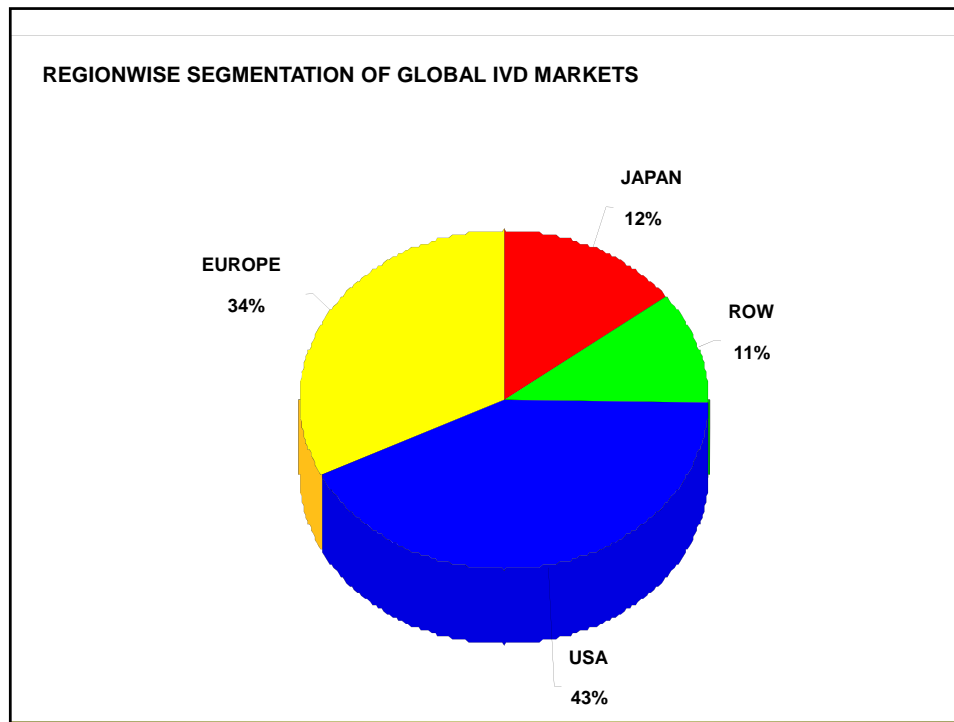


IDEAS TO PRODUCTS

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Effective diagnosis is a pre-requisite for successful therapy and early and accurate diagnosis results in timely and appropriate treatment.

Treatment without Diagnostics is blind



THE DEVELOPING WORLD –SITUATION

- Huge disease burden
- High morbidity and mortality rates
- Heavy economic impact of diseases
- Heavy dependence on State for Health Care
- Poor infrastructure and diminishing budgets
- Poor regulatory frame work
- Limited funds for health care
- Very limited usage of diagnostic tools
- Increasing resistance to conventional drugs
- Disease burden increasing despite treatment interventions

The treatment story



Clinical diagnosis: Magnitude of over-diagnosis /over-treatment

≤ 5 years MEDIAN PR = 20%
 6-14 years MEDIAN PR = 27%
 ≥ 15 years MEDIAN PR = 13%

Country	Year	≤ 5 years	6-14 years	≥ 15 years
Chad	2002	19	50	27
Tanzania	2005	21	17	8
Benin	2003	4%	0%	1%
Côte d'Ivoire	2002	36%	44%	26%
Burkina faso	2002	22%	37%	18%
Tanzania	2002	5%	7%	4%

Courtesy of: V. D'Acromont, C. Lengeler, B. Genton, Philadelphia, November 2007

DEVELOPMENT PRIORITY

Making available affordable, practical and relevant high quality diagnostic kits for the developing world by,

1. Selecting ideal test platforms
2. Selecting disease target /markers
3. Test design and development
4. Validation
5. Low cost manufacturing - indigenization
6. Scaling up for volumes and economies of scale
7. GMP and QMS
8. Regulatory compliance
9. Marketing

Development Issues

- Need assessment
- Test parameters
- Technology
- Reagents
- Test components
- Reference material
- Characterized samples
- Field trials and evaluations

Parameters for a Good Test

- Sensitivity and Specificity
- Accuracy and Reliability
- Avidity and Titre
- Test duration - Hands on time and total duration
- Ease of Use - Procedure
- Need for Equipment/s
- Need for trained personnel
- Storage and Shelf life
- Pack size and packaging
- Need for accessories
- Quantification and hard copy of results
- Single testing/ Batch Testing
- Automation for large volume processing
- Effective cost

Development Issues

- Need assessment
- Test parameters
- Technology
- Reagents
- Test components
- Reference material
- Characterized samples
- Field trials and evaluations

MANUFACTURING ISSUES

- Process Requirements
- Testing Requirements
- Scaling up
- Quality Assurance
- Quality Management Systems
- Regulatory requirements

Quality Management Systems

- ISO 9001: 2000 (General)
- ISO 13485 (Specific to IVDD)
- CE
- US FDA
- WHO ?

