KAS BIOTECH LIMITED

PROGRESSIVE REPORT-KBL

Company Background

Kas Biotech Limited, is a Manufacturing company legally registered as per law of Republic of Tanzania holding Certificate of Incorporation of a Company with No. 140992232.

Kas Biotech Limited planned to set up Manufacturing/Assembling facility to indigenously produce Rapid Diagnostic Test Kits devices – IVDD products within Tanzania.

While promoters of Kas Biotech Limited are from Kas Medics Limited-Tanzania, which is well established and reputable importer and distributor of Medical Devices, Diagnostics/Laboratory Equipment, Reagents and consumables, Branded Pharmaceutical Products, Critical Care Products, Radiology & Imaging System, General Hospital Equipment & Furniture who completed various projects successfully all across the country, partnering with Ministry of Health (MoH) as well various Private players and non-Governmental organizations.

Vision:

To become a leader in the global health sector by providing innovative, user-friendly, reliable, safe and affordable *in vitro* diagnostic products (IVDD) for the benefit of patient lives and overall public health.

Mission:

Develop and manufacture *in vitro* diagnostic products with the aim of improving and helping in the diagnosis of diseases to facilitate the patient's health by providing consistent, high-quality products that meet or exceed expectations within shortest time lead-time.

Product Portfolio:

- **Kas Malaria P.f/ Pan Ag kits**
- **Kas Malaria P.f Ag kits**
- **Kas H Pylori Ag kits**
- **Kas H Pylori Ab kits**
- **Kas HCV kits**
- **Kas HCG kits**
- **Kas HBsAg kits**
- **Kas Typhoid IgM / IgG kits**

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1. PLANNED ACTIVITIES FOR THE PERIOD

Establishment of Kas Biotech Limited was based on the Quality Management System to ensure that products that are manufactured attains their Quality, Efficacy and Safety.

The site is located at about 4 km from Julius Nyerere International Airport, located in Industrial Area.

Facility foundation consist of 5 phases

1. Premises Design and Construction,

2. Machinery Commissioning & Installment,

3. Approval from Regulatory bodies (TMDA, BRELA, NEMC etc)

4. Production processes &

5. Launching of products in Market

Design basis of facility is done by implementing & following up GMP Guidelines, regulatory compliances ISO 9001 & ISO 13485 Guidelines, safety and manufacturing capacity in consideration.

Premises and equipment are located, designed, constructed, adapted, and maintained to suit the operation to be carried out.

Their layout and design is in such a way that it is aimed to ensure errors are minimized by manufacturing in a uni-flow direction and ensure cleaning and maintenance is easily achievable in order to avoid contamination and any errors that may cause a decline in the quality of the product.

The premises used for manufacturing, processing, packing and testing, storage purposes are well maintained and adequate to allow orderly and logically placement of equipment and materials.

1. Premises Design and Construction:

Premise construction is divided into two phases i.e. Phase I & Phase II

Phase I production activities involve manufacturing of rapid test kits from semi-finished goods with the use of uncut sheets, refer section 4 for full details of manufacturing.

Phase II will involve the manufacturing of rapid test kits from components of different membranes to make uncut sheets then proceed to align with phase I.

Nature of construction and finishes

The construction of clean room facility is of modular sandwich panels and is adequate and suitable for manufacturing purposes of Medical devices.

Panels are powder coated and washable. All the panel joints are having aluminum coving which are fixed with silicon sealant to avoid accumulation of dust and ease of cleaning.

The manufacturing facility has smooth epoxy flooring.

The utility facilities are kept on the mezzanine floor where there is good air circulation and have adequate space.

The core manufacturing area is provided with two efficient De-Humidifying Units for the sensitive manufacturing rooms to avoid cross contamination.

De-Humidifying Units maintain the relative humidity and room temperatures as stated in the standard operating procedure. We also have backup Dehumidifier.

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The Ground working floor has the following Areas dedicated for specific activity.

Room	**Area (SQ. Mtr)**
Store room	55.33
Day Material Store	16
Coating Room	16
Reagent Prepration Room	16
Dehumidifier Room/ Clean Room-1	7.2
Inprocess Quality Check (IPQC) Room	4.5
Quality Control Lab	26.56
Waste Store room	4.64
Wash room	18
Dehumidifier Room/ Clean Room-2	26.11
Production Office	23.23
Printing Room	23.23
Reagent Filling Area	13.25
Packaging Room	22
Finished Goods Quarantine room	27.78
Finished Goods Warehouse	29
Rejected room	8.91
Corredor-1	20.2
Corredor-2	33.95
Inprocess Quality Check (IPQC) Room	4.27
Changing Room-1 Male	6.91
Changing Room-1 Female	6.91
Total Working Area	**409.98**

Ground Floor, Plot 11, Umoja complex Warehouse - GF09,

Vingunguti Industrial Area, along Nyerere Road, P.O.BOX 7856, Dar Es Salaam

Tel: 255 22 2861737/8 info@kasmedics.com

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Premises Design engineering	Started in March 2021 by hiring a Process Consultant from India.
Infrastructure related procurement	Materials like Panel walls, windows, ducting material, epoxy flooring material & electrical connectors, ceiling light panels we imported from India in March 2021.
Machinery Procurement:	Machines like De-Humidifiers, clean room pass boxes, HEPA ceiling filters which delivers controlled de-humidified environment for carrying out production related processes. The specific parameters like Humidity & Temperature are maintained throughout main production facility rooms.

