FIGHTING COUNTERFEITING OF MEDICINES:

Efforts at Safeguarding Public Health in Nigeria

Report of use of

Raman Spectrometer - TruScan®

Conducted By:
National Agency for Food and
Drug Administration and Control (NAFDAC)

Fighting Counterfeiting of Medicines:
Efforts at Safeguarding Public Health in Nigeria

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Hon. Minister of Health, Professor Christian Onyebuchi Chukwu who represented the President (middle) and flanked by Director-General, NAFDAC, Dr. Paul Orhii (left) and Permanent Secretary, General Services, Office of Secretary to the Government of the Federation, Mr. Femi Olayisade (right) who represented the SGF at the launch of the NAFDAC anti-counterfeiting Cutting-Edge Technologies in Abuja - 21st March, 2011

Acknowledgements

Nigeria with a large population and improving economic and health indices is a target and a destination for drug counterfeiters. The NAFDAC Management has broadened the scope of the Anti-counterfeiting war by initiating many programmes and policies including the adoption of cutting-edge technologies.

Thermo Fisher TruScan® is a hand-held Raman spectrometer designed to allow regulators and law enforcement deploy inspectors without any formal chemistry training to conduct field based screening of pharmaceutical samples to quickly and accurately identify counterfeits. Majority of pharmaceuticals are suited to rapid screening with Raman Spectroscopy, though a few are not.

A total of six units of the device were acquired by the Agency between November 2009 and January 2010 as part of the anti-counterfeiting drive. Regulatory Officers from Ports Inspection, Establishment Inspection, Enforcement and Laboratory Services Directorates nationwide were trained on aspects of the TruScan®, leading to capacity building and exposure of the staff to cutting-edge technology. National anti-counterfeiting survey using the TruScan® commenced

in January 2010, and thirty three states (33) and FCT were covered for the exercise. Findings from this study will provide a true picture about prevalence of counterfeit medicines in Nigeria.

The Management and Staff of NAFDAC would like to thank the President of the Federal Republic of Nigeria, Dr. Goodluck Ebele Jonathan, the Honourable Minister of Health, Prof. Christian Onyebuchi Chukwu, and the Governing Council of NAFDAC for the purchase of the TruScan® equipment and for funding the survey. Special thanks also to the participants in the survey for their diligence and commitment.

Dr. Paul Orhii, J.D., M.D., Ph.D.
Director General, NAFDAC

TABLE OF CONTENTS

List of Acronyms

AIDS	Acquired Immune-Deficiency Syndrome
API	Active Pharmaceutical Ingredients
BBC	British Broadcasting Corporation
cGMP	current Good Manufacturing Practices
DFID	Department for International Development
EDM	Essential Drug Monitoring
EID	Establishment Inspection Directorate
FCT	Federal Capital Territory
FDIC	Food and Drug Information Centre
FSHSS	Federal Service for Health Sphere Supervision
HCl	Hydrochloric Acid
HIV	Human Immunodeficiency Virus
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
KSZ	Kano Special Zone
LFN	Laws of the Federal Republic of Nigeria
LGA	Local Government Area
LSZ	Lagos Special Zone
MAS	Mobile Authentication System
MCA	Medicines Control Agency
MHRA	Medicines and Healthcare Products Regulatory Agency
MMIA	Murtala Mohammed International Airport
NDLEA	National Drug and Law Enforcement Agency
NAFDAC	National Agency for Food and Drug Administration and Control
NAHCO	Nigeria Aviation Handling Company PLC

NAIA	Nnamdi Azikiwe International Airport
NCZ	North Central Zone
NQCL	National Quality Control Laboratory
NSAIDS	Non-Steroidal Anti-Inflammatory Drugs
NWZ	North West Zone
OVD	Optically Variable Devices
PMS	Patent Medicine Store
RFID	Radio Frequency Identification
SAP	Structural Adjustment Programme
SEZ	South East Zone
SMS	Short Message Service
SON	Standards Organization of Nigeria
SP	Sulphadoxine/Pyrimethamine
SSFFC	Spurious Sub-standard Falsely-labelled Falsified Counterfeit
SSZ	South South Zone
SWZ	South West Zone
SZA	Special Zone Aba
SZO	Special Zone Onitsha
SZOA	Special Zone Abeokuta
UK	United Kingdom
US	United States
USFDA	United States Food and Drug Administration
USP	United States Pharmacopoeia
USSR	Union of Soviet Socialist Republics
WADRAN	West African Drug Regulatory Authority Network
WCO	World Customs Organization
WHO	World Health Organization
WTO	World Trade Organization

CHAPTER ONE

INTRODUCTION AND BACKGROUND OF THE STUDY

1.1 Background

Nigeria is a Federal constitutional republic comprising thirty-six states and its Federal Capital Territory, Abuja, which are further sub-divided into 774 Local Government Areas (LGAs). The country is located in West Africa and shares land borders with the Republic of Benin in the west, Chad and Cameroon in the east, and Niger in the north. Its coast in the south lies on the Gulf of Guinea on the Ocean. Nigeria has a varied landscape. The far South is defined by its tropical rain forest climate where annual rainfall is 6080 inches (1524-2032 mm) a year. The three largest and most influential ethnic groups in Nigeria are the Hausa, Igbo and Yoruba. Nigeria has a total area of 923,768 km^2 (356,669 m^2). Based on the estimated exponential growth rate of 3.2 percent from the 2006 population

census, Nigeria's population was estimated at above 162 million in 2011 (World Population Data Sheet, 2011), making it the most populous country, in Africa and the eighth in the world.

The economy of Nigeria is one of the fastest growing in the world. It is the second largest economy in Africa. It is listed among the "Next Eleven" economies and is a member of Commonwealth of Nations. Being an emerging economy, a large proportion of the population prefer to visit Patent Medicine Stores (PMS), Pharmacy or hawkers of medicines without prescription; a practice which endangers their lives, hence ensuring that quality medicines are sold over the counter is of paramount interest to the government.

1.2 History of NAFDAC

Nigeria with the above demographic, economic and health indices is a target and a destination for counterfeiters. In response to the challenge of counterfeiting of food, medicines, cosmetics and other related products, the Federal Government of Nigeria established the National Agency for Food and Drug Administration and Control (NAFDAC).

The formation of NAFDAC was inspired by a 1988 World Health Assembly resolution requesting countries' help in combating the global health threat posed by counterfeit pharmaceuticals. This led to the

Figure 1: Map of Nigeria showing states

creation of National Agency for Food and Drug Administration and Control (NAFDAC) out of the Federal Ministry of Health, Nigeria in 1993. The first governing Council of the Agency was inaugurated on 31st December, 1992, sequel to the promulgation of the enabling NAFDAC Decree 15 of 1993 as amended by decree 19 of 1999, now ACT CAP N1 LFN 2004 to regulate the importation, exportation, manufacture, distribution, sale, advertisement of food, medicines, cosmetics, packaged water, chemicals, detergents and medical devices. This inauguration provided the springboard for the commencement of full regulatory activities in 1993.

The goal of NAFDAC, in a nutshell is to ensure that only safe and registered regulated products are

consumed by the populace. The mission statement is 'Safeguarding the health of the nation'. NAFDAC is a parastatal under the Federal Ministry of Health within the control of the Honourable Minister of Health. It also has delegated powers of the Attorney General of the Federation by exercising prosecution as contained in the Counterfeit and Fake Medicines and unwholesome processed foods ACT CAP C34 LFN 2004, which empowers the Agency to investigate and prosecute offenders.

NAFDAC as a scientific Regulatory Agency is responsible for the regulation of the safety and quality of locally manufactured and imported regulated products in Nigeria. Its primary function is consumer protection.

1.2.1 Management Structure

NAFDAC *is headed by a Director General, who is the Chief Executive Officer. There are Thirteen directorates, headed by Directors, namely:*

1. *Accounts and Finance*
2. *Administration & Human Resources Management*
3. *Investigation and Enforcement*
4. *Chemical Evaluation and Research*
5. *Laboratory Services*
6. *Narcotics and Controlled Substances*

7. *Planning, Research and Statistics*
8. *Ports Inspection*
9. *Registration and Regulatory Affairs*
10. *Drug Evaluation and Research*
11. *Food Safety and Applied Nutrition*
12. *Pharmacovigilance and Post Market Safety Surveillance*
13. *Veterinary Medicine and Allied Products*

The Office of the Director General comprises the following units headed by the Director – Special Duties

i) *The Legal Unit: This is charged with offering legal advice and is the custodian of legal documents and all agreements relating to the Agency.*

ii) *The Public Relations and Protocol Unit: Its main function is to inform, sensitize, enlighten and create awareness concerning the role of the Agency in Food and Drug Administration. The Protocol is in charge of logistics.*

iii) *Internal Audit Unit: This provides a means of measuring the effectiveness of the system of internal control and accounting, and carries out special investigations.*

iv) *Technical services: Unit coordinates the collaborative efforts of NAFDAC with international organizations.*

v) *Lagos liaison office.*

vi) *Reforms Unit.*

vii) Engineering
viii) Procurement Division.

1.2.2 NAFDAC's Mode of Operation

The Agency has offices in all states of the federation with special zonal offices in the areas with endemic drug regulatory problems. These are in addition to the six (6) zonal offices representing the six geopolitical zones of the country and six laboratories spread over the country. NAFDAC is also present at the seaports, airports and the land borders to regulate the importation and exportation of regulated products.

Investigation and Enforcement Directorate works in partnership with other directorates and the general public to enforce the provisions of the NAFDAC mandate. It is responsible for the investigation, interrogation and compilation of case files in the Agency.

Narcotics and Controlled Substances Directorate controls the importation, distribution and use of narcotics and psychotropic substances.

1.3 Problems of Spurious Substandard and Falsely-labelled Falsified Counterfeit Medicines

Counterfeiting of medicines and the proliferation of substandard medicines, which is a major obstacle that prevents access to safe, quality and efficacious

medicines has become a global problem. Counterfeited pharmaceutical products belonging to almost all therapeutic classes have been found world-wide. However, counterfeit anti-infectives is a wide-spread problem.
The primary problem with counterfeit medicines is the significant danger they pose to public health and safety.

In developing countries, people and organizations are using the few resources they have to purchase life-saving medications. Some of the most vulnerable people in the world are being exploited because of their great health need. A number of incidents reveal the danger that counterfeit medicines pose to people around the world. One common incident that readily comes to mind is the case of death of a number of children in Nigeria due to Di-ethylene glycol (anti-freeze) poisoning from Paracetamol syrups in 2008.

It is also a fact that counterfeit medicines pose a great threat to public health and the attainment of the Millennium Development Goals 4, 5 and 6, which are; Reduction of infant mortality, Improving maternal health and Combating HIV/AIDS, malaria and other diseases respectively.
The World Customs Organization puts annual medicine counterfeiting business at US$200 billion as

at 2010. A study conducted by the National Agency for Food and Drug Administration and Control (NAFDAC) in collaboration with the World Health Organisation (WHO) and the Department for International Development (DFID) in 2005, revealed that pharmaceutical counterfeits in Nigeria was at 16.7 percent.

1.4 NAFDAC's Efforts in Fighting Counterfeit, Substandard and Fake Medicines and Food Products

NAFDAC has not relented in its efforts in ensuring that only genuine and good quality food, drugs, cosmetics and medical devices are sold and consumed in Nigeria. This is done through regular monitoring and inspection of locally manufactured and imported products, however, the challenges faced in its routine activities have not prevented the Agency from carrying out its functions.

1.4.1 Previous Efforts

Increased pharmacovigilance and reporting. *Pharmacovigilance is a key public health function. There is a need to accurately describe counterfeit related injuries and disease, identify their determinants and develop prevention strategies. The Pharmacovigilance unit in NAFDAC collates such data.*

Public Enlightenment Campaigns.

Establishment of Consumer Safety Clubs in Nigerian High schools, NAFDAC Green Pages, collaboration with Nigerian Youth Corp members.

National and International collaboration -

NDLEA, SON, Nigerian Customs Service, WADRAN, IMPACT, WHO, WTO.

- *Educating stakeholders to increase compliance with proper registration of medicines and all pharmaceuticals.*

Capacity Building - training of staff, restructuring and modernizing regulatory processes.

- *Beefing up of surveillance at all ports of entry.*
- *Post-market surveillance and mop-up of counterfeit regulated products from circulation.*
- *Enacting laws that impose stiffer penalties on counterfeiters.*

Stopping fake imports at source i.e. countries of production (pre-shipment testing).

The vast majority of counterfeit medicines are currently thought to be produced in some Asian countries. Presently, NAFDAC through collaboration with the governments of those countries has set up machinery to ensure that extensive analytical testing is carried out on medicines to be exported to Nigeria prior to shipping. Also, routine inspections are carried out in factories where these products are made to ensure that current Good

Manufacturing Practices (cGMP) are adhered to.

