

KAS BIOTECH LIMITED

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**PROJECT REPORT FOR STARTING NEW
RAPID TESTS STRIPS MANUFACTURING / ASSEMBLING LINE
IN UNITED REPUBLIC OF TANZANIA**

REPORT PREPARED

BY

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Company Background

Kas Biotech Limited, is company legally registered as per law of United Republic of Tanzania, recently in 2020 to start the Manufacturing / Assembling work for Lateral Flow (Rapid tests strips manufacturing) within Tanzania.

While promoters of Kas Biotech Limited is from Kas Medics Limited, Tanzania, which is well established reputed player in the field of Laboratory, Chemicals, Pharmaceutical and Medical Equipment's as one of leading Importer and Distributor in Tanzania, and completed various projects successfully all across the country, partnering with Ministry of Health as well various private players and Non-Governmental Organizations.

Management of Kas Medics Limited, strongly believes and focus on Knowledge based industry, which can match the vision of Government of Tanzania, as well create opportunities of employment for local community, as well support for local talent available in Tanzania.

Vision

To Become one of leading IVD Player in East Africa Region.

Mission

Working towards creating disease free society and committed to provide responsible solutions for the same.

Background of Business.

Under flagship of Kas Biotech Limited, we plan to offer solutions within Tanzania, for various Rapid Tests Strips (RTS), which are like Malaria, Hepatitis B, Hepatitis C, H- Pylori, Pregnancy Strips, Urine Strips etc. Same is also known scientifically Lateral Flow Assays.

Under the plan Kas Biotech Limited would like to start the manufacturing of all the Rapid Tests Strips within country, starting from Pregnancy, Urine and then to all others within 1-2 Years' time.

Full details of the product is as under.

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Basic Understanding of Product

<p>Common names for a lateral flow immunoassay</p>	<p>Lateral flow test (LFT) Lateral flow device (LFD) Lateral flow assay (LFA) Lateral flow immunoassay (LFIA) Lateral flow immunochromatographic assays Dipstick Express test Pen-side test Quick test Rapid test Tests strip</p>
<p>What is a lateral flow immunoassay?</p>	<p>So, what is a lateral flow immunoassay? Basically, it is a simple to use diagnostic device used to confirm the presence or absence of a target analyte, such as pathogens or biomarkers in humans or animals, or contaminants in water supplies, foodstuffs, or animal feeds. The most commonly known type of lateral flow rapid test strip is the pregnancy test. Lateral flow tests are widely used in human health for point of care testing. They can be performed by a healthcare professional or by the patient, and in a range of settings including the laboratory, clinic or home. In the medical diagnostic industry, there are strict regulatory requirements which must be adhered to for all products developed and manufactured.</p>
<p>Types of lateral flow tests</p>	<p>Lateral flow assays can be developed to be used in a dipstick format or in a housed cassette. Both dipsticks and housed tests will work in a similar way, it is just dependent on the industry, sample matrix, and the market requirement, as to which format is suitable.</p> <p>Sandwich assays – A positive test is represented by the presence of a colored line at the test line position.</p> <p>Competitive assays – A positive test is represented by the absence of a colored line at the test line position.</p>
<p>How does a lateral flow test work?</p>	<p>LFDs use immunoassay technology using nitrocellulose membrane, colored nanoparticles (or labels), and typically antibodies, to produce results. When a sample is added, the sample will flow along the test device passing through the conjugate pad into the nitrocellulose membrane and then onto the absorbent pad.</p> <p>The bullet points below demonstrate how a sandwich assay works:</p> <p>The sample pad acts as the first stage of the absorption process, and in some cases contains a filter, to ensure the accurate and controlled flow of the sample.</p> <p>The conjugate pad, which stores the conjugated labels and</p>