Facility Details are as under:

- Rapid Diagnostic Test Kits Mfg facility - Class 10,000 Clean Room, Area ~ 7600, sq. feet
- Production Area: HEPA Filtered Clean Air Rooms Class D
- Quality Control Lab:
- Production Machines: Technology Machines from Kin Bio China – Uncut Sheet Cutter, Roller Presser, Cassette assembly machine, Semi- Automatic buffer bottle filling / labelling machine, Laminators, buffer solution m/c
- Man-Material movement: Dedicated PAL & MAL – Personnel & Material Airlocks, GMP Compliance
- Utility Machines: Dehumidifiers to supply controlled clean air meeting mandatory Humidity(Rh) % & Temperature regulations
- Raw & Packaging Materials Area: Dedicated areas for storing Raw & Packaging materials - De-dusting / Quarantine / Cold storage Areas / Hazardous Chemical
- Raw + Packaging Materials sourcing: India / China vendors

Project Engineer	Joined us in June 2021 & we started built up of the facility carrying out following activities:

- EIA Approval from NEMC
- Infrastructure Built up of all areas using Ready Wall Panels
- Electrical fittings Installation

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- De humidifiers Commissioning & Installation
- Epoxy Flooring
- Pass Boxes Installation
- Plumbing
- Laying Utility line like for water
- Fire sensors & Panel commissioning & Installation

All the above-mentioned works completed in October 2021

Thereafter we obtained mandatory approvals from various Government Agencies like TMDA, NEMC, Fire, etc.

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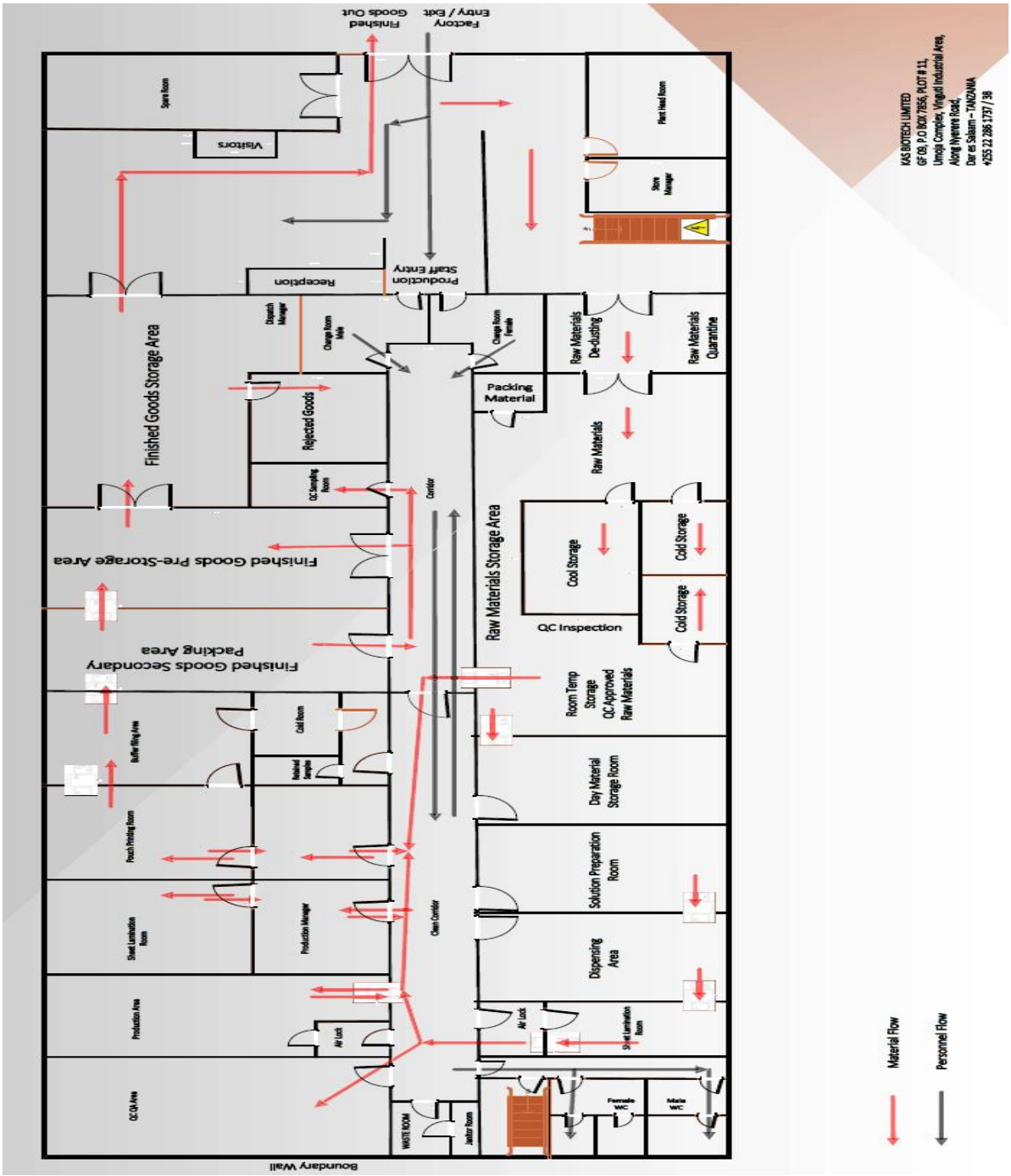
PLANT LAYOUT



