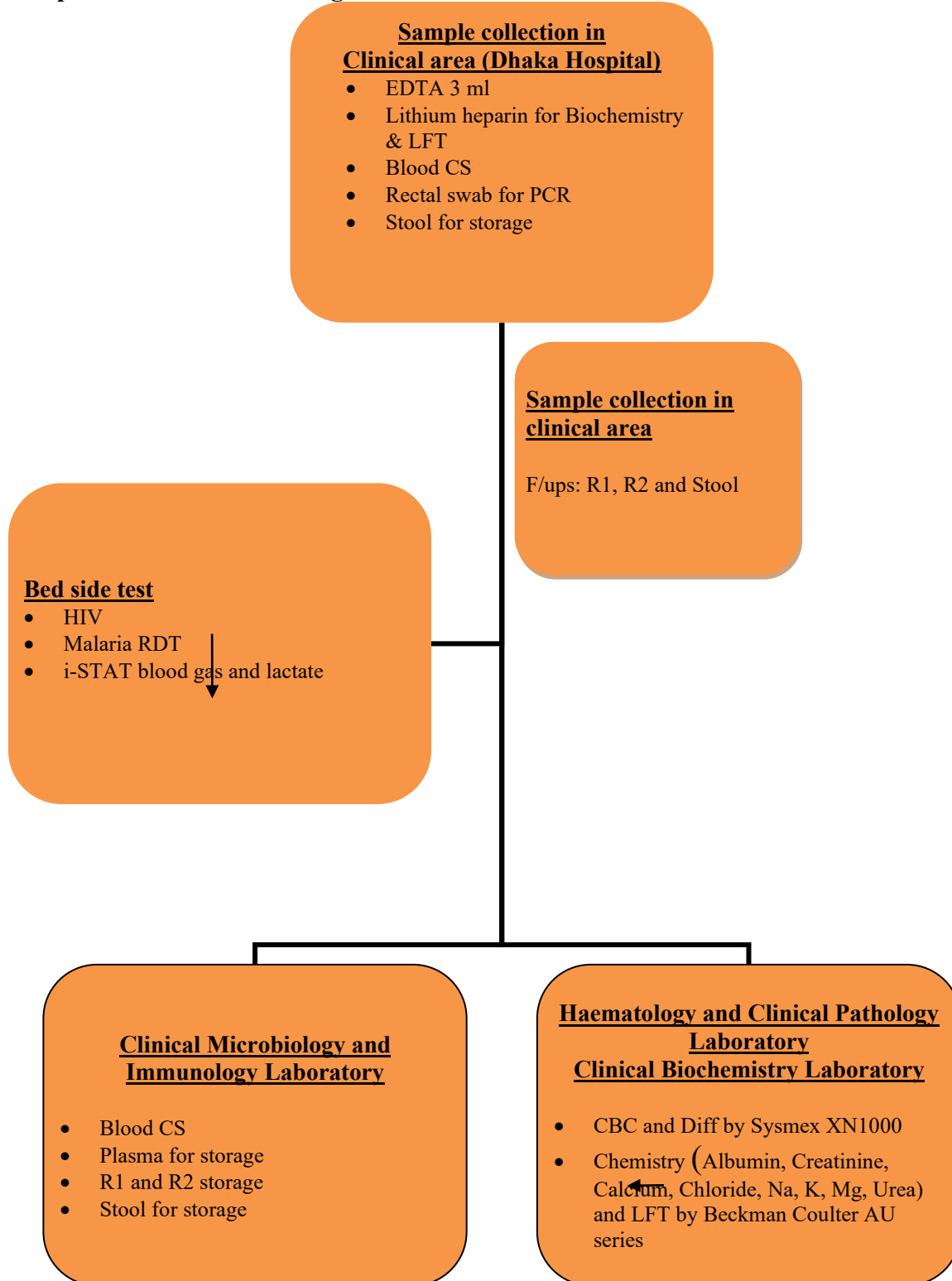


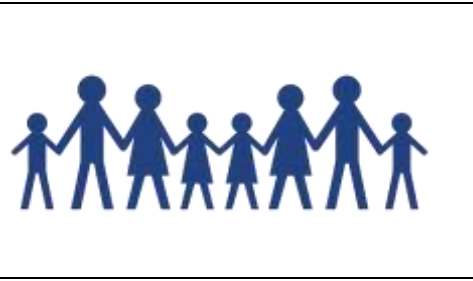
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## Sample Flow Charts for Bangladesh