REGULATORY ISSUES

- Diagnostics in India are classified under “Drugs” as critical (HIV, HCV, HBsAg, Blood Grouping) and non-critical
- Drug manufacturing license/ import license necessary
- Evaluation by NIB for critical products
- GMP requirements as per Schedule M
- Guidelines for minimum requirements for manufacture, under notification
- No national guidelines for IVD’s
- Regulation is only a formality and practically these are un- regulated

MARKETING ISSUES

- Sales and Marketing infrastructure
- Distribution
- Technical support
- Performance/ comparison data
- Customer education
- Trouble shooting
- Packaging
- Registrations

STRATEGIC ISSUES

- Cost reduction
- Local sourcing
- Backward integration
- Capacity utilization
- Contract development
- Contract manufacturing
- Mass production
- Scaling up
- New markers
- New emerging technologies

An Ideal Diagnostic Platform for the developing world

Adequately sensitive and specific
Reliable and accurate
Quick results and minimum hands on time
Simple and minimum procedure
Not needing equipment and additional accessories
Minimal training without need for specialized staff
No special storage conditions and long shelf life
Smallest pack size
Single testing and batch testing possibility
Self validation of each test
Lowest effective cost per test

IMMUNOCHROMATOGRAPHY (ICT/ RDT) – CLOSE TO THE NEED

Fast - Results in Minutes

Relatively Accurate and Reliable

Simple and User friendly

Storage at Ambient Temperatures

Minimal Training

No Instrumentation

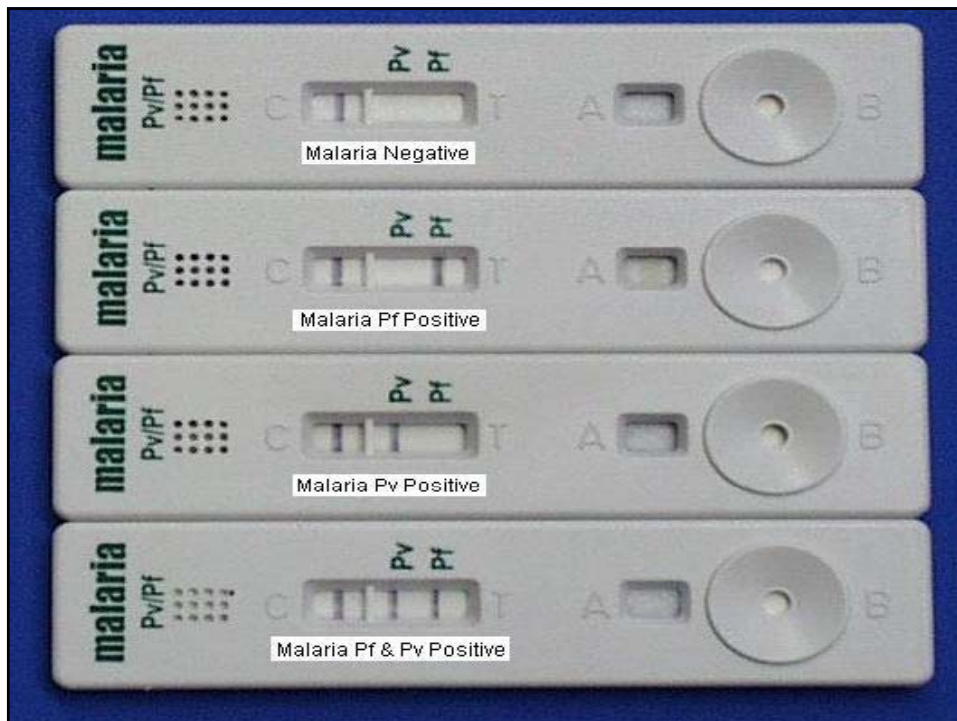
Long Shelf-Life

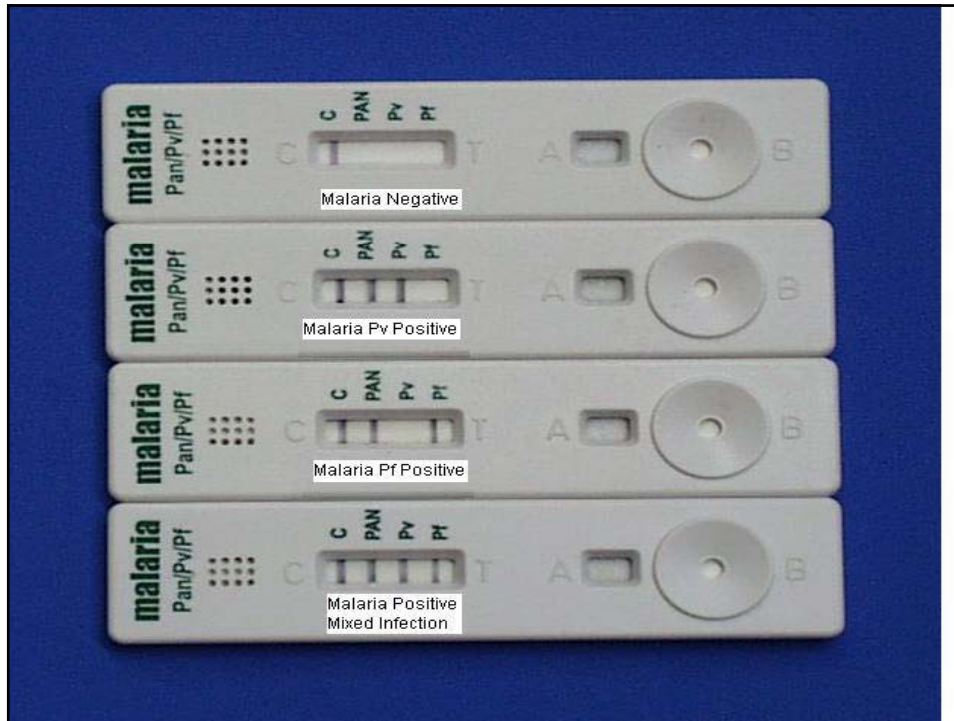
Low Effective Cost

Suitable for all levels - Lab.s, Physicians desk top,
POCT, Emergency, Screening, remote, Field level
etc.

IMMUNOCHROMATOGRAPHY

- Most popular in developing countries