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Process & Quality Control Machines Commissioning & Installation

Manufacturing process equipment's located and maintained to suit their intended purpose. They are designed as per GMP standards and are easily cleanable. The equipment's are cleaned on regularly according to written procedures and stored only in a clean and dry condition.

The contact parts of all the equipment used in manufacturing are of stainless steel (SS) and equipment are GMP models. All equipment are designed to follow cGMP norms and ISO 13485 guidelines for easy cleaning and maintenance.

Al the critical equipment's for production and Quality control activities have been Validated & Qualified as per requirement standards.

Process manufacturing machines: Kin Bio China, expert company who delivers systems & machines for medical devices manufacturing facilities.

Commissioning, Installation & Validation completed in February 2022

Quality Control Lab Equipment's: Imported from reputed International companies like Thermo USA, Nuve Turkey, Ohaus Germany, Labfolk India

Commissioning, Installation & Validation completed in March 2022

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Equipment and Instrument List

QUALITY CONTROL DEPARTMENT

SR. NO.	EQUIPMENT NAME	MODLE NO.	MAKE	EQUIPMENT ID
1	Digital Micrometer	YT72305	YATO	KB-QC-E-001
2	Digital Vernier Caliper	17116251	NPT	KB-QC-E-002
3	Microscope	B-192PL	OPTIKA	KB-QC-E-003
4	Weigh Balance	CS-200	OHAUS	KB-QC-E-004
5	pH meter	PH-016		KB-QC-E-005
6	Hot plate Magnetic Stirrer	78-I	KAS MEDICS	KB-QC-E-006
7	Magnetic Stirrer	SB 301	BIBBY SCIENTIFIC LTD	KB-QC-E-007
8	Nuve Water Bath	NB-20	NUVE	KB-QC-E-008
9	pH meter	a-AB33PH	OHAUS	KB-QC-E-009
10	Class-II Bio Safety Cabinet 1300 series A2	300394914	THERMO SCIENTIFIC	KB-QC-E-010
11	Double door Refrigerator TSX series	-	THERMO SCIENTIFIC	KB-QC-E-011
12	-20 Deep Freezer	703CU SR.N.-300100660	THERMO SCIENTIFIC	KB-QC-E-011
13	Hot Air Sterilizer	SR.N.-08	NARANG MRDICAL LIMITED	KB-QC-E-011
14	Centrifuge Machine	41898162	THERMO SCIENTIFIC	KB-QC-E-012
15	Hygrometer 2	TH90	AMTAST	KB-QC-E-013
16	Weigh balance	CS-5000	OHAUS	KB-QC-E-014
17	Weigh balance	S7700HR	FAZZINI	KB-QC-E-015
18	Thermometer 1	-	BRANNAN	KB-QC-I-004
19	Thermometer 2	-	BRANNAN	KB-QC-I-005
20	Thermometer 3	-	BRANNAN	KB-QC-I-006
21	RTD Sensor 1	-		KB-QC-I-007
22	RTD Sensor 2	-		KB-QC-I-008
23	RTD Sensor 3	-		KB-QC-I-009

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24	Velocity Sensor for Class-II A2 BSC 1300			KB-QC-I-010
25	Velocity Sensor for Class-II A2 BCS MS Advantage			KB-QC-I-011
26	Hygrometer 3	TH90	AMTAST	KB-QC-E-016
27	Stability Study Chamber	LI-SC-3(GMP)	LABFOLK	KB-QC-E-017
28	Leak Test Apparatus	-	LABFOLK	KB-QC-E-018
29	Thermometer	-	-	KB-QC-I-012
30	Thermometer	-	-	KB-QC-I-013
31	Thermometer	-	-	KB-QC-I-014
32	Single Door Refrigerator	USS690DTKLM-201000059999	SAFE	KB-QC-E-019