- *Enforcement of compliance to cGMP on local manufacturers.*
- *Streamlining and strict enforcement of registration guidelines, staff re-orientation and modernization of regulatory processes.*

1.4.2 Use of Modern Technologies

Technology plays a critical role in solving many serious health problems around the world. Since assumption of office as the Director General of NAFDAC in 2009, Dr. Paul Orhii strove beyond what he inherited from his predecessor by broadening the scope of the anti-counterfeiting war by initiating many programmes and policies. Among his initiatives is the use of cutting-edge technologies in the fight against counterfeiting. These include the Minilabs, Radio Frequency Identification (RFID) for securing NAFDAC documents, Mobile Authentication Service (MAS) (i.e. TEXT messaging), the use of Raman Spectrometer (i.e. TruScan®) for on-the-spot identification of counterfeit products, and Deep Infra-red Imaging (Black Eye).

Mobile Authentication Service (MAS)

One of the new technologies currently employed by NAFDAC in the war against counterfeiting is the Mobile Authentication Service™ (MAS) which empowers the customer to check the authenticity of the medicine through the use of a scratch - text card with a mobile phone before purchase. A concealed unique code (set of numbers) is

revealed upon scratching off the coating on the drug's packaging. The customer is directed to send the revealed unique code as an SMS to the open short code (38353) on the pack. The customer then receives an instant reply on the product's status as either "Genuine" or "Fake".

If the packaging contains a counterfeit code, the consumer will receive a message alerting him/her that the medicine may be a fake, and an accompanying phone number to report the incidence.

The Mobile Authentication Service (MAS) is free and available anywhere there is a mobile telephone service signal in Nigeria. It is compatible with all the country's mobile networks. Considering the widespread use of mobile telecommunication in Nigeria, the MAS service provides the unique advantage of ease of use and accessibility to much required information on authenticity of medicines to a large number of consumers, especially before purchase.

The Director General, Dr. Paul Orhii and his team with Mr Dan Rather a foreign journalist during a TruScan® Exercise at Apapa Port, Lagos in 2010

TruScan® (Raman Spectrometer)

Spectroscopy in general is the characterization of a substance based on the way it interacts with light. Raman spectroscopy is a vibrational spectroscopic technique. The sample of interest is illuminated with an intense single wavelength light source. The light-scatter from the sample gives a spectrum. In the resulting spectrum, different types of bonds show up as peaks of varying intensity creating a unique fingerprint for a particular compound.

Until the advent of miniaturized, portable versions, the Raman Spectrometer was a large, bulky laboratory instrument, which had been used for many years by analytical chemists in pharmaceutical laboratories due to its high selectivity and specificity.

The TruScan® device is Thermo-Fisher Scientific brand of Raman Hand-held spectrometer for on-the-spot detection of counterfeit medicines. It is designed to allow regulators and law enforcement officers without any formal chemistry training to conduct field-based screening of pharmaceutical samples to quickly and accurately identify counterfeits. Though not all pharmaceuticals are well suited to rapid screening with Raman Spectroscopy, it is believed that the majority are.

The spectrum generated by the TruScan® examines all the components of a pharmaceutical dosage form: Active pharmaceutical ingredients (API), excipients, fillers, dyes, coatings, etc. to generate a spectrum representative of all of them (and their relative concentrations). Any slight deviation from the original formulation will lead to a detectable change in the resulting spectrum. This makes it the ideal tool for rapid detection of counterfeit pharmaceuticals in the field.

1.5 Definition of Terms Used

Counterfeit

The World Health Organization (WHO) defines counterfeit medicines as "medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source". Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients, with the wrong

ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

Substandard

A genuine product can be considered as substandard if it does not meet the required specifications. Therefore, substandard medicines are genuine pharmaceutical products which do not meet the set quality specifications. This could be in terms of inability to meet active pharmaceutical ingredients (API).

Fake

The following statements qualify a medicine or pharmaceutical product as fake:

(a) Any medicine or pharmaceutical product which is not what it purports to be.

(b) Any medicine or pharmaceutical product, which is so coloured, coated, powdered or polished such that the damage is concealed, or which is made to appear to be of better or of greater therapeutic value than it really is, or which is not labelled in the prescribed manner, or which label or container or anything accompanying the medicine bears any statement, design or device which makes a claim for the medicine which is false or misleading.

(c) Any medicine or pharmaceutical product whose container is so made, formed or filled as to be misleading.

(d) Any medicine or pharmaceutical product whose label does not bear adequate directions for use and adequate warning for use in pathological conditions or by children where its use may be dangerous to health, or warning against unsafe dosage or methods of administration or duration of use.

(e) Any medicine or pharmaceutical product, which is not registered by NAFDAC in accordance with the provisions

of the Food, Medicines and Related Products (Registration) Decree or Law.

Spurious Substandard Falsely-labelled Falsified Counterfeit Medicines

Spurious Substandard Falsely-labelled Falsified Counterfeit (SSFFC) medicines are medicines that are deliberately and fraudulently mis-labelled with respect to identity and/or source.

i. Use of SSFFC medicines can result in treatment failure or even death.
ii. Public confidence in health systems may be eroded following use and/or detection of SSFFC medicines.
iii. Both branded and generic products are subject to counterfeiting.
iv. All kinds of medicines have been counterfeited, from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines.
v. SSFFC medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging.

SSFFC medicines are found everywhere in the world. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a SSFFC medicine is unknown and its content unreliable. SSFFC medicines are

always illegal. They can result in treatment failure or even death. Eliminating them is a considerable public health challenge.

1.6 Objectives of Study

i. To ascertain the effectiveness of detecting counterfeit medicines using cutting-edge technologies particularly Raman spectroscopy.
ii. To assess the correlation between results obtained using the TruScan® (Raman spectrometer) and those from the Laboratory.
iii. To determine the prevalence of counterfeited medicines in Nigeria.
iv. To determine the prevalence of the commonly counterfeited medicines in Nigeria.
v. To track-down the importers of the counterfeit medicines along the distribution chain.

CHAPTER TWO

GLOBAL CHALLENGES OF SPURIOUS SUBSTANDARD FALSELY-LABELLED FALSIFIED COUNTERFEIT, SUBSTANDARD AND FAKE PRODUCTS

2.1 Global Phenomenon of Counterfeiting

A counterfeit is an imitation, usually one that is made with the intent of fraudulently passing it off as genuine. Counterfeiting is an evil phenomenon that is almost as old as life; it is one of the fastest growing economic crimes of modern time. What was once a cottage industry has now become a highly sophisticated network of organized crime that has the capacity to threaten the very fabric of national economies, endanger safety and cause death. The phenomenon has

grown in recent years due to counterfeiting methods becoming more sophisticated and increase in the amount of merchandise moving in international commerce and across borders.

The list of products that can be counterfeited is unending: clothing, software, pharmaceuticals, watches, electronics, currency, company logos and brands. The counterfeiting of pharmaceutical products is a multi-billion dollar industry and measures must be taken by countries and pharmaceutical companies to protect products and profits.

A perception exists that counterfeit medicines are only a problem for developing countries. Historically this may have been the case, but the impact is increasingly being felt even in developed economies.

The problem of drug counterfeiting appears to be growing despite greater awareness with reports in newspapers, cinema, and television campaigns as well as information posted on the internet. WHO and International Medical Products Anti-counterfeiting Taskforce (IMPACT) estimated that counterfeit medicines constitute up to 25% of total medicines supply in developing countries and in some countries the figure is thought to be as high as 50%. (WHO/IMPACT Report, 2006).

The advent of the internet has opened up trade in counterfeit pharmaceuticals to all inhabitants across the globe. The internet provides criminals with anonymity; moreover it provides them the ability to operate their activities from any location that has communications equipment.

2.2 Historical Background of Counterfeiting

Since our ancestors began trading several millennia ago, counterfeit and substandard medicines have been a recurring problem, with history punctuated by crises in the supply of anti-malarials such as fake cinchona bark in the 1600s and fake quinine in the 1800s. Unfortunately, this problem persists particularly in developing countries afflicting unsuspecting patients. (Newton et al., 2010).

The appearance of counterfeit medicines in international commerce was first mentioned as a problem at the WHO Conference of Experts on Rational Drug Use in Nairobi, Kenya, in 1985. Since then, public awareness of the problem of counterfeit medicines has grown. Both government authorities and manufacturers have been concerned with efforts aimed at preventing the problem and WHO has received reports related to counterfeit medicines from some of its member states on a voluntary basis. According to this information, the problem is known to affect both developed and developing countries.

Between January 1999 and October 2000 alone, forty-six (46) confidential reports relating to such medicines were received by WHO from twenty (20) countries. About 60% of these reports came from developing countries whereas the remaining 40% were reported by developed countries. This information clearly shows that the problem exists. (WHO Technical Report, 2011). The extent of counterfeiting is impossible to quantify. However, the number of incidents detected in 2007 increased to over 1500 (that is on average more than four cases a day), roughly a 20% increase with respect to 2006 and a ten-fold increase compared with 2000. These increases reflect improved detection and reporting capacity, but also indicate that the problem is growing in numbers (WHO Report, 2008).

2.3 Global Trends of Counterfeiting

Counterfeit pharmaceutical products were previously thought to be a substantial and increasing problem of low-income countries, most of the time caused by weak administrative systems. At the first global forum on pharmaceutical anti-counterfeiting held in Geneva, in September 2002, many participants brought to light the counterfeiting problems that existed in their various countries (Reconnaissance Int'l, 2002).Several cases of court actions resulting from patients treated with fake or counterfeit medicines were reported in the United States, notwithstanding their drug distribution chain

being one of the most regulated and policed pharmaceutical markets in the world (Cockburn et al., 2005). Counterfeit medicines had been detected through referrals from public and professional bodies, whistle blowers and covert test purchases according to a report presented by the Medicines Control Agency (MCA) of the United Kingdom. It is noteworthy that the types of counterfeit pharmaceuticals found in the UK are similar to those found in other countries. These include look-alikes, identical copies, relabelled products, expired authentic and rejected authentic products that found their way back to the markets. Examples include Nubian (Nalbuphine HCl) injection, multi-dose presentations not licensed in UK and Viagra (Sildenafil Citrate) with contents varying between 40-100% of claim (MHRA, 2005).

Recently, a report from BBC News announced that a man was jailed for eight years for being part of the plot involving the importation of 72,000 packs of counterfeit medicines with retail value of 4.7million pounds from China to the UK (BBC News, 2011).

The distribution of medicines also poses a problem, as there are about 40,000 small outlets and kiosks selling medicines. New pharmacies on wheels have also joined in this business of distributing medicines and causing further chaos (Muhammed, 2008).

Interest in the problem of counterfeiting is relatively new for transitional economies, such as Ukraine. It is estimated that the amount of counterfeit medicines found in some countries of the former USSR is up to 30%. For instance, the Ukrainian officials shut down nearly 150 pharmacies in the first half of 2010 because they were suspected to be selling counterfeit medicines. This is because there was no adequate control of import and distribution of pharmaceutical products despite a national legislation for the control of the pharmaceutical market.

2.4 Counterfeiting in Africa

In Africa, the incidence of fake and counterfeit medicines is difficult to estimate because of poor communication, the non-existence or ineffectiveness of drug regulatory authorities, poor drug procurement practices, low literacy levels, low awareness of the existence of fake and counterfeit medicines, political instability, and high level of smuggling of pharmaceutical products into the region.

In 2005, a random survey in Kenya by the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons Board revealed that almost 30% of the medicines in Kenya were counterfeit. Some of the medicines were no more than just chalk or water marketed as legitimate pharmaceutical products.

According to figures from the Kenyan Association of Pharmaceutical Industry, counterfeit pharmaceutical products account for approximately $130 million annually in sales in the country (Commonwealth Health Minister's Meeting, 2007).

Within the West African sub-region, there are very high activities in inter-boundary trade in pharmaceuticals. Many West African countries, such as Togo, Benin, Chad, Niger, Ghana and Cameroon buy their medicines from Nigeria because Nigeria has the biggest drug market in the sub-region. In the Republic of Benin, for instance, this inter-boundary trade is known as the "parallel market". An Essential Drug Monitoring (EDM) report quotes the Beninoise National Office of Health Protection as estimating patronage of this parallel market to be around 85% of the population. These counterfeit medicines were generally reported to come from Gabon, Nigeria, and from Asia, Europe and North America. This market is often controlled by travelling sales persons who have no training and lack all necessary skills to dispense medicines. In that event, the situation in Nigeria naturally reflects that of other countries in the sub-region (NAFDAC, 2009).

2.5 Nigerian Perspective

Even though the counterfeiting of pharmaceutical products is a global phenomenon, some countries, including Nigeria, are more affected than others.

The high incidence of fake medicines in Nigeria was a fallout from the haphazard ways import license on medicines were issued to anyone by the then politicians and military leaders in the early 80's, disregarding the eventual public health implications of their actions. Some of the beneficiaries of the import license found out that a lot of money could be made from the drug business, and suddenly became emergency drug importers. With the booming market and competition, some of them looked at the option of importing fake products in order to have an edge over their competitors. The situation got worse with the adverse economic effects of the Structural Adjustment Programme (SAP) introduced in mid 1980's and progressively worsened until 2001 when NAFDAC started an aggressive war against fake medicines.

In Nigeria today, it is common knowledge that medicines are treated as general merchandise, which can be easily sourced from open markets, moving vehicles, faceless medicine stores, ferries, and even in the provision stores. This is because the drug distribution business has been left in the hands of non-

professionals who just want to make profit at the expense of the consuming public (NAFDAC, 2006).