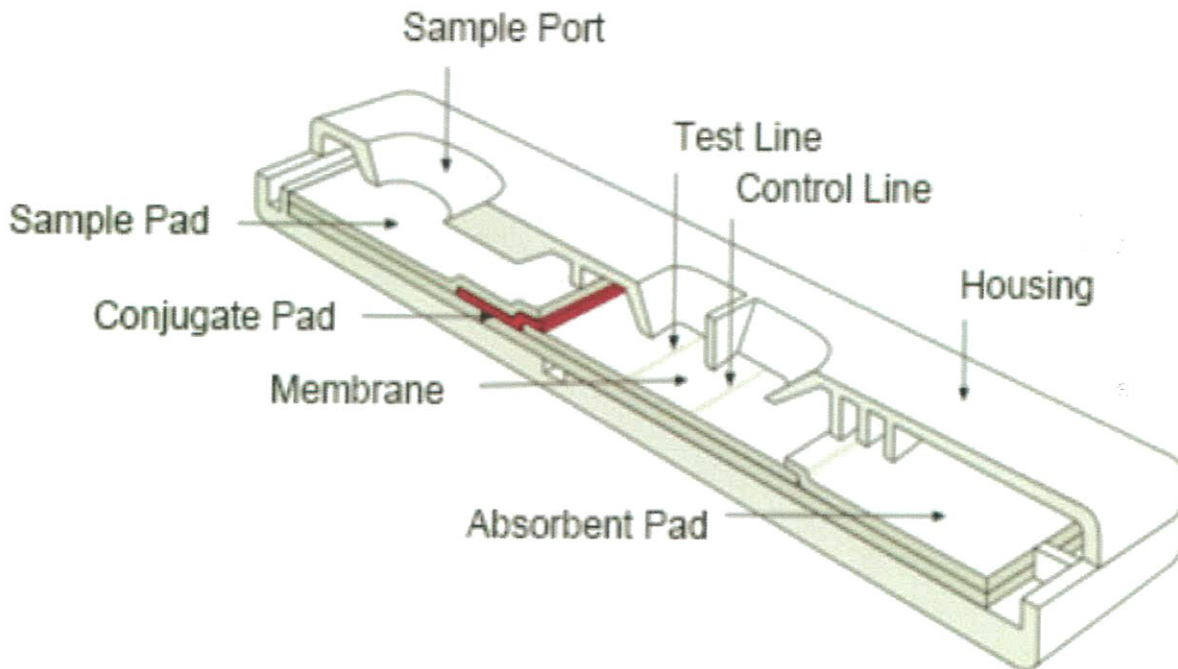
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antibodies, will receive the sample. If the target is present, the immobilized conjugated antibodies and labels will bind to the target and continue to migrate along the test.

As the sample moves along the device the binding reagents situated on the nitrocellulose membrane will bind to the target at the test line. A colored line will form and the density of the line will vary depending on the quantity of the target present. Some targets may require quantification to determine target concentration. This is where a rapid test can be combined with a reader to provide quantitative results.