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PRODUCTION DEPARTMENT

SR. NO.	EQUIPMENT NAME	MODLE NO.	MAKE	AREA	EQUIPMENT ID
1	Kinbio Laminator MTB300	MTB300 SR.N.-21260126	KINBIO	Lamination Room	KB-PD-PD001
2	Hygrometer	TH90	AMTAST	Lamination Room	KB-PD-002
3	Kinbio Laminator MTB300	MTB300 SR.N.-21260125	KINBIO	Lamination Room	KB-PD-003
4	Kinbio Laminator MTB300	MTB300 SR.N.-21260124	KINBIO	Lamination Room	KB-PD-004
5	Static Pass Box	-	SUPREME	Lamination Room and Dispensing	KB-PD-005
6	Static Pass Box	-	SUPREME	Lamination Room	KB-PD-006
7	Static Pass Box	-	SUPREME	Cutting Room	KB-PD-007
8	Strip Cutter	ZQ2002 SR.N.-21041346	-	Cutting Room	KB-PD-008
9	Sealing Machine	FR-900 SR.N.- S00011O1O130776013	DINGYE	Cutting Room	KB-PD-009
10	Assembly Roller	YK725 21101395	KINBIO	Cutting Room	KB-PD-010
11	Domino Printer	Ax150i SR.N.- AX0000039176	DOMINO	Pouch Printing	KB-PD-011
12	Class-II Bio Safety Cabinet	SR.N.- 42618257	THERMO SCIENTIFIC	Buffer Filling	KB-PD-012
13	Static Pass Box		SUPREME		KB-PD-013
14	Conveyer Belt				KB-PD-014
15	Hot Oven	DZF 6050		DHU-1	KB-PD-015
16	Vertical labelling Machine	CLT 500-B	Kinbio	Labelling room	KB-PD-016
17	Sealing Machine	000110101307764013		DHU-2	KB-PD-017
18	Sealing Machine	000110101307780013		DHU-2	KB-PD-018
19	Strip Cutter	CTS-300 SR.N.-21180743	KINBIO	Dispensing Room	KB-PD-019
20	XYZ- Dispenser	HM3035 21290323	KINBIO		KB-PD-020
21	Assembly Roller	YK725 21101394	KINBIO	Dispensing Room	KB-PD-021

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MAINTANANCE

SR. NO.	EQUIPMENT NAME	MODLE NO.	MAKE	AREA	EQUIPMENT ID
1	UPS	EP-UPS6501442-UK	EUT	Server Room	KB-MN-E-001
2	Desktop	9B1939A21200	DELL	Reception	KB-MN-E-002
3	UPS	BV6501-MSK	APC	Reception	KB-MN-E-003
4	Dehumidifier 1	194A	SUPREME	Utility Area	KB-MN-E-004
5	Dehumidifier 2	194A	SUPREME	Utility Area	KB-MN-E-005
6	Magnehelic Guage1		DAWYER	Production	KB-MN-I-001
7	Magnehelic guage2		DAWYER	Production	KB-MN-I-002
8	Magnehelic guage3		DAWYER	Production	KB-MN-I-003
9	Magnehelic guage4		DAWYER	Production	KB-MN-I-004
10	Cold Room 1			Warehouse	KB-MN-E-006
11	Cold Room 2			Warehouse	KB-MN-E-007
12	Cold Room 3			Warehouse	KB-MN-E-008
13	RTD Sensor 4	SUB-ZERO	CAREL	Warehouse	KB-MN-I-004
14	RTD Sensor 5	SUB-ZERO	CAREL	Warehouse	KB-MN-I-005
15	RTD Sensor 6	SUB-ZERO	CAREL	Warehouse	KB-MN-I-006
16	RTD Sensor 7			Utilities Area	KB-MN-I-007
17	RTD Sensor 8			Utilities Area	KB-MN-I-008
18	RTD Sensor 9			Utilities Area	KB-MN-I-009
19	RTD Sensor 10			Utilities Area	KB-MN-I-010
20	Differential Pressure Switch 1			Utilities Area	KB-MN-I-011
21	Differential Pressure Switch 2			Utilities Area	KB-MN-I-012
22	Voltmetre	041035427	HIOKI	Server Room	KB-MN-006
23	Dehumidifying Unit	WKM-320		Production area	KB-MN-E-009
24	Compressor	OLF 660-4		Production area	KB-MN-E-010

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2. Regulatory Approvals from TMDA:

2.1 REGULATORY APPROVAL FOR PREMISES (JAN-2022)

After facility was built, TMDA carried out regulatory Inspections from their East Zone & Head Office Regulatory team of auditors

TMDA Facility Premises Approval: **Received in January 2022, premise Reg No. TMDA - WEB0021/MDR/0029**