The first phase of the study in six major drug markets across the country by NAFDAC in 2002, to measure the level of compliance to drug registration revealed that 67.95% were unregistered by the Agency. A repeat of this study in 2003 revealed an 80% reduction. The second phase of the study conducted in 2005 in collaboration with WHO and DFID included laboratory testing and further investigations of the surveyed drug products revealed the level of fake and substandard medicines in the country to be 16.7% (NAFDAC/WHO/DFID, 2005).

2.6 Causative Factors

The factors facilitating the occurrence of counterfeit medicines vary from country to country. However, the most common factors are considered to be: lack of legislation prohibiting counterfeiting of medicines, weak penal sanctions, weak or absence of national drug regulatory authorities, weak enforcement of drug laws, shortage or erratic supply of medicines, lack of control of medicines for import/export, trade involving several intermediaries and free trade zones, sales of medicines over internet, corruption and conflict of interest (WHO, 1999; 2003; 2004; Public Health, Innovation and Intellectual Property Rights, 2006).

In a study on prevalence of fake and counterfeit medicines in Nigeria, porous borders, greed and corruption were identified as the major factors responsible for the thriving and persistence of fake medicines in Nigeria. Other factors that pose threat were identified as poverty, weak legislation and high cost of life-saving medicines while the current economic meltdown is not of any threat to the persistence in the incidence of fake medicines.

It is increasingly apparent that counterfeit products are part of the income generating and laundering sides of organizations devoted to crime and terrorism. Interpol reported that counterfeit products, including medicines account for much of the money the international terrorist network depends on to feed its operations (Millar, 2002).

In the past decade or so, the pharmaceutical industry has shifted a large part of its manufacturing operations and supply sourcing overseas. Today, nearly forty percent of the medicines Americans take are imported and nearly eighty percent of the active ingredients in the medicines on the American market come from overseas sources (Hamburg, 2010).

In Nigeria, seventy percent of medicines consumed are imported. So, in addition to the growth in volume of

imports, there has been a dramatic increase in the variety and complexity of imported products. As a result, the supply chain from raw material to finished product has become more complex and complicated involving a web of re-packagers and distributors in a variety of locations. Like any chain, the medicine supply chain is only as strong as its weakest link, and the proliferation of additional handlers, suppliers and middlemen creates new entry points through which contaminated, adulterated and counterfeit products can infiltrate the drug supply. Counterfeits, diversions and cargo theft are all part of a growing criminal enterprise, which also includes the deliberate adulteration of medicines and consumer products to maximize profits and unknown threats that are yet to surface.

2.7 Global Threats of Counterfeiting

Counterfeit products are estimated to comprise 5-7% of global trade (International Chamber of Commerce 2011). Particularly insidious are counterfeit medicines, which the International Policy Network estimates result in 700,000 deaths per year from counterfeit versions of medications for malaria and tuberculosis alone (Harris, Stevens and Morris, 2009). In 2008, more than eighty children in Nigeria died after being given medicine for teething pain and a similar case was reported in Bangladesh where more than twenty

children died after being given acetaminophen. In addition to injury and death, global economic harm results from sales of counterfeit medicines. The U.S.-based Center for Medicine in the Public Interest' predicted that counterfeit drug sales will reach $75 billion globally in 2010, an increase of more than 90% from 2005 (Counterfeiting Facts and Statistics, 2009).

2.8 Anti-counterfeiting Measures

Tom Woods of Woods International suggested the need for better cooperation and optimization of resources to combat the growing international public health threat of counterfeit medicines. At the 6th Global Forum on Pharmaceutical Anti-counterfeiting held in London UK, in May 2011, Roger Bates revealed that one major thing that needs to happen to improve international cooperation is to make the falsification of medicines an international public health crime. He expounded that without an international law against falsified medicines, there is little chance of extradition, few prosecutions, and almost no attention given to the middle of the counterfeit supply chain (Reconnaissance International, 2011).

Another measure is the recognition that pharmaceutical security is moving away from the package and towards the product itself. Taggants and markers are now being incorporated into genuine

products (a move recognized by the US Food and Drug Administration in its draft Guidance Document on the use of physical-chemical identifiers issued in July 2009); similarly, small scale, hand-held analytical devices are being deployed to enable rapid differentiation between genuine and doubtful products in the field. The outcome of these new techniques, combined with established technologies, is that pharmaceutical authentication is faster and more reliable than it has been (6th Global Forum on Pharmaceutical Anticounterfeiting and Diversion, 2011).

Other measures include:

- Determining the real extent of the problem
- Strengthening regulatory infrastructure and effective collaboration between agencies
- Making judicial proceedings effective by speedy trials and imposing tougher penalties
- Securing the medicinal product totally from the procurement of raw material to effective post marketing vigilance system
- Dealing with corruption
- Improving healthcare systems

2.9 New and Innovative Solutions

New solutions being developed involve technology. Some of these are simple technology, such as

colorimetric (colour) assays developed for artemisinin and used successfully to identify fake artesunate anti-malaria.

The "Minilab" developed by German Pharma Health Fund is a relatively simple tool used to determine the authenticity of a wide range of essential medicines. The USFDA recommended that pharmaceutical companies should start using radio frequency identification technology (RFID) as a means of tracking medicines more effectively. Several pharmaceutical companies are experimenting with RFID and optically variable devices (OVDs) or at least using bar codes or other technologies such as web portals that can help track and authenticate the medicines. Some companies are also testing holograms, colour shifting inks and watermarks that can help them authenticate the package and actual pills. Others are experimenting with using inks or dyes and some are already using tamper-resistant packaging tape on some of their products (WHO, 2006).

Other technological solutions currently being tested are relatively expensive. One of them is TruScan®, a device which is being deployed to enable rapid differentiation between genuine and doubtful medicines in the field. NAFDAC in an effort to employ a multi-dimensional approach to tackle the issue of

counterfeiting of regulated products is spearheading global efforts in the use of cutting-edge technologies. TruScan®, a hand-held device used to detect counterfeit medicines was deployed in Nigeria in January 2010. It has the capability of detecting fake medicines within a couple of minutes. This makes NAFDAC the first regulatory agency in the world to deploy TruScan® in this manner and will go a long way to further checkmate the influx of counterfeit medicines into the country.

CHAPTER THREE

MATERIALS AND METHODOLOGY

3.1 Methodology

This survey employed quantitative approach for collecting samples of medicines to be tested across all the states and Federal Capital Territory in Nigeria using multistage selection. At the first stage of this study, a list of the commonly counterfeited medicines was used as criteria for medicines selection. The second stage entails dividing the study group into six (6) teams; on the average each team visits ten (10) outlets sited in different geographical locations of the state under consideration. Medicines to be tested are randomly selected at the third stage during the field visits. Selected medicines are tested on the spot using TruScan®, subsequently same samples are sent to Laboratory (the gold standard) for confirmatory test. The results are recorded and captured electronically for ease of data analysis.

A NAFDAC Officer during a TruScan® Survey Exercise in Taraba State

3.2 National Survey Using the TruScan®

The TruScan® is Thermo-Fisher Scientific brand of portable Raman spectrometer for on-the-spot detection of counterfeit medicines. Four units of TruScan® device were purchased by the Agency in November 2009 as part of the anti-counterfeiting drive. Additional two units were acquired in January 2010. This survey was designed primarily to ascertain the prevalence of counterfeit medicines in the thirty six States of the Federation and the FCT; and to determine the effectiveness of deploying modern (cutting-edge) technology (i.e. Raman spectroscopy) for more rapid, and on-site detection of counterfeits. The Director

General of NAFDAC, Dr. Paul Orhii, mandated the study team to embark on a national survey of medicines using the TruScan® equipment with the following objectives:

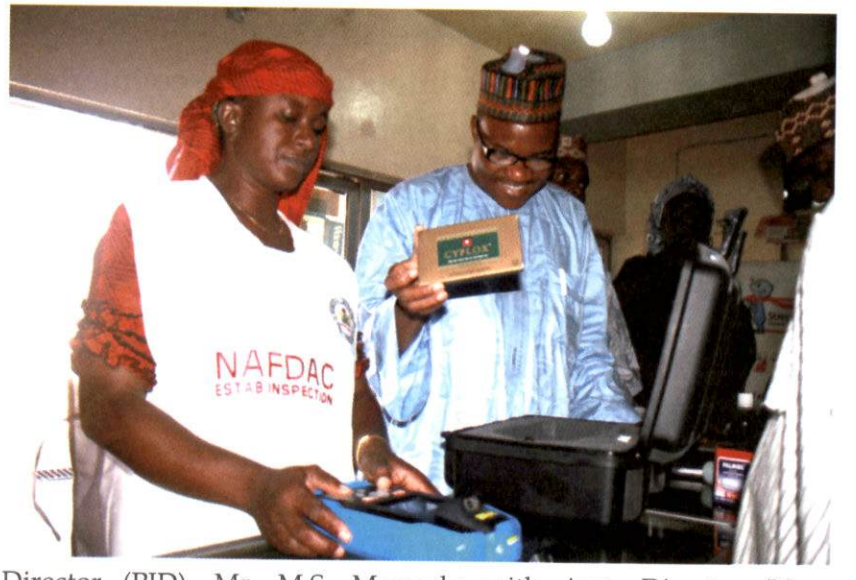
i. To ascertain the effectiveness of detecting counterfeit medicines using cutting-edge technologies particularly Raman spectroscopy.
ii. To assess the correlation between results obtained using the TruScan® (Raman spectrometer) and those from the Laboratory.
iii. To determine the prevalence of counterfeited medicines in Nigeria
iv. To determine the prevalence of the commonly counterfeited medicines in Nigeria.
v. To track-down the importers of the counterfeit medicines along the distribution chain.

3.2.1 Training

Regulatory officers from various Directorates of the Agency commenced training in December 2009 on all aspects (Administration, Method Development and Operations) of the TruScan®, leading to capacity building and exposure of the staff to cutting-edge technology. The training focused on enlightening the data collectors with the aim of acquainting them with what will be done in the field. Of importance at the training was how to select the medicines to be tested and the use of the device for testing the selected medicine.

3.2.2 Study Description

An earlier surveillance indicated antibiotics and anti-malaria medicines to be the most counterfeited medicines in Nigeria. Medicines with high retail prices are also frequent targets of counterfeiting as well as reputed top selling brands, hence the use of these categories of medicines as the focus of this study. In all the locations visited so far, medicines were sampled in both registered pharmacies and patent medicine outlets. Irrespective of the TruScan® results (i.e. pass or fail), all the medicines were sampled for laboratory confirmation. The laboratory and TruScan® results for each sample were then recorded and compared.



Director (PID), Mr. M.S. Momodu with Asst. Director (New Technologies) Mrs. Leli Aigbomian during a TruScan® Survey Exercise in Kano state

3.2.3 Method Development

Some Regulatory Officers were trained specifically on Method Development which is essentially building a database/spectral library for the TruScan®. Several batches of authentic medicines were obtained from the manufacturers, analyzed and their signatures captured and stored in the TruScan® as a reference standard.

Over 150 signatures have been successfully acquired for the TruScan® library. The determining factors for candidacy for method development include:

- *Tendency or likelihood of being counterfeited*
- *Interceptions at the ports of entry/land borders*
- *Complaints of counterfeiting by companies and the general public.*

It is noteworthy that effort has been made to acquire signatures for many other products which either have weak spectrum or are not compatible with the TruScan®.

3.2.4 Preparation for Fieldwork

The TruScan® kits are normally inspected before each field activity to ensure that the accessories are complete. The device is calibrated with the polystyrene standard to ensure functionality. The field folders are equipped with the relevant documents and materials; field jackets are also made available for the operation. There are usually six teams, each assigned a TruScan® device. Each team is made up of a Team Leader, TruScan® Operator, Recorder, State EID officer as guide, Police Officers and members of the press.

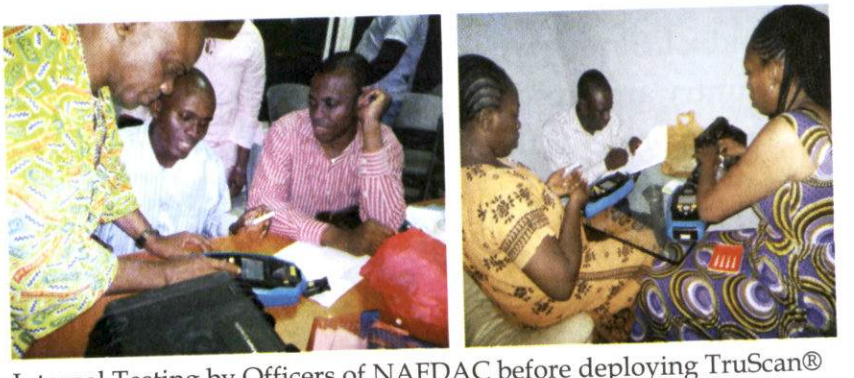
The State Head (EID) would have been given prior notice to purchase medicines randomly (based on brands compiled from the TruScan® list of methods) from pharmacies and shops for internal testing. This gives an indication of the prevalence of counterfeit medicines in that state and the areas to concentrate on.