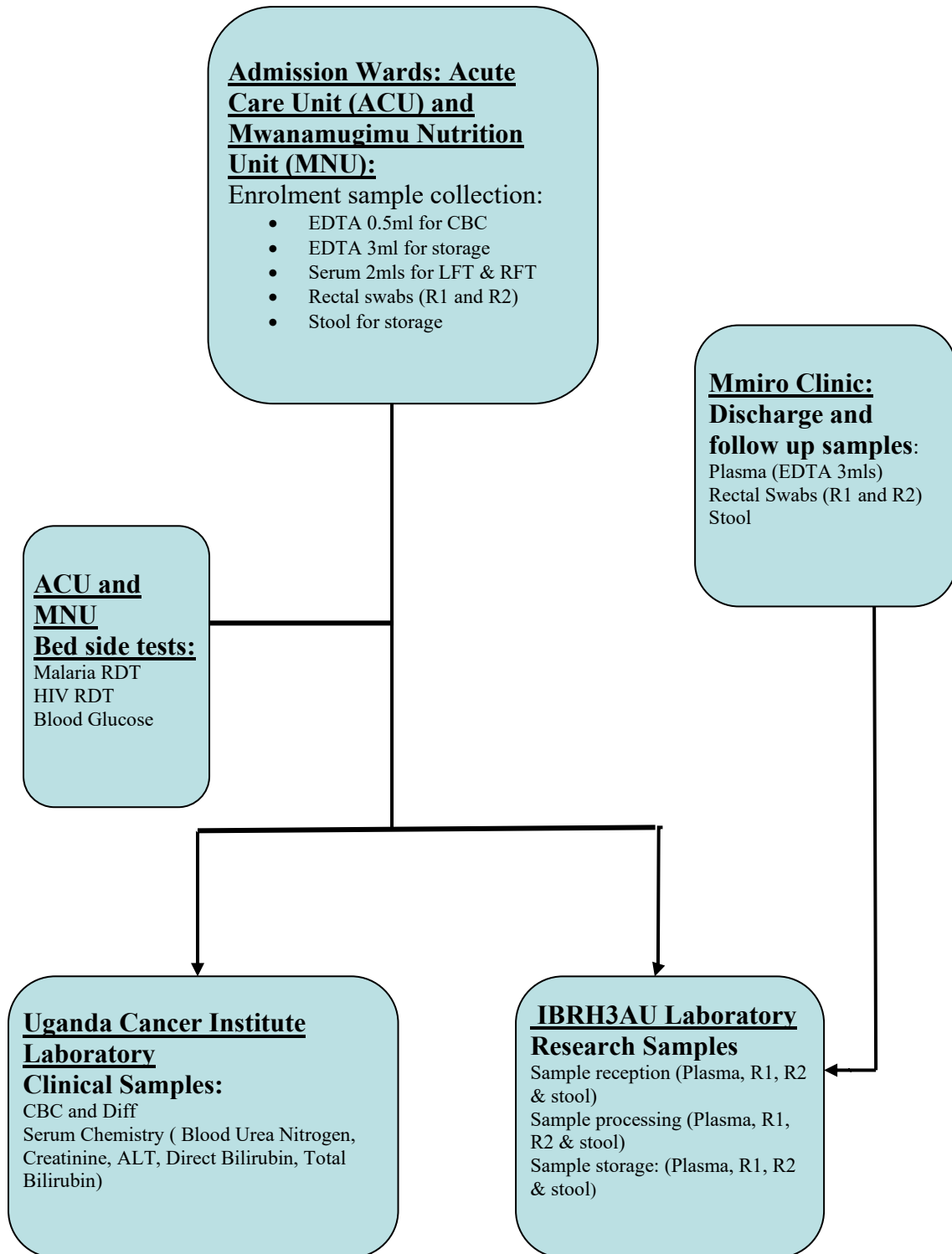


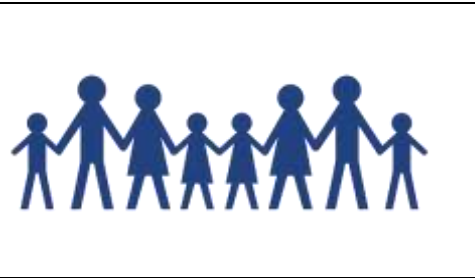
Childhood Acute Illness & Nutrition Network

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Sample flow chart for Kampala (Uganda)