- Significant impact in managing some diseases eg. Malaria, HIV
- Limitations of Sensitivity and Specificity for many diseases
- Quantitation not possible
- Limited multiplexing capability
- Hence, more refinement and improvement required





FUTURE

- Fluorescent particles
- Microfluidics
- Multiplexing – Protein arrays
- Novel molecular platforms
- Lab-on-a-Chip
- Nanotechnology
- New markers

BUSINESS POTENTIAL

- Technology driven
- Low capital costs for start up
- Good returns for quality
- Ideal for the SSI/SME segment, especially for technical entrepreneurs

MARKET POTENTIAL

- Domestic – about Rs. 1000 crores and growing at about 20 % annually
- Global – over 35 billion US dollars

ENTRY BARRIERS FOR MANUFACTURE

- Duty free imports of many diagnostic kits
- Duty on components and basic reagents
- New and fast changing technologies
- Competition from international products, especially very low priced products from China, Korea
- Poor Regulatory frame work
- Lack of policy and guidelines

TULIP GROUP HIGHLIGHTS

- Established in 1990 by three entrepreneurs
- Started with a capital of \$ 10,000 and a workforce of 23
- First year turnover – \$ 60,000
- Current turnover – \$ 45 Million
- Current workforce – over 1300
- Exports to over 65 countries and to NGOs such as WHO, UNICEF, UNDP, USAID, MSF, PSI etc.
- Current export business – \$ 23 Million
- ISO 9001:2000, ISO 13485, CE

TULIP GROUP

Manufacturing companies

- **Tulip Diagnostics (P) Ltd** – Blood grouping/typing, agglutination tests, Coagulation, microbiology
- **Orchid Biomedicals** – Rapid tests for pregnancy, HBsAg, Pf malaria
- **Qualpro Diagnostics** – HIV, HCV, HBsAg, Syphilis - rapid and Elisa
- **Coral clinical Systems** – Clinical Biochemistry
- **Zephyr Biomedicals** – Infectious diseases, cardiac markers, cancer markers