The study team and EID officers from neighbouring states arrive and check into a secure accommodation a day to the exercise. A preliminary meeting is held to brief the members from the states on the modus operandi and to fine-tune preparations for the assignment of the following day. The final team list and the itinerary are worked out to ensure reasonable coverage of the area. The medicines purchased by the State EID are internally tested during the briefing. The press and the policemen are not present at this preliminary meeting.

On the day of the exercise, the six teams assemble for final directives before departing to their various assigned locations. A team is always assigned to mandatorily cover the popular medicines market in the state being surveyed.

3.3 Sampling and Selection Procedure

The personnel in charge of the medicine outlets are briefed on the purpose of the visit before commencing test on the medicines. The medicines, whose signatures are on the TruScan® library, are sampled randomly from the shelves. The labelling details (Batch Number, Manufacturing Date, Expiry Date, and NAFDAC Registration Number) are recorded on the appropriate forms before the medicines are tested with the TruScan® device and the results obtained recorded.

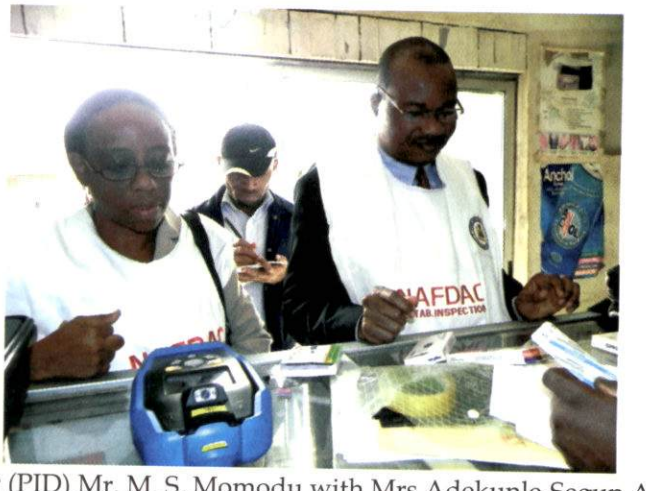


Internal Testing by Officers of NAFDAC before deploying TruScan® to outlets for the survey

For medicines that fail the TruScan® test, the products are documented and withdrawn. The owner of the premises/superintendent pharmacist is served a letter of invitation to report at the State EID office for interrogation the following day. Any outlet with high failure rate is placed '**ON HOLD**' (temporarily sealed) for further investigation.

The inventory of the withdrawn medicines is taken and a duly signed copy given to the shop owner. The medicines that pass the TruScan® test are paid for and receipts obtained. All the medicines tested in the field are sent to the laboratory for confirmation. Each team is expected to cover an average of ten outlets and at the end of the exercise, the groups converge at the state EID office for data collation, de-briefing and press briefing.

All the Thirty-six (36) states of the six geo-political zones of Nigeria including the Federal Capital Territory were covered in the study. Detailed information about the locations visited are presented in Appendix I. Similarly, list of medicines sampled across the country are presented in Appendix II. Chapter 4 of this report presents findings from the survey. Findings are presented according to the survey objectives.



Director (PID) Mr. M. S. Momodu with Mrs Adekunle-Segun Asst. Director (Method Development-TruScan®) during a TruScan® Exercise at Makurdi, Benue State

CHAPTER FOUR

DATA ANALYSIS AND RESULTS

4.1 Data Analysis

Analysis plan based on the study objectives described in Section 1.6 was developed. In order to provide reliable answers to each of the objectives, specific analyses to the objectives were carried out. For the purpose of this report, all analyses are limited to descriptive analysis through frequency and percentage distributions; and graphical representations. Inferential analysis will be explored for dissemination of these findings in peer reviewed journal articles and presentations at conferences.

4.2 Sampled Medicines

In this survey, different classes of medicines were sampled for investigation (test). The medicines are classified into: Antibiotics, Antidiabetics, Anti-malarial and other

medicines. Table 4.1 presents the findings on the frequency distribution of different classes of medicines tested using the TruScan®. Overall, a total of 6,419 medicines of various classes comprising 1,683 Antibiotics, 234 Antidiabetics, 3,441 Anti-malarial and 1,061 of other classes of medicines were sampled and tested.

The number of classes of medicines tested varies across NAFDAC's Zonal and Special Zonal offices. In total, 786 Medicines were tested in North West Zone, - 1,323 tested in North Central Zone, 1,341 tested in South South Zone, and 642 in North East Zone. Also, 742 Medicines were tested in South East Zone, 688 tested in South West, 101 tested in Kano Special Zone, and 313 tested in Lagos Zone. Findings show that 71 Medicines were tested in Special Zone Onitsha, 210 tested in Special Zone Abeokuta, and 202 tested in Special Zone Aba.

Table 4.1: Frequency distribution of medicines sampled according to NAFDAC's operation zones

Zone	Classes of Medicines				Total
	Antibiotics	Antidiabetics	Anti-malarial	Others	
North West Zone (NWZ)	223	21	383	159	**786**
North Central Zone (NCZ)	375	59	673	216	**1,323**
South South Zone (SSZ)	358	45	753	185	**1,341**
North East Zone (NEZ)	202	18	258	164	**642**
South East Zone (SEZ)	147	23	484	88	**742**
South West Zone (SWZ)	175	22	345	146	**688**
Kano Special Zone (KSZ)	7	14	80	0	**101**
Lagos Zone (LZ)	68	9	193	43	**313**
Special Zone, Onitsha (SZO)	13	10	48	0	**71**
Special Zone, Aba (SZA)	51	4	117	30	**202**
Special Zone, Abeokuta (SZOg)	64	9	107	30	**210**
Total	**1,683**	**234**	**3,441**	**1,061**	**6,419**

Figure 4.1: Map of Nigeria showing states where medicines were sampled

Figure 4.1 shows map of Nigeria with the states visited indicated in varying colour. Of the 36 states and Federal Capital Territory, samples of medicines were collected from 33 states and the FCT. Logistic challenges have inhibited access to the remaining three states (Borno, Plateau and Yobe). Arrangement to visit these states at the earliest time has been concluded. A large percentage of the products that were tested with TruScan® were also sent to NAFDAC's Laboratories across the country. This is to serve as a gold standard (confirmatory test).

Table 4.2 presents the frequency distribution of all medicines that were sampled across NAFDAC's zones and the tests (TruScan® and Laboratory) status as at the time of writing this report. In general, all sampled medicines (6,419) were tested using TruScan® device. However, only 5,986 of these sampled medicines were sent to Laboratory for confirmatory tests. The remaining 433 were not sent to Laboratory.

Of these, results of laboratory tests were only available for 2,205 while 3,781 samples of medicines of different classes were pending for laboratory test (as at the time of this report). In total, almost three-fifths (58.9%) of the samples collected and tested with TruScan® are pending for laboratory test. For detailed findings, see Table 4.2 and Figure 4.3.

Figure 4.2: Bar chart showing frequency distribution of sampled medicines across NAFDAC's operation zones

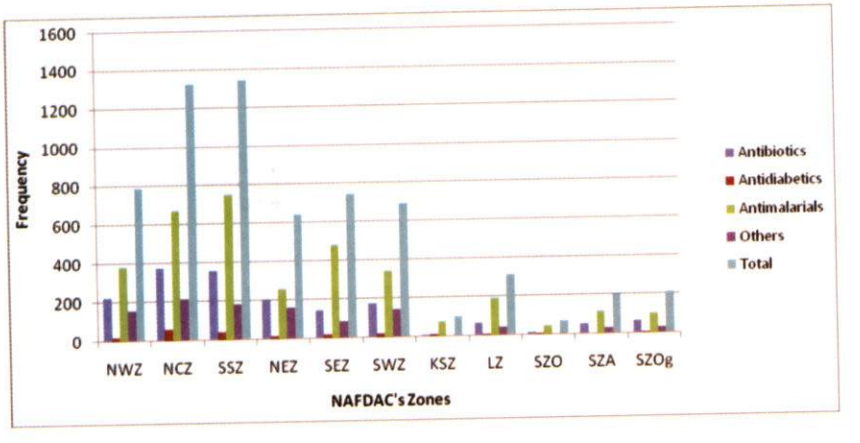
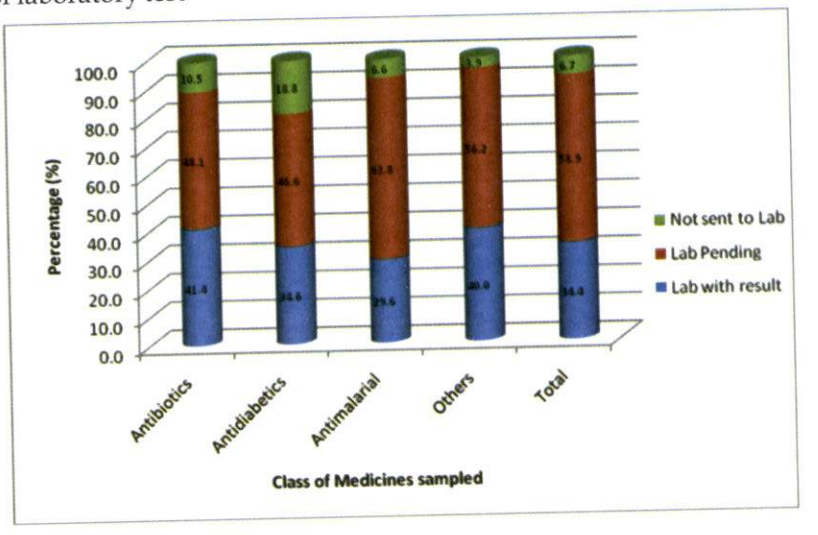


Table 4.2: Frequency distribution of all medicines tested with TruScan® device, in the Laboratory and samples pending for Laboratory testing

	Antibiotics				Antidiabetics				Antimalarials				Others				Total			
Zones	TruScan® with results	Lab with result	Lab Pending	Not sent to Lab	TruScan® with results	Lab with results	Lab Pending	Not sent to Lab	TruScan® with results	Lab with results	Lab Pending	Not sent to Lab	TruScan® with results	Lab with results	Lab Pending	Not sent to Lab	TruScan® with results	Lab with results	Lab Pending	Not sent to Lab
NWZ	223	29	154	40	21	4	10	7	383	58	295	30	159	20	120	19	**786**	**111**	**581**	**94**
NCZ	375	153	153	69	59	22	22	15	673	215	433	16	216	88	106	22	**1323**	**478**	**722**	**123**
SSZ	358	192	116	50	45	22	23	0	753	315	438	0	185	100	85	0	**1341**	**614**	**727**	**0**
NEZ	202	96	106	0	18	10	8	0	258	96	162	0	164	48	116	0	**642**	**250**	**392**	**0**
SEZ	147	38	109	0	23	3	20	0	484	63	421	0	88	36	52	0	**742**	**140**	**602**	**0**
SWZ	175	122	53	0	22	10	12	0	345	181	164	0	146	88	58	0	**688**	**401**	**287**	**0**
KSZ	7	1	0	6	14	2	0	12	80	10	0	70	0	0	0	0	**101**	**13**	**0**	**88**
LZ	68	16	56	0	9	2	7	0	193	20	114	61	43	18	25	0	**313**	**56**	**196**	**61**
SZOnitsha	13	0	0	13	10	0	0	10	48	4	0	44	0	0	0	0	**71**	**4**	**0**	**67**
SZA	51	0	51	0	4	0	4	0	117	0	117	0	30	0	30	0	**202**	**0**	**202**	**0**
SZAbeokuta	64	49	15	0	9	6	3	0	107	57	50	0	30	26	4	0	**210**	**138**	**72**	**0**
Total (No)	**1,683**	**696**	**809**	**178**	**234**	**81**	**109**	**44**	**3,441**	**1,019**	**2,194**	**228**	**1,061**	**424**	**627**	**41**	**6,419**	**2,205**	**3,781**	**433**
Total (%)		**41.4**	**48.1**	**10.5**		**34.6**	**46.6**	**18.8**		**29.6**	**63.8**	**6.6**		**40.0**	**56.2**	**3.8**		**34.4**	**58.9**	**6.7**

Figure 4.3: Percentage component bar chart showing percentage distribution of samples tested in the laboratory and samples pending for laboratory test



4.2 Sensitivity and Specificity of TruScan® Device

Sensitivity is a technique for determining reliability of a new method compared with a gold standard. In this case, a new method is the use of TruScan® device for measuring quality of medicines produced while the gold standard is the use of Laboratory test as a confirmatory test to the TruScan®. Therefore, the words "sensitivity" and "specificity" are two commonly used words in screening tests for diseases. From a single test, one may have the disease or may not have the disease (i.e. disease free). For instance, in this situation a medicine tested using TruScan® may pass or fail the quality test. Though these tests are generally or remarkably accurate, they still make some errors that must be accounted for or at least mentioned.