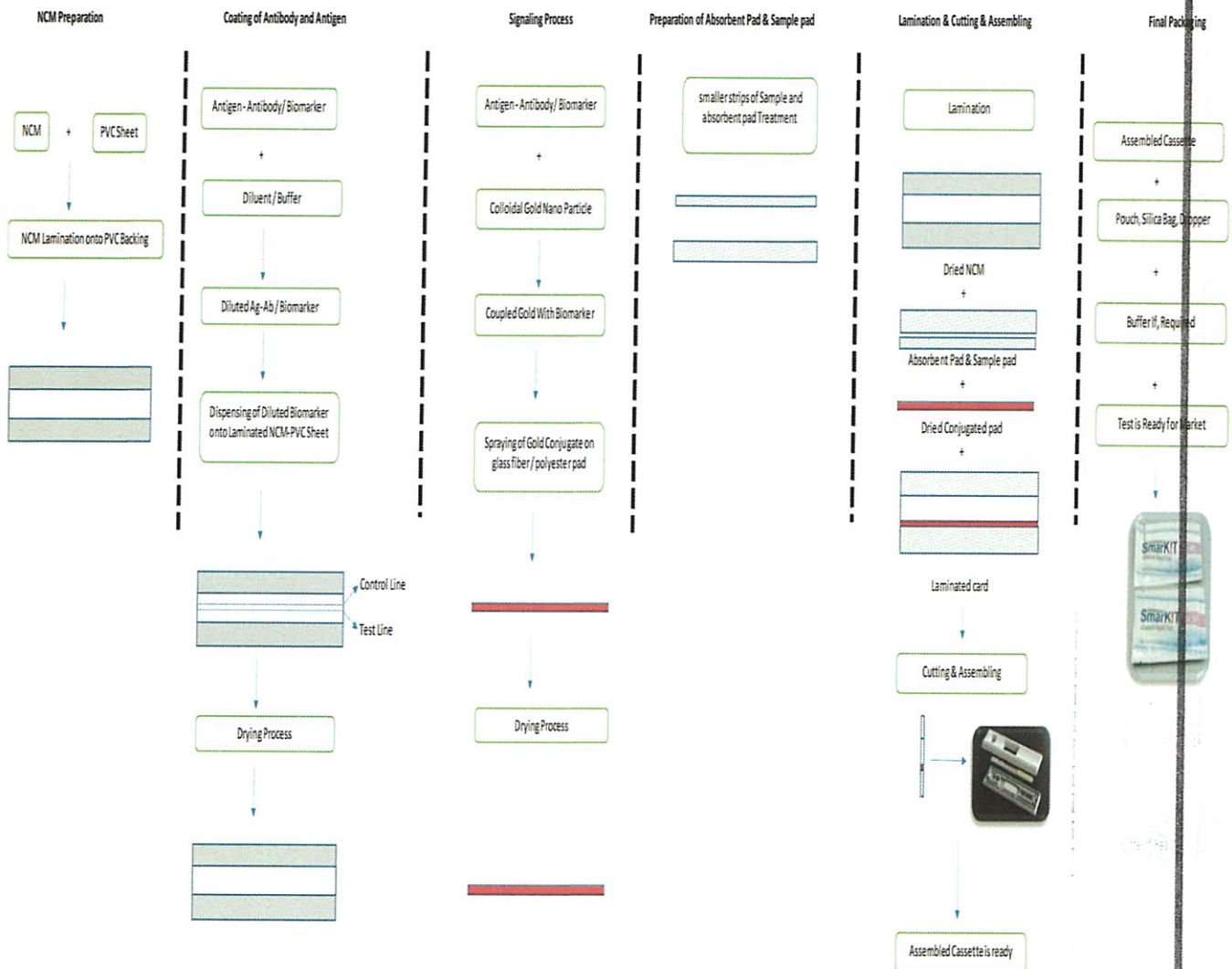
The sample will pass through the nitrocellulose membrane into the absorbent pad. The absorbent pad will absorb the excess sample. The specification of the absorbent pad will have an impact on the volume of sample the test can incorporate.



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Lateral Flow Test Manufacturing Process



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Project Establishment Process: Time 6 Month (Total)

Sr · N o.	Task	Importance	detail
1	Location Analysis	Analysis of existing plant layout and surrounding environment/ Place	Already Done
		Measurement of each Area / Room	NEMC Going on
		Start Drafting Design Plant Layout for submission to Local Government for approval.	Already Ready
2	Factory Designing	To Design factory with meet and compatible to requirement of production of rapid test.	Already Lay Out Ready
3	Equipment Selection	To select best and cost-effective equipment for set up complete production line of rapid test cassette.	Research and Development Production QC QA
4	Department Designing & Providing Training to each department regarding work responsibility	To design department within company to distribute work responsibility and also train to different department for work process.	