2.2 REGULATORY APPROVALS FOR FINISHED PRODUCTS (SEP-2022 and still ongoing)

We started working upon 8 products dossiers preparation, initial product development, importation of raw materials in February 2022

Dossiers submission to TMDA: June 2022 along with samples submission

Receipt of 1st TMDA Approvals: September 2022 namely for Typhoid Antibody & H Pylori Antibody kits

Receipt of 2nd set TMDA Approvals: November 2022 namely for H Pylori Antigen Kits & UPT Kits

Receipt of 3rd set TMDA Approvals: July 2023 namely for Hepatitis C Kits

SN	Finished Product Name	Devices Classification	Submission date	Registration Number	Date of Registration
1.	KAS H.Pylori Antibody Rapid test Kit	B	30-06-2022	TAN 22 MDR 0154	30/09/2022
2.	KAS Typhoid IgG/IgM Antibody Rapid test Kit	B	30-06-2022	TAN 22 MDR 0155	30/09/2022
3.	KAS H.Pylori Antigen Rapid test kit	B	30-06-2022	TAN 22 MDR 0230	07/12/2022
4.	KAS HCG Pregnancy Rapid test kit	B	30-06-2022	TAN 22 MDR 0247	07/12/2022
5.	KAS Hepatitis (HCV) Rapid test Kit	D	30-06-2022	TAN 23 MDR 0118	13/07/2023

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Currently 3 finished products namely Malaria Pf/Pan, Malaria Pf & Hepatitis B Kits TMDA approvals are still pending & the process is on-going

SN	Finished Product Name	Devices Classification	Submission date	Registration Status
1.	KAS Hepatitis B (HBsAg) Rapid test Kit	C	30-06-2022	Waiting Approval from TMDA
2.	KAS Malaria Pf. Antigen Rapid test Kit	C	30-06-2022	Waiting Approval from TMDA
3.	KAS Malaria Pf/PAN Antigen Rapid test kit	C	30-06-2022	Waiting Approval from TMDA

Products Validation:

As recommended by TMDA, we carried out our products validation & verification from Muhimbili Hospital Central Pathology Lab and National Health Laboratory (NHL) from September 2022 to December 2022, all our samples were passed at CPL Lab, Muhimbili Hospital & NHL.

3. Production

Production activities: Commenced in November of 2022 with the production of KAS H. Pylori Antibody Rapid test Kit and KAS Typhoid IgG/IgM Antibody Rapid Test kits.

Production of KAS H. Pylori Antigen Rapid test kit and KAS HCG Pregnancy Rapid test kit commenced in December of 2022.

Production capacity: Currently is 15,000 test kits per day for products that are test strips forms and 9,000 a day for products that are Test cassettes forms. The capacity can be increased to 50,000 Test strips per day and 25,000 Test Cassettes per day.

Production procedures: All required production activities are conducted as per the Standard Operating Procedures (SOP's).

Raw materials and Packaging materials are supplied by a qualified vendor in compliance to our particular specifications.

In Process Quality Control (IPQC) checks are constantly conducted during the production activities to ensure continued and consistent quality. Products that have gone through the production process are analyzed by Quality control personnel for adherence to the release specifications for finished products before release to market.

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Materials received are dedusted in the dedusting area and received against a material received checklist. Intimation for sampling is done by Store personnel to Quality Control department upon which sampling and analysis is done. Once materials are released by Quality control department for production activities, Production manager intimates to the Quality Assurance Manager for manufacturing of a batch. A unique Batch number and Batch manufacturing record is issued for every product. Production then submits these documents to stores personnel for issuance of materials required for the particular batch.

The first stage of Phase I manufacturing is cutting of uncut sheets that are product specific. The sheets are cut as per the specifications stated in the Batch Manufacturing Record (BMR), for cassette products the following steps are cassetting then packaging into aluminum pouches. Whereas test strips are directly cut and packaged into aluminum pouches. The above-mentioned procedures are all conducted in a controlled environment i.e Temperature and Humidity, through the De-Humidifying Unit (DHU).

Once the product is packaged into the primary packaging of aluminum pouches it is transferred to the secondary packing area. Here filled aluminum pouches are packaged as per the Batch manufacturing record requirement into inner box secondary packaging together with the required accessories. The third and final step is packaging into tertiary packaging of corrugated boxes, ready for dispatch to market.

In Process Quality Control (IPQC) checks are constantly conducted during the production activities to ensure continued and consistent quality. Products that have gone through the production process are analyzed by Quality control personnel for adherence to the release specifications for finished products before release to market.