The main goal for confirmatory test is to validate the TruScan® device and investigate the possibility of false positive or false negative results. Table 4.3b displays the results from our survey of quality of medicines in Nigerian markets.In line with the first objective of this study on ability to ascertain the effectiveness of TruScan® in detecting counterfeit medicines, this requires understanding the sensitivity and specificity of the device. Sensitivity and specificity are statistical measures for assessing the performance of a binary classification test or device. Sensitivity measures the ability of a test/device to detect the true (actual) positives/passed which are correctly identified by the test/device as positives/passed. For instance, sensitivity of TruScan® is the percentage of medicines that are correctly classified as passed by the device. Specificity on the other hand measures the ability of a test/device to detect the true (actual) negatives/failed which are correctly identified by the test/device as negatives/failed. Therefore, it is essential to assess the sensitivity and specificity of TruScan® as a device for detecting counterfeit medicines before considering it for assessing quality of medicines. As a consequence, attempt was made to assess the sensitivity and specificity of the TruScan® device compared with the gold standard i.e. Laboratory test. To achieve this, we limit analysis to the samples that were tested with both TruScan® and Laboratory. Therefore, 2,205 samples

that have both TruScan® and Laboratory results were used for this purpose. Tables 4.3a-4.3c present the sensitivity results for different scenarios. While Table 4.3a presents the overall results for both TruScan® and Laboratory tests, Table 4.3b presents the overall sensitivity and specificity analyses for all the medicines combined. In Table 4.3c, sensitivity and specificity analysis for each of the classes of medicines is presented.

Table 4.3a: Frequency distribution of classes of medicines tested with both TruScan® and Laboratory analysis

	Passed Both		Failed Both		Passed TruScan® but failed Lab		Failed TruScan® but passed Lab		Total
Medicines	Number	%	Number	%	Number	%	Number	%	Number
Antibiotics	539	77.4	101	14.5	12	1.7	44	6.3	696
Antidiabetics	60	74.1	4	4.9	0	0.0	17	21	81
Antimalarials	712	69.9	174	17.1	22	2.2	111	10.9	1019
Others	372	91.0	5	1.2	3	0.7	29	7.1	409
Total	**1,683**	**76.3**	**284**	**12.9**	**37**	**1.3**	**201**	**9.1**	**2,205**

In general, sensitivity is the probability that TruScan® says that a medicine has passed when in fact it has passed (i.e. of good quality). Thus, this can be written as

$$P(TruScan = Passed \mid Lab = Passed) = \frac{1,683}{1,683 + 201} = \frac{1,683}{1,884} = 89.3\%$$

Intuitively, sensitivity is a measure of how likely it is for a test to correctly diagnose that a medicine has passed when indeed it has passed.

Specificity is the probability that the test says a medicine has failed (poor quality) when indeed the medicine is of poor quality. From our scenario in Table 4.3b, specificity is

$$P(TruScan = Failed \mid Lab = Failed) = \frac{284}{(284 + 37)} = \frac{284}{321} = 88.5\%$$

Table 4.3b: Contingency table presenting TruScan® vs. Laboratory results

TruScan® Test	Laboratory Test: Passed	Laboratory Test: Failed	Total
Passed	1,683	37	**1,950**
Failed	201	284	**447**
Total	**1,884**	**321**	**2,205**
Sensitivity	*89.3%*		
Specificity	*88.5%*		
Proportion agreement	*0.89*		
Kappa	*0.641*		

Findings revealed that TruScan® is about 92% likely to detect a medicine with high quality when indeed it is of high quality and about 90% likely to detect a medicine that is of low quality (counterfeit) when indeed the medicine is faked.

Attempt was made to investigate the sensitivity and specificity of TruScan® to different classes of medicine. Table 4.3c presents these findings for Antibiotics, Antidiabetics and Antimalarials tested using TruScan®. Findings showed that the sensitivity of TruScan® in testing Antidiabetics is least compared to the other two classes of medicines: Antibiotics and Antimalarials; but highest in testing Antibiotics compared with the other two classes of medicines. Therefore, in a future research, attempt should be made to investigate the composition of different classes of medicines that may be associated with or accountable

for the differentials in the sensitivity of TruScan® to determine high quality. Similarly, such efforts should be targeted at the specificity of TruScan®.

4.3 Correlation of Results (TruScan® vs. Laboratory Test)

Until recently, the use of laboratory test analysis for determining quality of medicines has been known to be the gold standard. The process in conducting a laboratory test takes a long time. With the advent of technology, efforts at improving the process of determining quality of medicines with the aim of getting results within a short time have been the target. This is to assist regulatory agencies in enhancing their work without further delay. TruScan® was one of the products of these efforts. In this Section, attempt was made to address Objective 2 of this study: "assessing the correlation between results obtained using the TruScan® and confirmatory test from Laboratory".

Proportion agreement index is a measure of agreement between two methods or devices or approaches of carrying out a particular test; usually between a traditional method (gold standard) and modern method (new). In this study, attempt was made at determining possible correlation between results from TruScan® and Laboratory using Proportion Agreement index. Tables 4.3b & c provide information about the Proportion Agreement Indices for different scenarios. Table 4.3b shows the Proportion Agreement

index for all the sampled medicines tested with both TruScan® and Laboratory as 0.89; while Table 4.3c shows the Proportion Agreement index for different classes of medicines sampled. The Proportion Agreement indices were estimated as 0.93 for Antibiotics, 0.83 for Antidiabetics, and 0.90 for Antimalarial. Although there is no known (or documented) threshold values for determining the strength of association using Proportion Agreement index, however, findings from this analysis show a strong association between TruScan® and Laboratory results for all the scenarios considered.

Table 4.3c: Contingency tables presenting TruScan® and Laboratory results for individual medicines (i.e. Antibiotics, Antidiabetics and Antimalarials)

		Laboratory Test								
TruScan® Test		*Antibiotics*			*Antidiabetics*			*Antimalarials*		
		Passed	*Failed*	*Total*	*Passed*	*Failed*	*Total*	*Passed*	*Failed*	*Total*
	Passed	539	12	551	60	0	60	712	22	734
	Failed	44	101	145	17	4	21	111	174	288
	Total	583	113	606	77	4	81	823	196	1019
	Sensitivity	*92.5%*			*77.9%*			*86.5%*		
	Specificity	*89.4%*			*100.0%*			*88.8%*		
	Proportion agreement	*0.92*			*0.79*			*0.87*		
		0.734			*0.258*			*0.641*		

CHAPTER FIVE

DISCUSSION OF RESULTS

In the survey, 6,419 medicines have been tested so far. As at the time of compilation of this report, 6,419 samples of medicines were tested, 53.6% were Anti-malarial, 26.2% Antibiotics, and 3.6% Antidiabetics while Others (Anti-hypertensive, Non- Steroidal Anti-Inflammatory Drugs (NSAIDS), etc.) were 16.6%. Anti-malarial constituted the largest proportion of medicines sampled.

In the survey, out of the 6,419 medicine sampled so far, 2,205 have had their TruScan® results compared with confirmatory laboratory results, which is the benchmark for interpretation of results in this report. Of the 2,205 medicines that have both laboratory and TruScan® results, 1,683 (76.3%) passed both TruScan®

and Laboratory tests while 284 (i.e. 12.9%) failed both tests. Further, 37 (i.e. 1.3%) passed TruScan® but 201 (i.e. 9.1%) failed TruScan® but passed laboratory test.

The medicines sampled that passed TruScan® but failed confirmatory laboratory tests were anti-malarial medicines of Sulfadoxine-Pyrimethamine (SP) combination which are known to have high Raman signal. All the SP combinations in this category however yielded content uniformity test results below that of standard specification (out-of-specification). This is expected as there are chances that such could pass a degraded product. On the contrary, samples that gave a Fail result on the TruScan® but passed confirmatory laboratory test such as Artesunate is known to have weak Raman signal. This accounted for a large proportion of Artesunate products failing the TruScan® test but passing confirmatory laboratory tests. Some lifesaving medicines such as antibiotics (brands of Amoxycillin, Ciprofloxacin, Ampicillin-Cloxacillin, Cefuroxime); anti-malarial (brands of Sulfadoxine-Pyrimethamine, Artemether-Lumefantrine, and Artesunate) and anti-diabetics (Metformin) failed TruScan® and were confirmed by the Laboratory to contain little or no active ingredients. For details, see Tables 5.1 and 5.2.

On the basis of the confirmatory laboratory tests, artesunate brands of anti-malarial medicines seem to be the most commonly counterfeited (i.e. failing both the TruScan® and confirmatory tests).

5.1 Limitations of TruScan® (Raman Spectroscopy)

Some limitations in employing Raman spectroscopy for finished pharmaceutical products have also been confirmed from outcomes obtained. These include:

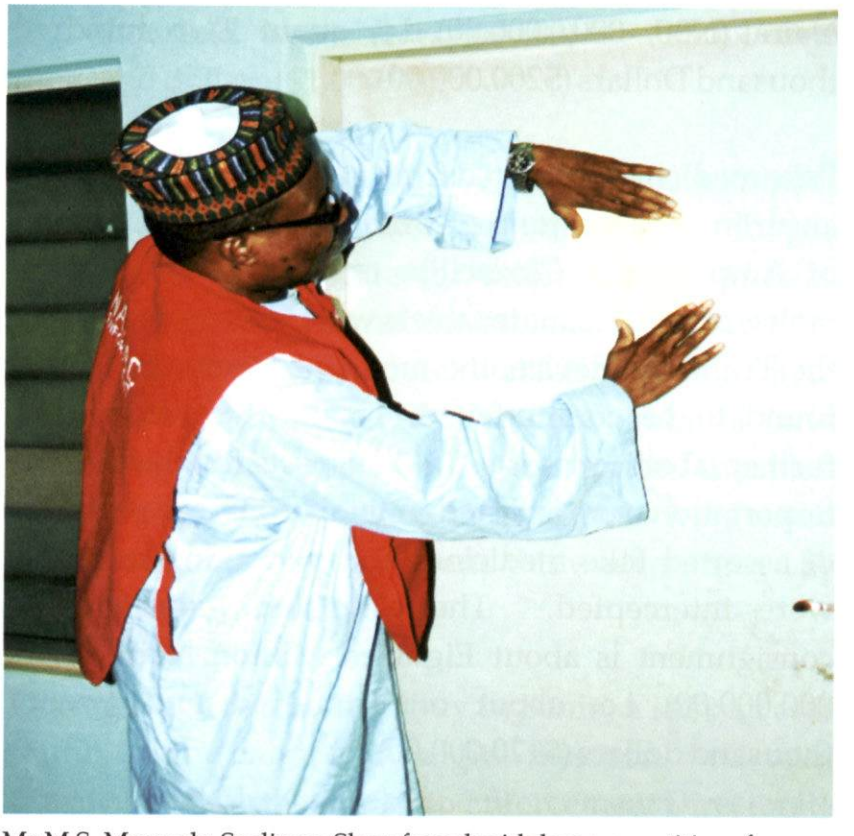
- Some samples may have too much fluorescence to acquire a reasonable reference spectrum.
- There are certain medicines (such as Acetaminophen and Sulfadoxine-Pyrimethamine) which have a very strong Raman signal that the TruScan® is not able to differentiate between different concentrations of the active ingredient and brands. Some degraded SP products which were not necessarily fake products but had been poorly stored, passed the TruScan® test but failed laboratory analysis.
- Some medicines produce weak Raman spectra thereby giving irregular results with the TruScan® e.g. Artesunate.
- Some products which were not necessarily fake products but had been poorly stored failed the

TruScan® test but passed laboratory analysis for active ingredients.

This is because the TruScan® devise does not only test for the active, but take cognizance of the entire formulation.

5.2 Excerpts of NAFDAC Sanctions

On Wednesday 13th January, 2010, NAFDAC officers on a routine inspection at NAHCO Shed 4 intercepted a consignment of nine (9) packages comprising 10,000 sachets of 6 tablets each of a popular brand of Artemether + Lumefantrine combination packed in green woven polythene sacks concealed within bags and shoes covered with blankets. The outer packets of the products and the blisters/sachets were packed separately. Using the TruScan® device, the medicine was tested and found to be counterfeit and this was confirmed by laboratory tests. The main suspect and importer (name withheld) has been arrested and case is currently in court. The estimated cost of the consignment is about Ten Million Naira (N10, 000, 000, .00) i.e. about Sixty Seven Thousand Dollars ($67,000.00).



Mr M.S. Momodu Sealing a Shop found with large quantities of Counterfeit Medicines during TruScan® Exercise, in Kano State

A consignment of a popular brand of Ciprofloxacin tablets accompanied by an importer (name withheld) was intercepted at the Nnamdi Azikiwe International Airport, Abuja. Using the TruScan® device, the medicine was tested and found to be counterfeit and this was confirmed by laboratory tests. The suspect has been arrested and is currently being tried in court. The estimated value of the consignment was Thirty Million

Naira (N30, 000, 000.00) i.e. about Two hundred thousand Dollars ($200,000.00).

Fake medicines imported from Hong Kong to Lagos on an airline in May/June 2010 including a popular brand of Ampicillin + Cloxacillin capsules, Ciprofloxacin tablets and Artesunate tablets were intercepted. Using the TruScan® device, the medicines were tested and found to be counterfeited. This was confirmed by further laboratory tests. Two suspects involved in the importation were arrested. A total of 53 large packages of assorted fake medicines and packaging materials were intercepted. The estimated value of the consignment is about Eighteen Million Naira (N18, 000,000.00) i.e. about one hundred and twenty thousand dollars ($120,000.00).