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5	Employment Selection	Conducting an interview and to select employee based on judgment of skills	Raw Material Storage
			Production
			Finish Good Storage
			Dispatch Department
6	In House production for Lateral Flow Test Strips	Validation & Verification of Factory, Employee Product (From Ready-made Uncut sheet)	
		Installation of Equipment & Training	
		Prototype development and Production	Selection of Biomarker
			Dispensing/ Coating of Antigen and Antibody
		Selection of colloidal gold nano particle	

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			Bio-Conjugation of Antibody and Antigen
			Lamination Process
			Cutting and Scanning and Assembly process of cassette
			Packaging Process
7	Product selection form uncut sheet and implemetation into production including stability study	Uncut Sheet	
8	Outsourcing of cost - impactive raw material	Antibody-Antigen Supplier	
		Utility Equipment	
		Cassette	
		Dropper	
		Silica Bag/Desiccant bag	
		Aluminum Pouch and other raw material	
9	Design of Documentation	Quality Policy	
		SOPs	
		Testing Procedure of raw material	
		Testing Procedure of finished product testing	
		Product Dossier training	

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		Technical File development training	
10	Selection of product Portfolio & Business Target Support	To Select Best Product which can be launch into market and also has high profitability	
		Presentation on marketing strategy for product launch into market	
11	Product Launch in Market	To Check Final Stability and start up first production batch to produce rapid test Cassettes	

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Equipment supply for Rapid test Cassette Manufacturing

Equipment	Qty	Function
Weight Balance Machine	1	Sartorius :- Digital Weighing of Chemical
Magnetic Stirrer	2	Remi: -Dissolve Chemical as stirring Purpose
Magnetic Stirrer cum hot plate	3	Remi: - Mfg. of Colloidal Gold & Dissolve Chemical
pH Meter	5	Systolic :- Measure the pH
Dehumidifier	3	Maintain Humidity
Air Conditioner	20	Temperature Control with air filter
Strip Cutting Machine	2	to cut Uncut sheet into smaller strip
Cassette Pressing Equipment	2	Press the cassette
Hot Air Oven	3	Activate Silica Gel
Inject Printer	4	Printing details such as lot number, mfg. date, exp. Date on aluminum pouch
Pouch Sealing Machine	2	Sealing of aluminum pouch
Shrink Wrap Machine	1	Shrink Wrap of plastic on Packaging Box
Deep Fridge	4	Store raw material
Refrigerator	3	Store raw material
Micropipette	10 Set	Volume measure
Stability Chamber	1	to study stability
Foil Pouch Pager	1	Pouch feeder equipment where inject printer has to attached for printing activity
Cold Room	3	Keeping Large Raw Materials, and Keeping Stock, for checking
Automatic Packaging	1	To Pack Dropper, Desiccant Bag, Assemble Caseates in to Pouch

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The above materials do not include any Infrastructure Materials, which will be used to make the complete room, under clean room for area to develop cutting facilities, since same can't be cut in dusty area.

Complete details of PUFF Panels and other aluminum work structure are mentioned clearly into the Working Map.

USER PROFILE. (Customer / Required for Manufacturing) – Manpower Required.

Customer

Lateral Flow products are generally used in all hospitals, Private and Public Institutions, also most retailer also keep the same stocks in to their pharmacy. Major customer will also be MSD, and other government or non-government organizations.

Manufacturing

To start manufacturing apart from Infrastructure, we will be required certain set of skills as under.

General Manager / Business Head – Same must have some current exposure of the products, and he/ she must be working in any existing plant, with robust scientific background.

Plant Manager – Must be working in any existing running plant anywhere in world, and have proper exposure of each and every process, wherein he / she must be able to derive the same independently.

Finance - Must have exposure of same commodity, their sources and pricing etc.

Procurement – Must have exposure of same, willing to learn newer processes.

Sales and Marketing Head- Must be composed, and willing to work with flexible timing etc. and have similar exposure.

Others. Whole project will be able to create the employment of around 60 Members, which means directly or indirectly this will be impacting around 300 People lives, while all basic procurement will be done locally, like packaging materials etc. to support the objective of government.

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OBJECTIVE OF KBL.

Kas Biotech Limited, will be professionally managed organization, and in the process of establishing the same KBL has short term and long-term objective as under.

KBL Short Term objective.

Being first in region, KBL immediate priority is to support the government objective to make the country self-sufficient and start product which is very high in quality and acceptable by all required regulatory bodies in country. Make sure KBL wins most government or non-government organization trust, within short possible time, by offering very high standard services, and matching international quality, with affordable price.