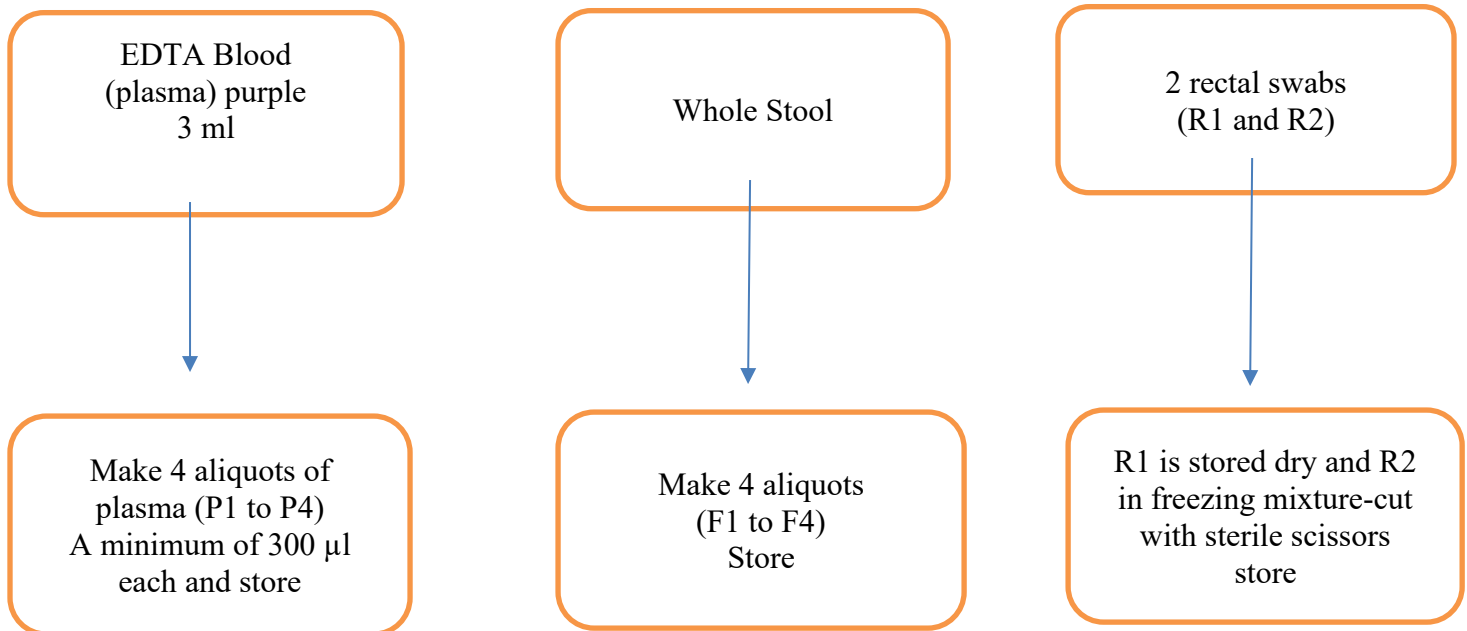


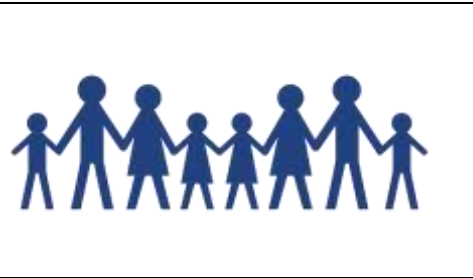
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## Sample Flow Charts for Malawi





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## Sample Flow Chart For Mbagathi Site.

Sample collection in Kemri WT Mbagathi county hospital clinical room/Mbagathi County Hospital ward 3  
AO,DO,

- Clinical samples/POC testing
  - Malaria RDT
  - HIV RDT
  - Blood Glucose
- Research Samples(Transported to Mbagathi STAT Lab)
  - EDTA 3ml for storage
  - Rectal swabs (R1 and F2)
  - Stool for storage

Sample collection in Kemri WT Mbagathi county hospital clinical room  
F/UPS

- Rectal Swabs (R1 and R2)
- Stool

MABAGATHI STAT LAB  
Sample reception and processing of:

- EDTA 3ml for storage
- Rectal swabs (R1 and R2)
- Stool for storage

EDTA Blood (plasma) purple 3 ml

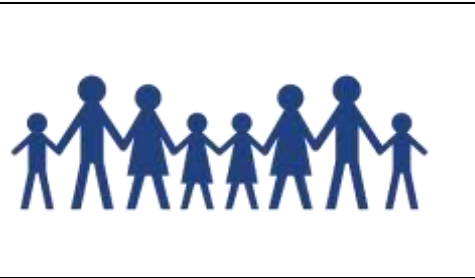
Whole Stool

2 rectal swabs (R1 and R2)

Make 4 aliquots of plasma (P1 to P4)  
A minimum of 300 µl each and store (-80 degrees freezer)

Make 4 aliquots (F1 to F4)  
Store (-80 degrees freezer)

R1 is stored dry and R2 in freezing mixture-cut with sterile scissors store(-80 degrees freezer)



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Version	Author	Approved by	Dated
<b>1.0 Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children</b>	Robert Musyimi	Robert Bandsma	30/10/2021
<b>2.0 Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children</b>	Robert Musyimi	Robert Bandsma	04/06/2022