On 4th of January, 2011, a popular businessman in Abeokuta (name withheld) was transferred to the Enforcement Directorate for selling suspected fake products including a discontinued brand of Griseofulvin tablets, Ciprofloxacin tablets, Sulphadoxine + Pyrimethamine combination tablets and other unlabelled tablets in transparent polythene bags. Using the TruScan® device, the medicine was tested and found to be counterfeit and this was confirmed by laboratory tests. The estimated value of the consignment was about One hundred and Seventy

five thousand Naira (N175,000.00) i.e. about One thousand dollars ($1,000.00).

On the 8th of March, 2011, a suspect (name withheld) from Ile-Ife, Osun state was transferred to the Enforcement Directorate for selling suspected fake products namely Cefuroxime tablets, combination of Amoxicillin + Clavulanic Acid tablets, combination of Sulphadoxine + Pyrimethamine tablets and combination of Ampicillin + Cloxacillin capsules. Using the TruScan ® device, the medicines were tested and found to be counterfeits and this was confirmed by further laboratory tests.

During the TruScan® Survey in Benin, a suspect was found with banned Analgin injection and was transferred with the exhibit to Enforcement Directorate for further investigation. Three premises were sealed at Minna, Niger State during the survey. Two of the premises were found to be selling banned Analgin injection while all other products tested at the third premises failed. The suspects and the exhibits were handed over to the State Taskforce for further investigation.

A number of seizures have also been made at the various ports of entry using the TruScan®. Some of them are stated below:

a. Ampicillin + Cloxacillin combination capsules and Artesunate tablets smuggled from the tarmac to a warehouse in 'No man's land' were tracked down and tested on the spot with the TruScan® and laboratory tests revealed that they contained no active ingredients.

The estimated value was about Eighteen Million Naira (N18,000,000.00) i.e. about One hundred and twenty thousand Dollars ($120,000.00).

b Thirty-three (33) large packages of assorted medicines [popular brands of a combination of Ampicillin + Cloxacillin capsules, Ketoconazole tablets, Artesunate 50mg tablets, Lincomycin capsules] were intercepted at NAHCO shed. The cost is about Eighteen Million Naira, (N18,000,000.00) i.e. about One hundred and twenty thousand Dollars ($120,000.00).

c Huge seizures of fake medicines: popular brands of Ciprofloxacin, Mefloquine tabs and Bromazepam 3mg worth about Thirty Million Naira (N30, 000,000.00) i.e. about Two hundred and one thousand Dollars ($201,000.00) were tested with the TruScan® and seized from Murtala Mohammed International Airport (MMIA) and Nnamdi Azikiwe International Airport (NAIA) between 23 - 25th June 2010.

d A consignment of Tramadol HCl, an Opioid analgesic, was intercepted at Mallam Aminu

Kano Intl Airport, Kano on 23rd July 2010 and tested with the TruScan®.

e A consignment of a popular brand of Griseofulvin Tablets, whose production has been discontinued by the manufacturer since 2002 was intercepted and seized in December 2010 in a suburb of Abeokuta Ogun State. The value was about Thirty Million Naira (N30, 000,000.00) i.e. about two hundred and one thousand Dollars ($201,000.00).

A Shop Being Put "On Hold" for Stocking Large Consignments of Counterfeit Medicines during TruScan® Exercise, in A Border Town

5.3 Collaboration with other Government Agencies, the Private Sector and International Organizations

Although the Agency's regulatory service is within Nigeria, in pursuance of its functions carries out some foreign regulatory activities in conjunction with the regulatory bodies of such countries to inspect factories before registering products of such countries in Nigeria.

The Agency has technical collaboration with the following international organizations to achieve some of its global mandate:

i. World Health Organization (WHO),
ii. World Trade Organization (WTO),
iii. World Bank,
iv. United Nations Drug Control Programme (UNDCP),
v. Food and Agricultural Organization (FAO),
vi. United Nation Children's Fund (UNICEF),
vii. International Narcotics Control Board (INCB),
viii. United States Environmental Protection Agency (USEPA),
ix. International Atomic Energy Agency (IAEA),
x. The Codex Alimentarius Commission of Food and Agricultural Organization (CACFAO),
xi. The Environmental and Occupational Health Sciences Institute (EOHSI), and

xii. United State Food and Drug Administration (USFDA).
xiii. Health Canada (HC),
xiv. Asia-Pacific Economic Cooperation (APEC)

To function effectively the Agency has some cooperation agreements with the following government agencies in Nigeria;

i. Nigeria Police Force (NPF),
ii. Nigeria Customs Service (NCS),
iii. Standards Organization of Nigeria (SON),
iv. National Drug Law Enforcement Agency (NDLEA),
v. State Security Service (SSS),
vi. Pharmacists' Council of Nigeria (PCN),
vii. Institute of Public Analysts of Nigeria (IPAN), and
viii. National Institute for Pharmaceutical Research and Development (NIPRD).
ix. Nigeria Ports Authority (NPA) and
x. Ports and Terminal Operators

The Nigeria Police Force has an operational component known as the Police Squad of the Federal Task Force on counterfeit and fake Drugs and unwholesome processed foods miscellaneous ACT CAP C34 LFN 2004.

The Nigeria Custom Service (NCS) is responsible for import and export trade at all the points of entry into the country. NAFDAC is the only government organization at the ports that makes input on Customs documents (Entries) relating to NAFDAC regulated products because of the sensitivity of her work. As part of the collaboration efforts, Customs mandatorily demands for NAFDAC stamp on import entries of NAFDAC regulated products before such consignments are released. NAFDAC is also a member of various trade facilitation committees set up by the Federal Government.

Standards Organisation of Nigeria (SON), NDLEA and SSS are the other government agencies at the port that also assist NAFDAC in the performance of her functions. The Agency also collaborates with some private organizations to achieve her mandate. It collaborated with Biofem, GlaxoSmithKline (GSK), Green Life Pharmaceutical, Geneith Pharmaceutical, St. Michaels, Janssen-Cilag etc. in the text messaging programme for detecting fake and counterfeit medicines.

NAFDAC trained a team of Officers from the National regulatory body of Sierra Leone on Method Development and Operations using the TruScan®.

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

Addressing the problem of counterfeit medicines has to be seen as part of a strategy to bring social justice around the world.

At the same time, greater resolve is needed to tackle the problem locally and globally as only coordinated action will achieve success. All stakeholders, governments, the pharmaceutical industry, healthcare professionals, police, customs, distributors, patients, Charity and faith based organizations, and those concerned about people's rights must unite against the scourge of counterfeit medicines.

Protecting public health is an obligation of government that cannot be deferred as every citizen in Nigeria has a right to good health. NAFDAC has not relented in her

efforts to live up to its slogan of 'Safeguarding the Health of the nation' by adopting the following measures:

* **Increased pharmacovigilance and reporting adverse events of medicines -**
  Pharmacovigilance is a key public health function. There is a need to accurately describe counterfeit related injuries and diseases, identify their determinants and develop prevention strategies. The Pharmacovigilance unit in NAFDAC collates such data.
* **Public Enlightenment Campaigns -**
  establishment of Consumer Safety Clubs in Nigerian High schools, NAFDAC Green Pages, collaboration with National Youth Service Corps (NYSC) members, enlightenment through the mass media and grassroots sensitization programmes.
* **National and International collaboration -**
  National Drug Law Enforcement Agency (NDLEA), Standards Organization of Nigeria (SON), Nigeria Customs Service (NCS), West African Drug Regulatory Agencies Network (WADRAN), International Medicinal Products Anti-Counterfeiting Task Force (IMPACT), World Health Organization (WHO), World Trade Organization (WTO), Asia-Pacific Economic Cooperation (APEC), Health Canada, etc.

* Educating stakeholders to increase compliance with proper registration of medicine.
* Capacity Building -training of staff, restructuring and modernizing regulatory processes.
* Beefing up of surveillance at all ports of entry and the land borders.
* Post-market surveillance and mop-up of fake regulated products from circulation.
* Enacting laws that impose stiffer penalties on counterfeiters.
* Stopping fake imports at source i.e. countries of production. The vast majority of counterfeit pharmaceutical products are currently thought to be produced in some parts of Asia. Presently, NAFDAC through collaboration with the governments of these countries has set up machinery to ensure that extensive analytical testing is carried out on medicines to be exported to Nigeria prior to shipping. Also, routine inspections are carried out in factories where these products are made to ensure that current Good Manufacturing Practices (cGMP) are adhered to.
* Introduction of cutting-edge technology i.e. Raman Spectroscopy, Mobile Authentication Service (MAS), Minilab, RFID and Black Eye.

* Enforcement of compliance of local manufacturers to cGMP.
* Streamlining and strict enforcement of registration guidelines, staff re-orientation and modernization of regulatory processes.

Counterfeit products have been cited as one of the many reasons why some diseases in the developing world have become resistant to treatment. NAFDAC is championing the cause to ensure that public confidence in the quality of medicines is not eroded and creating a favourable business climate for genuine manufacturers and importers. NAFDAC is currently employing a multi-dimensional, well coordinated approach to tackle the issue of counterfeiting in our nation and is spearheading global efforts in the use of cutting-edge technologies such as the Mobile Authentication System, RFID and Raman spectroscopy (TruScan®).

The survey using the TruScan® gives a performance index of the success rate of the anti-counterfeit drive. Though counterfeit products are still in the pharmaceutical market, from the results obtained, it appears that there is some measure of sanity especially in the registered pharmacies. This is attributable to the multipronged approach to the anti-counterfeiting drive as well as the seizures and interceptions at the

ports and land borders which prevents these products from getting into circulation. The wide publicity given to these seizures is also a deterrent to intending counterfeiters.

Considering the usefulness of the TruScan® as an on-the-spot anti-counterfeiting tool as evidenced in the survey, every state should be equipped with the device to facilitate thorough and effective screening and mop up of spurious medicines from the nooks and crannies of every state and Local Government Area.

The issue of porous borders is currently being addressed by NAFDAC. The results obtained from survey and feasibility reports revealed that states with land borders had higher incidences of counterfeit medicines necessitating the opening of NAFDAC offices along identified smuggling routes (border posts). This measure will minimize the entry of counterfeit medicines into Nigeria.

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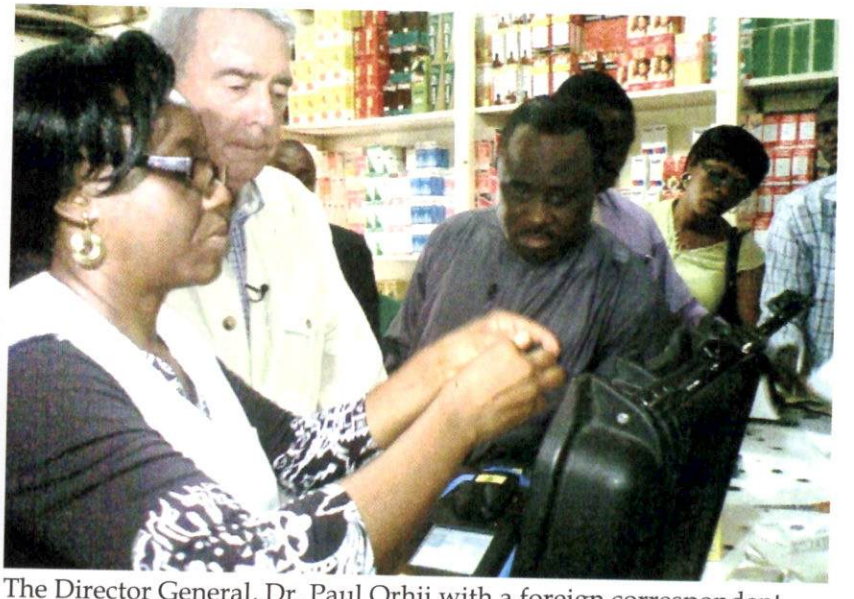
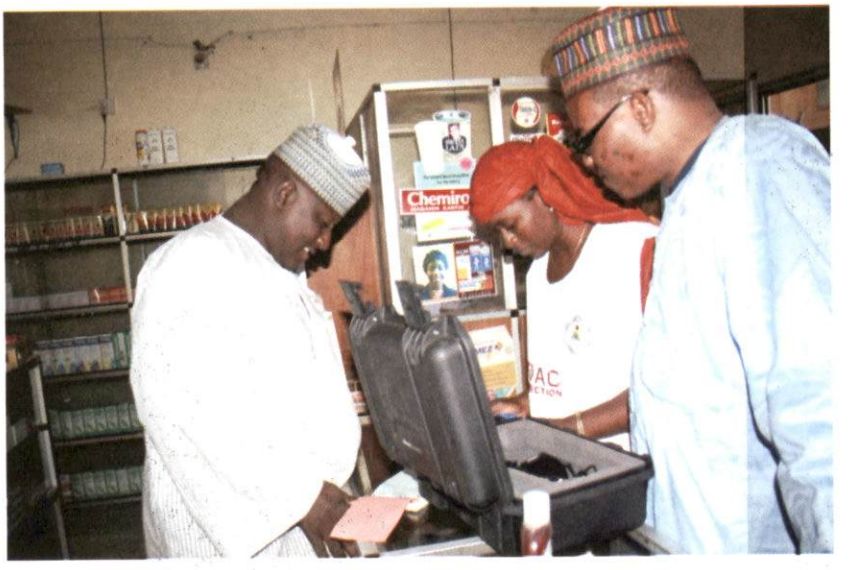
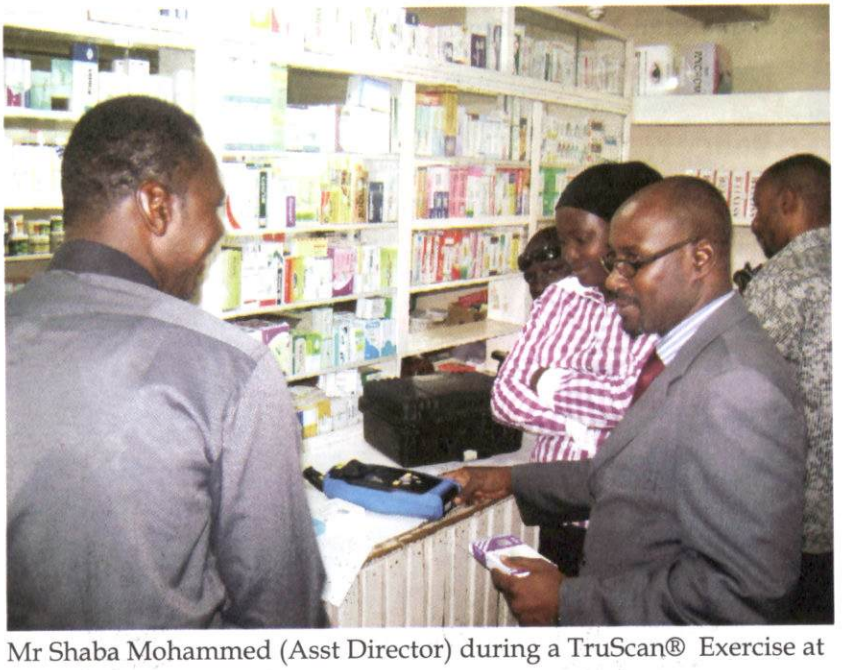