KBL Long Term Objective.

KBL long term objective, is to make sure that it becomes the preferred partner in the region of Africa, and able to fulfil demand by expanding services, and manufacturing capabilities, as while starting the manufacturing facility, same capacity is going to be around 27 Million Per Year.

To make sure, Plant becomes WHO Certified and offered more reliability to get outsource from many top MNC's.

MARKET ANALYSIS

Based on the raw figure or data available, as per estimate Tanzania, uses around 15-20 Million Tests Per Year, which doesn't include the HIV and Malaria, so initial capacity of 27 Million Tests to produce every year will be ok, and some of other market where we will be able to export from Tanzania, based on well connectivity and cost per tests will be still affordable will be as under..

	Tanzania	Nigeria	DRC	Zambia	MZ	Malawi	Uganda	Burundi	Ghana	Total
Population	60	160	65	20	15	15	30	15	25	405
Annual Requirement (Tests)	15	40	15	5	4	4	7	4	6	100

As we gain confidence on the products, and quality is assured, within 2-3 years, we will be able to expand market to these markets, by enhancing our capacity, once we reach to these markets, we can easily cover mostly half of continent.

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FINANCIAL

Fund / Capital Required.

To start manufacturing facility in full, fledged, KBL Must have capital reserve required around 770,000 USD, which will be used as under.

Infrastructure.

This includes complete Puff Panels, by which whole set up will be ready and clean room will be ready to cut the strips in the absolute clean room. Also there will be furniture necessary for operations and office work. The approximate estimated cost of same will be around 100,000.00 USD.

This will also include, other basic requirements like Air Conditioners etc.

Machines & Equipment's.

This includes, all the basic machines which will be required to start the work includes majorly Cutter, Automatic Machines, Lamination Machine, and also 3-4 cold rooms, and packaging machine which required to be bought before we start production.

Total cost of the machines immediate or with in 1 years will be required around 400,000.00 USD.

With these machines we will be able to produce around 27 to 30 Million Tests Strips Per Year.

Other Fix Assets Expenses.

KBL Must have capital to buy basic needs like vehicles for delivery and other transportation as well to hire/ buy place to store goods, in case of high production capacity. Cost of the same will be for 2-3 years will be around 50,000.00 USD.

SUMMARY OF INVESTMENT BREAKDOWN		
S/N	DESCRIPTION	AMOUNT(Usd)
1	Land/Building	-
2	Plant	400,000
3	Vehicles	50,000
4	Furniture & fittings	100,000
5	Pre-expenses	20,000
6	Others	-
7	Working capital	200,000
	Total	770,000

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Operational Expenses.

To make sure that ABL Buys the enough raw materials which can run the company for minimum 1 years, and finished products is out within specific time limit.

Raw Materials.

Salaries of Employees

Packaging Materials

Utilities Bills

Premises Rent in case if rented.

Local Regulatory approvals, and testing's

Samples to initiate the work

Above will be required, around 546,300.00 USD.

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SUMMARY

Project Name:	Kas Biotech Limited
Project For:	To start production of Lateral Flow Production (IVD Rapid Tests Strips)
Fund Required:	Total 770,000.00 USD (Capex & Opex)
Employment Generation:	60 Employees, in first year (Regular & Temporary)
Capacity:	27 Million Tests Per Year.
Technical Partnership:	Kin Bio
Source of Raw Material:	Cloongen Biotech Ltd. Shanghai, China, Local Suppliers
End Product:	Pregnancy Strips, Urine Strips, HBC, HCV, Syphilis, H – Pylori, Malaria.