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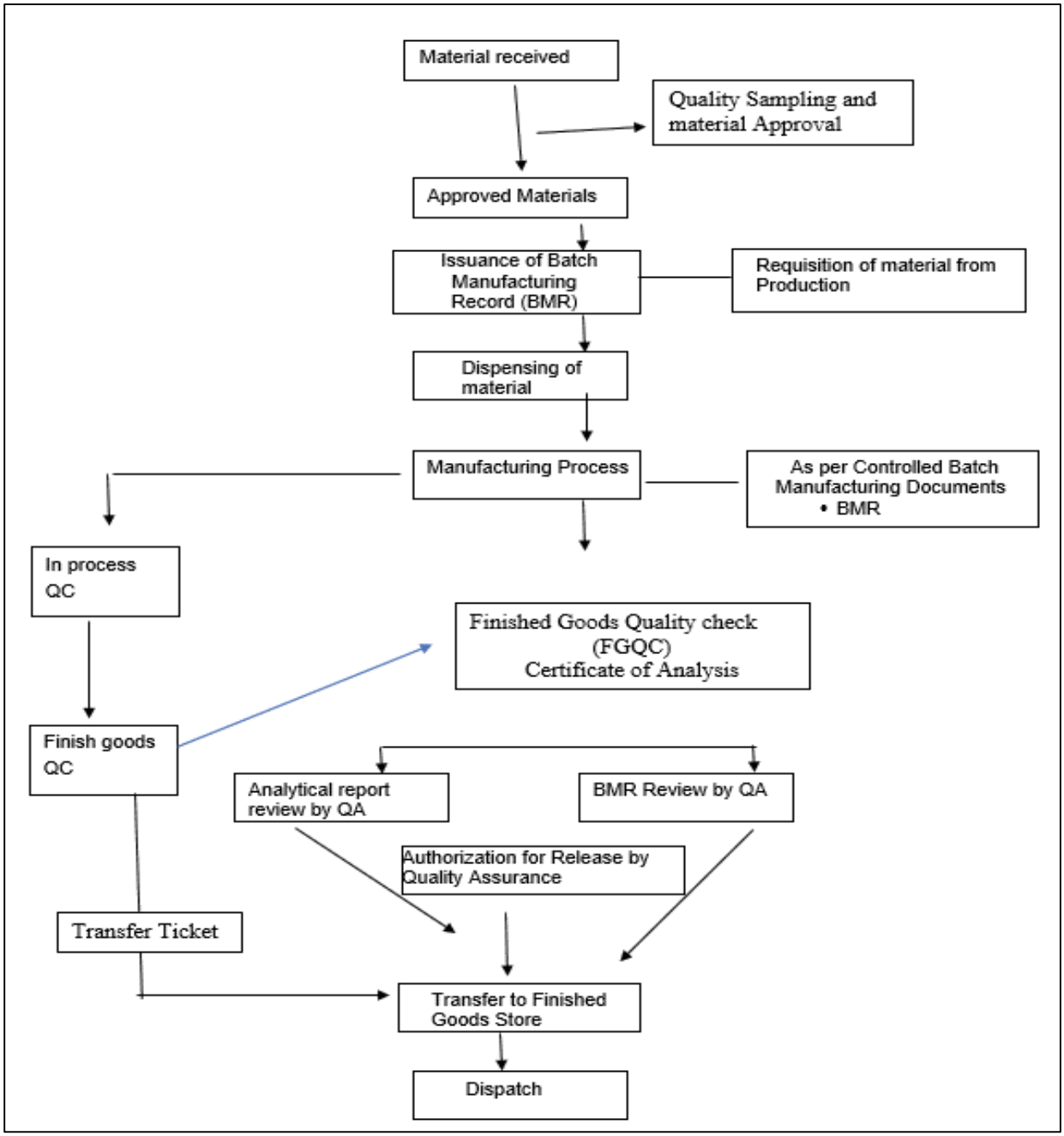
Material and Process Flowchart



Ground Floor, Plot 11, Umoja complex Warehouse - GF09,

Vingunguti Industrial Area, along Nyerere Road, P.O.BOX 7856, Dar Es Salaam

Tel: 255 22 2861737/8 info@kasmedics.com

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Product Launch

Products Launch:	December 2022 The response from market has been very positive with a good number of repeat customers established in few months only. Customer satisfaction follow ups have been done regularly & desired satisfaction of the clients are met accordingly Our product has been supplied to all four climatic regions of Tanzania and have performed as per the preset standards consistently. **Successful is selling our products to Clinics, Dispensaries, Hospitals, Health centers, NGO Organizations & Distributors**