The Director General, Dr. Paul Orhii with a foreign correspondent Dan Rather, Mrs Adekunle-Segun (Asst. Director) during a TruScan® Exercise at Idumota area, Lagos.

TruScan® Exercise, Makurdi, Benue State

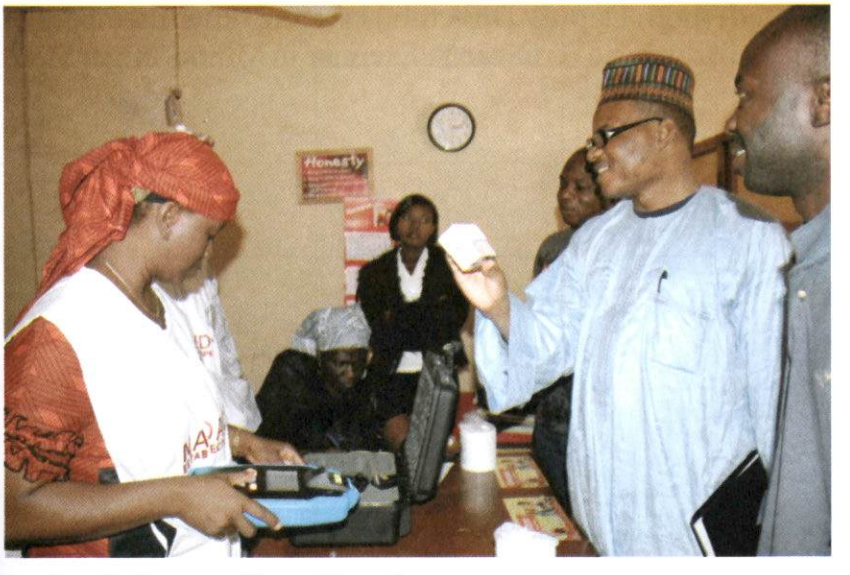


TruScan® Exercise, Kano, Kano State



Mr Shaba Mohammed (Asst Director) during a TruScan® Exercise at Osogbo, Osun State

TruScan® Exercise, Kano, Kano State



TruScan® Exercise, Kano, Kano State

Mrs. C M Makanjuola (holding paper) and Mr S A Adeleke (seated) (both Deputy Directors) briefing other members of the team during a TruScan® Exercise in Minna, Niger State

APPENDIX

SELECTED MEDICINES TESTED WITH TRUSCAN AND CORR ESPONDING LABORATORY RESULTS

S/N	NAME OF PRODUCT	STATE/ TOWN	GROUP NO.	NAME OF OUTLET	BATCH NO.	MFG. DATE	EXP. DATE	NAFDAC REGN. NO.	TRUSCAN RESULT	LAB RESULT	% OF CONTENT
1	*BRAND OF:* SULPHADOXINE/PYRIMETHAMINE 25MG TABLET	OGUN/ Abeokuta	TWO	GLORY MEDICINE STORE,OBAFEMI AWOLOWO WAY	AMEH0151	Jun-09	May-13	04-0966	FAILED	FAILED	Sulf:2.48,Pyri:21.45
2	*BRAND OF:* GRISEOFULVIN 500MG TABLET	BAUCHI/ Rafin Zinfi	FOUR	CORNERSTONE	A08681	04/2008	-	-	FAILED	FAILED	GRISEO:ABS
3	*BRAND OF:* ARTESUNATE 50MG TABLET	ENUGU Achara	FOUR	REGINA PATENT MED STORE	07015FX	07/10	06/13	04-3397	FAILED	FAILED	Art: 15.22

4	*BRAND OF:* SULPHAMET OPYRAZINE/ PYRIMETHA MINE, 25MG TABLET	RIVERS/ D-line Port-Harcourt	FOUR	DE-ELBON PHARMACY	E979A	Feb-07	Feb-11	04-3861	FAILED	FAILED	SULF:61.98, PYRI:29.77
5	*BRAND OF:* ARTEMETHE R 80/LUMEFA NTRINE 480 TABLET	ADAMAWA YOLA	FOUR	–	LD-53	06/2009	11/2011	04-9927	FAILED	FAILED	ART:43.39 LUM:ABS
6	*BRAND OF:* CIPROFLOX ACIN 500MG TABLET	BAYELSA	FOUR	SELAK PHARM LTD	VM925	09/09	08/12	04-1928	FAILED	FAILED	Cipro:0.83
7	*BRAND OF:* AMPICILLIN 250/CLOXAC ILLIN250MG CAPSULE	ADAMAWA YOLA/ Atiku Abubakar Rd.	FOUR	NAFAS	40317	01/2008	02/2013	-	FAILED	FAILED	AMP:37.64 CLOX:7.46
8	*BRAND OF:* SULPHADOX INE/PYRIME	LAGOS/ Idumota	TWO	JUDE OFOR	L26047	04/2008	04/2013	04-0154	FAILED	FAILED	SULF:0 PYRI:130.82

THAMINE 25MG TABLET										
BRAND OF: SULPHADOX INE/PYRIME THAMINE 25MG TABLET	BENUE/ Lafia Rd. MAKURDI	THREE	BOBSON PHARMACY NIG. LTD	AMN 196	08/2008	07/12	04-0966	FAILED	FAILED	SULF.1.36, PYRI 9.17
BRAND OF: CEFUROXIM E 250MG TABLET	ABIA/ Faulks Rd. ABA	SIX	PERSON PHARMACE UTICALS	C113066	07/08	07/12	04-0433	FAILED	FAILED	CEF. 6.19

87

4	*BRAND OF:*	RIVERS/	FOUR	DE-ELBON	L979A	Feb-07	Feb-11	04-3861	FAILED	FAILED	SULF:61.98,

CHART SHOWING RAMAN SPECTRA OF PASS/FAIL SAMPLE RUNS ON THE TRUE SCAN

Run Label:	Run-Tosin-20090823-131505
Run Time:	23-Aug-2009 13:16
Device Serial:	TS2562
Method:	ampiclox 500mg cap-ampic+cloxacillin
Sample ID:	ampicillin+cloxacillin
Pval:	0.000000
Note:	
Result:	Fail

AhuraScientific

TruScan TS2562

User Name:	Tosin
Login Time:	23-Aug-2009 12:22
Software Version:	1.2.1 (Build 6964)
Last Tested:	06-Jun-2009 19:04
Last Test Result:	Fail
Calibration Check:	Pass
CCD Check:	Pass
Laser Power:	Pass

Warnings: none

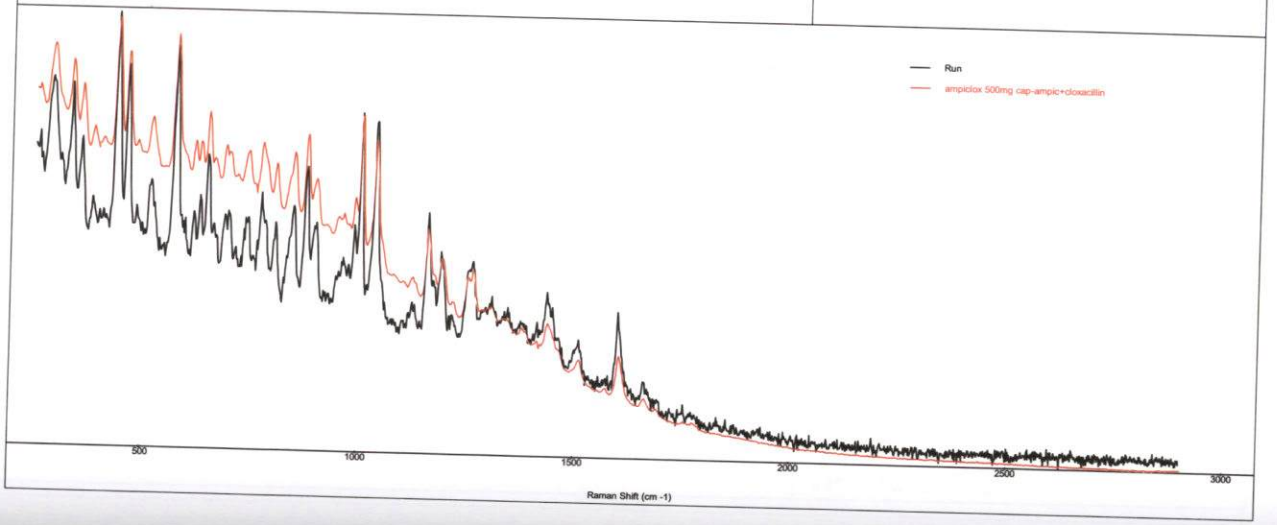
Run Label:	Run-Administrator-20110315-142254
Run Time:	15-Mar-2011 14:23
Device Serial:	TS2559
Method:	ampiclox 500mg cap-ampic+cloxacillin
Sample ID:	ampicillin+cloxacillin
Pval:	0.434317
Note:	
Result:	Pass

AhuraScientific

TruScan TS2559

User Name:	Administrator
Login Time:	15-Mar-2011 13:59
Software Version:	1.2.1 (Build 6964)
Last Tested:	28-Feb-2011 16:04
Last Test Result:	Pass
Calibration Check:	Pass
CCD Check:	Pass
Laser Power:	Pass

Warnings: none



Raman Shift (cm -1)

Run Label:	Run-Administrator-20101222-122913
Run Time:	22-Dec-2010 12:30
Device Serial:	TS2559
Method:	LONART-DS -Art 80mg +Lum480mg
Barcode:	8906009238180
Sample ID:	Artemether 80mg+Lumefantrine 480mg
Pval:	0.003799
Note:	
Result:	Fail

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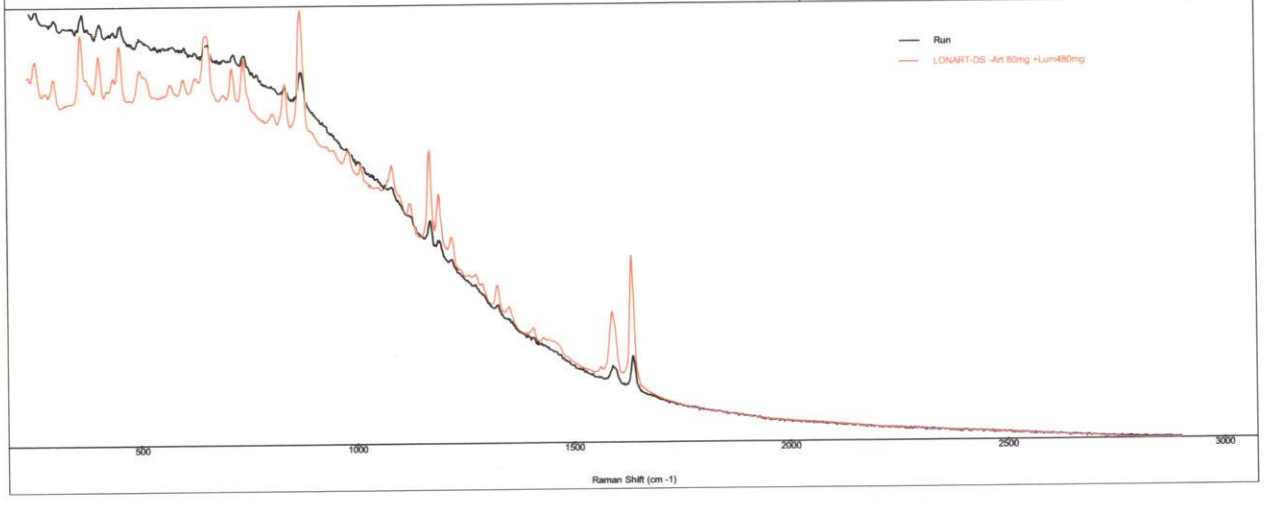
TruScan TS2559