KAS BIOTECH LTD
Projected statement of Profit & Loss

Particulars	Amount in USD				
	1ST YEAR 2021	2nd Year 2022	3rd year 2023	4th year 2024	5th Year 2025
Total Production Capacity	27,000,000	27,000,000	27,000,000	27,000,000	27,000,000
Operated capacity	20%	40%	60%	80%	100%
TEST	5,400,000	10,800,000	16,200,000	21,600,000	27,000,000
SP	0.05	0.10	0.15	0.17	0.20
Total Sales for the year	270,000	1,080,000	2,430,000	3,672,000	5,400,000
Cost of Sales per test	0.04	0.04	0.08	0.10	0.12
Cost of in Amount	189,000	432,000	1,296,000	2,160,000	3,240,000
GP	81,000	648,000	1,134,000	1,512,000	2,160,000
GP %	30%	60%	47%	41%	40%
Ware House Expenses	48,000	52,000	80,000	75,000	85,000
Employment Expnese	200,000	250,000	350,000	400,000	450,000
Admin Expenses	60,000	100,000	150,000	170,000	200,000
Depreciation	137,500	103,125	77,344	58,008	43,506
Selling Expneses	10,800	32,400	121,500	183,600	270,000
Finance Charges	90,000	87,000	79,000	81,000	73,000
Total Cost	546,300	624,525	857,844	967,608	1,121,506
Net Profit (NPBT)	(465,300)	23,475	276,156	544,392	1,038,494
Taxation		7,043	82,847	163,318	311,548
Net Profit (NPAT)	(465,300)	16,433	193,309	381,075	726,946
Net Profit on sales	-172%	2%	8%	10%	13%

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Projected Cash Flow Statement

Particulars	Amount in USD				
	1ST YEAR 2021	2nd Year 2022	3rd year 2023	4th year 2024	5th Year 2025
CASH IN FLOW					
Cash & Bank Balance in Hand	1,000	2,266	3,766	5,266	42,766
Capital Introdcution	212,766				
Collection from AR	202,500	877,500	2,092,500	3,361,500	4,968,000
Total Cash Inflow	416,266	879,766	2,096,266	3,366,766	5,010,766
Cash Out Flow					
Vendore Payment					
Raw Meterial supplier	55,000	391,500	1,272,000	2,016,000	3,060,000
Long term creditors repayment		50,000	50,000	50,000	50,000
Over Head payments					
Ware House Cost	36,000	45,000	80,000	94,000	85,000
Employment Cost	175,000	195,000	325,000	500,000	430,000
Admin Cost	50,000	80,000	125,000	210,000	200,000
Selling Cost	8,000	20,000	80,000	210,000	285,000
Finance Cost	90,000	87,000	79,000	81,000	73,000
Taxation		7,500	80,000	163,000	727,000
Total Cash Pay Out	414,000	876,000	2,091,000	3,324,000	4,910,000
Net Surplus / (Deficit)	2,266	3,766	5,266	42,766	100,766

P.O.Box no 7856,Dar Es Salaam

Projected Statement Of Finanacial Position

Particulers	Amount in USD				
	1ST YEAR 2021	2nd Year 2022	3nd year 2023	4th year 2024	5th Year 2025
Assets					
Non Current Assets					
Propetry Plant & Equipment	412,500	309,375	232,031	174,023	130,518
	412,500	309,375	232,031	174,023	130,518
Current Assets					
Inventory	47,250	108,000	324,000	540,000	810,000
Trade Receivables	67,500	270,000	607,500	918,000	1,350,000
Other Receivable	-	7,043	89,889	253,207	564,755
Cash & Cash Euivalents	2,266	3,766			
	117,016	388,809	1,021,389	1,711,207	2,724,755
Total Assets	529,516	698,184	1,253,421	1,885,230	2,855,273
Capital & Liability					
Share Capital	212,766	212,766	212,766	212,766	212,766
Long Term creditors	250,000	200,000	150,000	100,000	50,000
Ratined Earnings	(465,300)	(448,868)	(255,558)	125,516	852,462
	(2,534)	(36,102)	107,208	438,282	1,115,228
Currnet Liabilities					
Trade & Other Payables	532,050	734,285	1,146,213	1,446,948	1,740,045
	532,050	734,285	1,146,213	1,446,948	1,740,045
Total Equity & Liability	529,516	698,184	1,253,421	1,885,230	2,855,273