Ground Floor, Plot 11, Umoja complex Warehouse - GF09,

Vingunguti Industrial Area, along Nyerere Road, P.O.BOX 7856, Dar Es Salaam

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2. ACHIEVEMENTS MADE ON PROJECT IMPLEMENTATION TO DATE

1. Though project was conceptualized in 2020 but due to the pandemic (Covid) the active work got started in 2021, we expected to import materials from China and India, unfortunately exportation was affected due to lockdown and travel restriction which led to delay in implementation of our project. from start to finish the project was built up in 16 months starting from June 2021 to September 2022.
2. Infrastructure built up to address manufacturing simultaneously multiple products – IVDD rapid diagnostic kits.
3. The Facility was registered by TMDA on Jan 2022 and issued an EIA approval from NEMC
4. The facility is visited by several important delegates from Government Organizations, few hospitals, Distributors & is well appreciated for the infrastructure & processes being followed up on day to day basis for manufacturing operations
5. Received Products registrations for 5 products from 8 products we applied to TMDA.
6. Best Product Evaluation Report from CPL, Muhimbili i.e. 100% Sensitivity and 100% Specificity, all samples passed for quality tests giving us confidence to promote & sale our goods to Government & Private Hospitals, Dispensaries & Clinics of Tanzania.
7. We possess a good **manufacturing capacity** of all types of Rapid Tests. Currently we have production capacity of nearly **15,000 kits pieces per day can be ramped to 80,000 kits pieces per day** with the facility we have.
8. Nearly Tzs 200 Million shillings of Kits have been introduced in market within 6-7 months.
9. We are able to generate employment for nearly 25 people who cater to day to day production & quality of kits, after we have increased sales & requirements from markets we plan to increase man-power to nearly double to cater to increased production volume of Kits.
10. Within 6-7 months we are successful in introducing our products to various regions like Tanga, Lindi, Aarusha, Mwanza, Dodoma, Mbeya Morogoro apart from Dar es Salaam customers

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11. Also after clients were satisfied with quality of our products we have been receiving repeat orders from several clients
12. We Kas Biotech also started exploring export market & have shipped 2 consignments recently to Ethopia & Zambia and focusing on other countries within SADC region.

S/No	Information	Description	Current Project status
1	Shareholders information	Current Shareholder names, nationality and percentage of ownership	1. Kas Medics Ltd (United Republic of Tanzania)-29% 2. Artemislife Science Ltd (Dubai, UAE)-71%
2	Company communication information	Email Adress: Mobile number: Land line Telephone number: Physical address:	info@kasbiotech.com +255 658 550 017 +255 22 286 1737/8 P.O Box 7856, Plot No. 11, Umoja Complex Vingunguti, Area Along Nyerere Road Dar Es Salaam, **TANZANIA**
3	Contact person	Name: Position: Email: Mobile:	Naveen Kuckian Director Naveen.kuckian@artemislife.com +255 658 550 017
4	Incorporation	Certificate of incorporation Number	140992232
5	TIN information	Tin Certificate No.	140-992-232
6	Project Objective	Project core Activity	Manufacturing of Pharmaceutics and Medical Devices (IVD's)
7	Capacity	Project capacity per year	
8	Direct Employment	Foreign men: Foreign women: Local men: Local women:	2 NIL 8 5
9	Indirect Employment	Types/area of indirect employment	1. Clearing Agent-1 2. NEMC Consultancy-2 3. Regulatory Consultancy-1 4. Engineer - 1

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3. PROJECT FINANCIAL EXPENDITURE TO DATE (USD)

	Foreign (USD)	Local (USD)	Total (USD)
Land and Building			
Plant and Machinery		590,758.00	590,758.00
Vehicle/Aircrafts			
Furniture		8,800.00	8,800.00
Office equipment			
Insurance cover			
Pre-operational expenses		31,800.00	31,800.00
Working sub-total capital			
Grand Total	0	631,358.00	**631,358.00**

4. PROJECT FINANCING

	Amount (USD)	Source Country
Local equity	16,604.00	United Republic of Tanzania
Local loans		
Foreign equity	264,150.00	Dubai, UAE
Foreign Loans		
Total Investment	**280,754.00**	

5. PROBLEMS AND SOLUTIONS

While executing Project we encountered following problems:

1. **Electric supply Problem**

Our manufacturing facility is designed to have a constant power supply to manage running of Machines and also Temperature & Humidity control so that we cannot interfere with the quality of our products. We always experience frequent power outage which affects daily facility operation. This also increase our daily expenses as we need to use backup (Generator) which is costly.

Solution; The Government should ensure constant electric supply especially in industrial areas where most of the production activities which has a big contribution to national economy (GDP).

2. **Skilled Man-power:**

Our project falls in Life Science Industry, which required skilled man power in all stages of the project from Design to Project execution to regular day to day Operations. As this facility being the first to be installed in our country we had to employ foreigner experts.

Solution; Tanzania Government should train local citizen to cope with emerging technology especially in Medical field.

3. **Limited resources for Facility Infrastructure within Tanzania:**

As this facility which we have set up is a cleanroom Medical devices manufacturing facility, there are various Infrastructure materials required to set up the facility we not only had to import but also the materials which we procured / sourced locally from Tanzania Industry / market was also not manufactured at Tanzania because of that the Project could not be completed in anticipated budget & we had to invest extra budget to complete the infrastructure of the facility.