User Name:	Administrator
Login Time:	22-Dec-2010 12:26
Software Version:	1.2.1 (Build 6964)
Last Tested:	22-Dec-2010 08:23
Last Test Result:	Pass
Calibration Check:	Pass
CCD Check:	Pass
Laser Power:	Pass

Warnings: none



Run Label:	Run-Administrator-20090505-125903
Run Time:	05-May-2009 12:59
Device Serial:	TS2562
Method:	LONART-DS -Art 80mg +Lum480mg
Barcode:	8906009238180
Sample ID:	I3
Pval:	0.721510
Note:	
Result:	Pass

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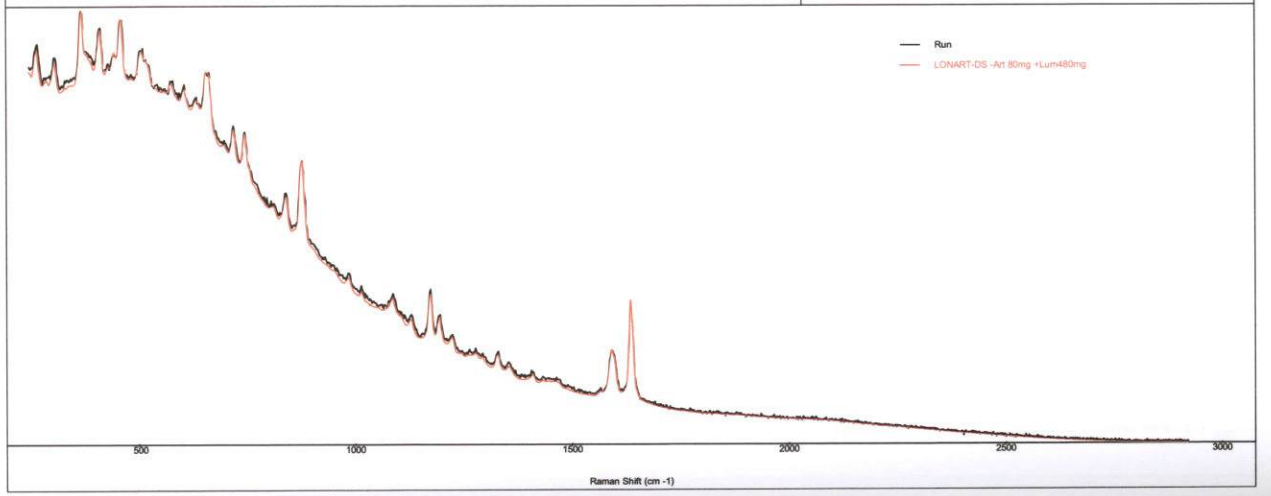
TruScan TS2562

User Name:	Administrator
Login Time:	05-May-2009 11:48
Software Version:	1.2.1 (Build 6964)
Last Tested:	08-Feb-2009 14:10
Last Test Result:	Pass
Calibration Check:	Pass
CCD Check:	Pass
Laser Power:	Pass

Warnings: none



Raman Shift (cm -1)

Run Label:	Run-Administrator-20100329-131140
Run Time:	29-Mar-2010 13:12
Device Serial:	TS2534
Method:	Dettol 125ml
Barcode:	50158904
Sample ID:	
Pval:	0.394287
Note:	
Result:	Pass

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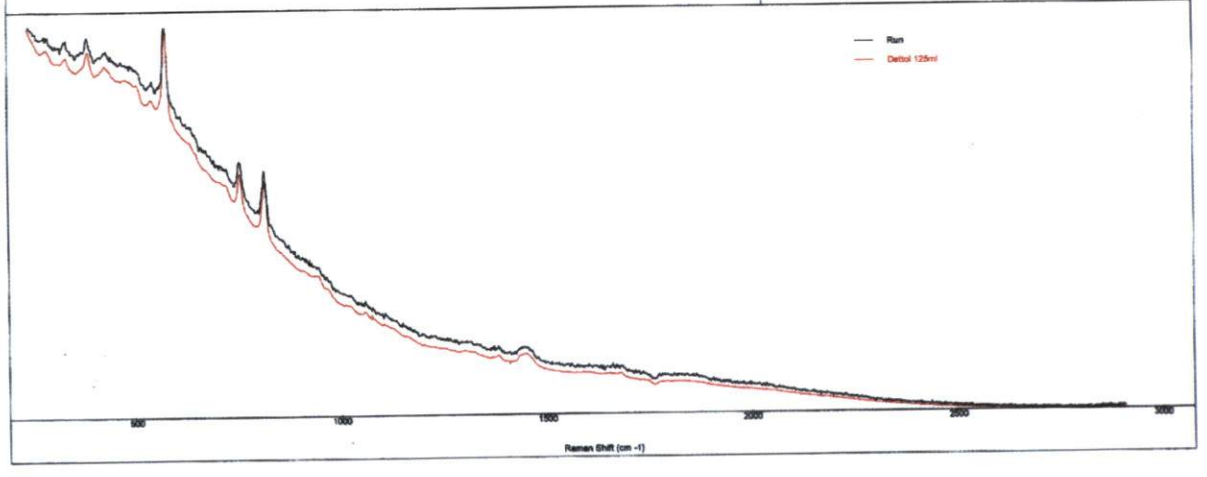
TruScan TS2534

User Name:	Administrator
Login Time:	29-Mar-2010 13:00
Software Version:	1.2.1 (Build 6964)
Last Tested:	11-Feb-2010 13:32
Last Test Result:	Fail
Calibration Check:	Pass
CCD Check:	Pass
Laser Power:	Pass

Warnings: none



Run Label:	Run-Administrator-20100826-162742
Run Time:	26-Aug-2010 16:30
Device Serial:	TS2562
Method:	Fansidar Tab-sulfadoxi+pyrimethamine
Sample ID:	sulfadoxine+pyrimethamine26047
Pval:	0.000000
Note:	
Result:	Fail

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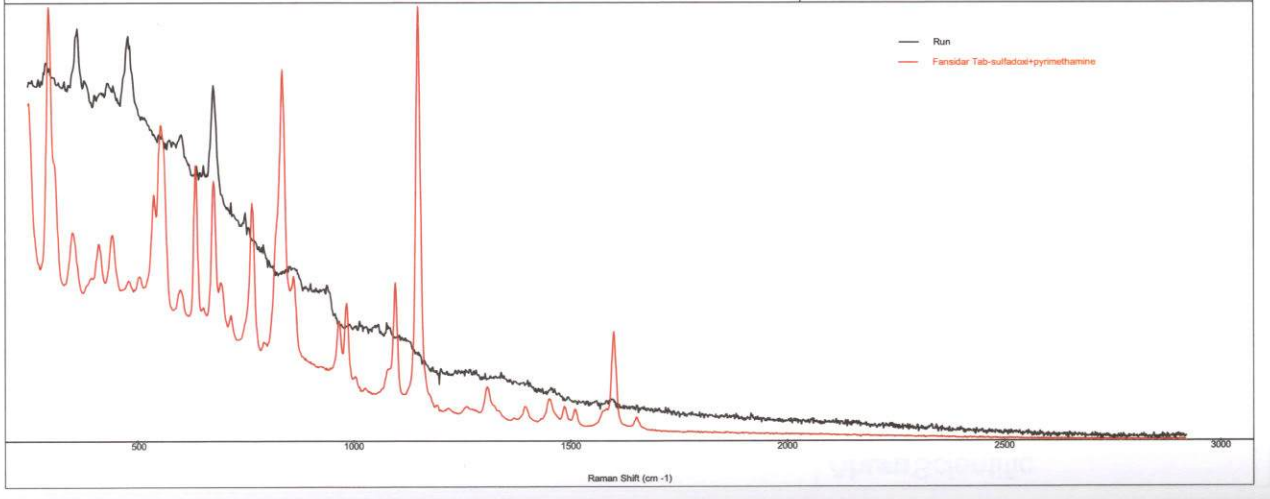
TruScan TS2562

User Name:	Administrator
Login Time:	26-Aug-2010 16:23
Software Version:	1.2.1 (Build 6964)
Last Tested:	06-Jun-2009 19:04
Last Test Result:	Fail
Calibration Check:	Pass
CCD Check:	Pass
Laser Power:	Pass

Warnings: none



Run Label:	Run-Administrator-20090328-173949
Run Time:	28-Mar-2009 17:40
Device Serial:	TS2562
Method:	Fansidar Tab-sulfadoxi+pyrimethamine
Sample ID:	sulfadoxine+pyrimethamine
Pval:	0.471411
Note:	
Result:	Pass

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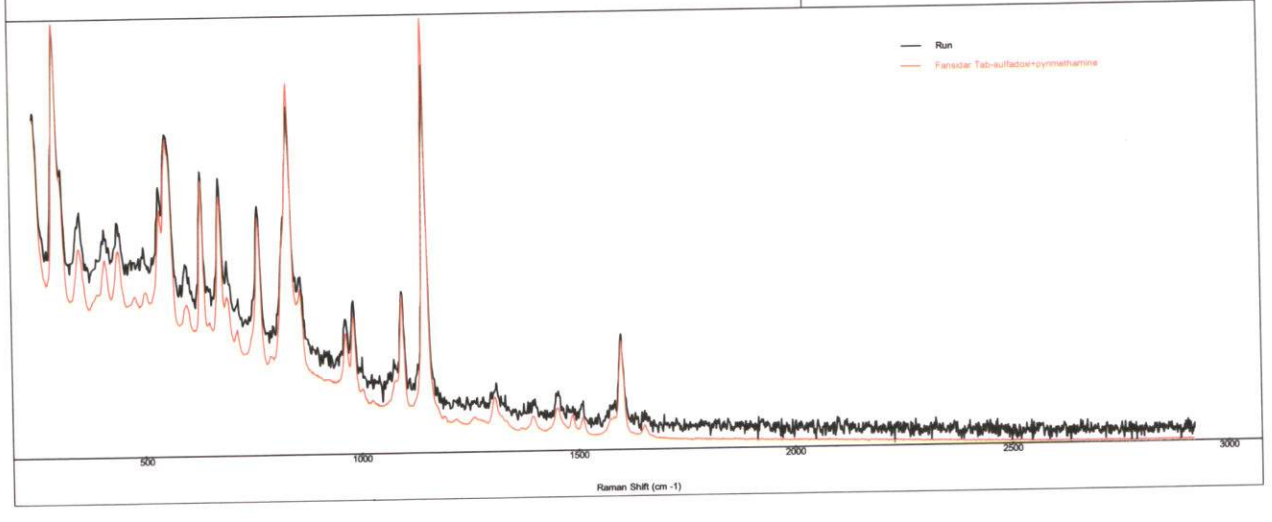
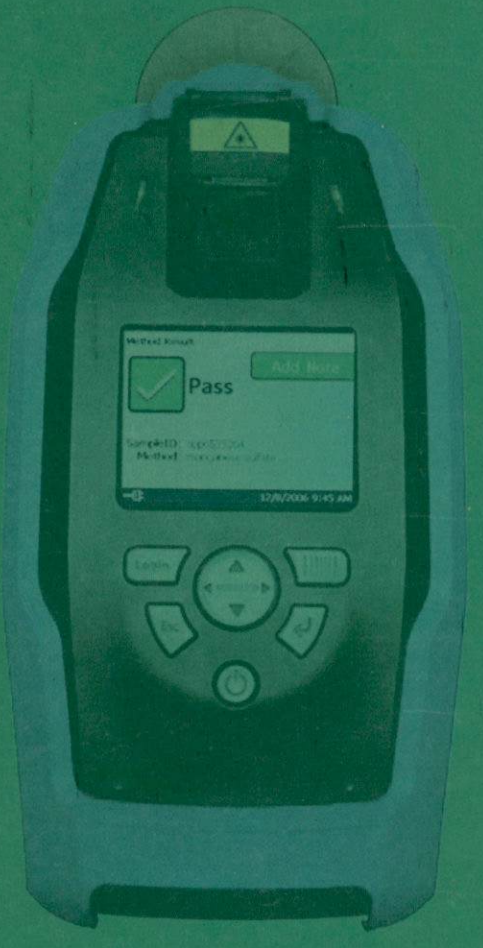
TruScan TS2562

User Name:	Administrator
Login Time:	28-Mar-2009 17:20
Software Version:	1.2.1 (Build 6964)
Last Tested:	08-Feb-2009 14:10
Last Test Result:	Pass
Calibration Check:	Pass
CCD Check:	Pass
Laser Power:	Pass

Warnings: none





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