Solution; From the list of Infrastructure materials we procured if even 30-40% are available in Tanzania from local manufacturing market the projects can be set up at lower costing.

4. **Facility EIA Approval:**

To obtain mandatory EIA approval for the facility it took us lots of months to coordinate with various Government Agencies which resulted in delays for setting up facility for subsequent construction stages, this resulted in delay of project execution while increasing our CAPEX costs.

Solution; Various Government Agencies involved in awarding EIA clearance certificate to new Projects can fasten up the process so that companies can complete projects timely within anticipated Project timelines.

5. **Delay in receiving Market Authorization from the Regulatory Authority:**

We submitted registration applications for our eight (08) products on 30th June 2022, first product approval for 3 products received on September 2022, however there are still three pending application that are waiting for Market approval.

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1.	KAS H.Pylori Antibody Rapid test Kit	B	30-06-2022	TAN 22 MDR 0154	30/09/2022
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6	KAS Hepatitis B (HBsAg) Rapid test Kit	C	30-06-2022		Waiting Approval from TMDA
7	KAS Malaria Pf. Antigen Rapid test Kit	C	30-06-2022		Waiting Approval from TMDA
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Solution: The regulatory authority needs to develop a plan for domestic manufacturer promotion that will facilitate the fast and easy registration of products and facilitate GMP/QA inspection. To ensure that Medicines, Medical devices, and IVDs are available in our country without relying on importation from outside the country.

6. FUTURE PLANS

Future Plans:

Premises & Production processes Future Plan:

- Currently TMDA has approved our facility as Phase 1 wherein we make our finished products from semi-finished ready raw materials we receive from our overseas vendors.
- Above manufacturing process involves very few process steps to convert semi-finished to finished products.
- In future we intend to enter into Phase 2 manufacturing stage wherein we will receive basic raw materials e.g., various membranes sheets which will go through lamination process & gets converted finished product.
- We shall be informing TMDA whenever we are ready so that they can inspect our facility & award us Phase 2 manufacturing approval for our processes.

Future additional products pipeline:

Currently as we manufacture 8 different Rapid kits, in future we are working upon to launch additional kits products e.g., for

1.Typhoid Antigen Rapid Kit,

2. Syphilis Rapid kit,

3. HIV Rapid kit

4. Laboratory Reagents & also few cancer markers.

7. RECOMMENDATIONS AND ANY OTHER COMMENTS

Recommendations:

Custom Duties: As our IVDD medical devices is very competitive Industry & we at Kas Biotech Limited are trying to manufacture & deliver IVDD Rapid kits at very reasonable prices to Tanzanian Population & various Government Institutions, we hereby request to waive off any custom duties applicable on various components & raw materials used in the manufacturing process, few of the raw materials used in manufacturing of Rapid kits are:

1. Uncut Sheet For HCV Rapid Test kits
2. Uncut Sheet For HBsAg Rapid Test Kits
3. Uncut Sheet For HIV 1& 2 Rapid Test Kits
4. Uncut Sheet For Typhoid IgG/IgM Antibody Rapid Test Kits
5. Uncut Sheet For Typhoid Antigen Rapid Test Kits
6. Uncut Sheet For H.Pylori Antigen Rapid Test Kits
7. Uncut Sheet For H.Pylori Antibody Rapid Test Kits
8. Uncut Sheet For HCG Rapid Test kits
9. Uncut Sheet For Troponin I Rapid Test kits
10. Uncut Sheet For Malaria Pf. Antigen Rapid Test Kits
11. Uncut Sheet For Malaria Pf./PAN Antigen Rapid Test Kits
12. Uncut Sheet For Syphilis Anti TP Antibody Rapid Test Kits
13. Uncut Sheet For Sickle cell Anemia Rapid Test Kits
14. Uncut Sheet For Urine analysis Strips (1 Para to 12 para conditions)
15. Uncut Sheet For Dengue Rapid test kits
16. Buffer Reagents for Rapid test kits
17. Printed Plastic Cassettes for Rapid Test kits
18. Printed droppers for Rapid Test kits
19. Specimen Transfer devices
20. Lancets
21. Alcohol Swabs
22. Silica desiccants
23. Plastic buffer bottles and FOB tubes
24. Reagents for manufacturing Biochemistry Reagents
25. Chemicals and reagents
26. Proteins and buffer reagents

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27 Gold chloride,
28 Centrifuge Machine
29 Nitrocelluose membrane,
30 PVC Backing cards for manufacturing of Rapid test kits
31 Filter papers
32 Sonicator machine
33 Hot Plate Magnetic Stirrer
34 High sensitive Weighing Balance
35 Aluminum Plastic laminated 3 or 4 layer packaging pouch
36 Inner Boxes for rapid test (paper / card board material)
37 Corrugated Boxes
38 Kit inserts

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