Statistical Analysis on the Efficiency of Cutting-Edge Technology (TruScan) Compared To Gold Standard (HPLC) In Detecting Counterfeit Medicines in Nigeria

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Abstract- ***Cutting-edge technologies are new innovation introduced into regulatory industries or organisations to ease operations. In this thesis, therefore examines the efficiency of TruScan to determine the counterfeited medicines compare to HPLC which is the gold standard. More so, to assess the correlation between the results obtained using TruScan® (Raman spectrometer) and those from the HPLC. It was realised at the end of the analysis that, TruScan has 88% efficient compare to HPL which is the gold standard could do. Also the device has the ability of 89% to detect that the product has passed when indeed it passed; again, it has 85% confirmatory that the drugs failed the Test when HPLC has already stated (see R-Language software results obtained in Chapter Four). In kappa agreement, the analysis shows that the device has 62% substantial agreement or correlation between HPLC. McNemar's analysis also shows that there exists a relationship between TruScan and HPLC which is the gold standard.***

Indexed Terms- Cutting-edge, Efficacy, Medicine, TrueScan

I. INTRODUCTION

Counterfeiting of medicines are global problem not only Nigeria even the developed countries face similar problem. A counterfeit drug, by definition, is one that has been made by someone other than the genuine manufacturer of the item. It is done by either copying the formulation of the drug or imitating it without permission to do so. The World Health Organisation (WHO) defines counterfeit drugs as "drugs that have been deliberately or fraudulently mislabeled with respect to identity and/or source' [1]. Counterfeit drugs in Nigeria include preparations without active ingredients, toxic preparations, expired drugs that are relabeled, drugs issued without complete manufacturing information and drugs that are unregistered with the National Agency for Food and Drug Administration and Control (NAFDAC). Current estimate suggests that 10% of prescription drugs sold worldwide is counterfeits, fake or contaminated, and in parts of Africa and Asia, the figures exceed 50% [2].

The production of counterfeit medicines is a broad and under reported problem particularly affecting poorer countries which Nigeria is not left out. It is an important cause of unnecessary mortality and morbidity, and loss of public confidence in medicines and health structures.

Empirical observations show that there may be more counterfeit drugs than genuine ones in circulation but industry and regulatory authorities (e.g.NAFDAC) are fighting back with new measures to identify rogue shipments and coordinated action to disrupt the supply chain that criss-cross the globe; Nigeria Regulatory Agency of pharmaceutical and food products has been working tireless to make sure that the prevalence of counterfeit medicines is reduce to the barest minimum in the country. There are factors contributing to the prevalence of counterfeit medicines in Nigeria. This include ineffective enforcement of existing laws, nonprofessional in drugs business, loose of control system, exorbitant of genuine drugs, poverty, corruption, ignorance, illegal importation of drugs, desire to acquire more wealth, chaotic drugs distribution chain among other factors. The economic implication of counterfeit medicines in our society, Pharmaceutical products now account for more than half of all goods seized, according to the World Custom Organisation (WCO) which reported that

painkillers were the most frequently intercepted illicit drug at $36,324,200 in 2014. More than half of the $95,273,060 counterfeit medicines impounded last year (2016) came from India and China. Among the seizures was a supply of erectile dysfunction pills that contained a drug that could cause kidney failure.Malaria costs African nations $12 BN annually in lost economic output (exaggerated by Counterfeit). Higher estimates for TB and HIV/AIDS Loss of tax revenue. Limitations of travel/tourism due to public health concerns as a result of treatment failures caused by counterfeit medicines. The economics of fake products for individuals lies in the price at which they purchase popular brands even along the streets or in small shops since they cannot afford shopping in department stores. Ironically, rich people also visit chain stores that sell at prices relatively cheaper than similar stores in towns. Incidentally, some of the products in shelves may be counterfeit.

The reality is that in both developed and developing countries, governments are concerned about fake products only to the extent that it affects revenue and employment. Although health and environmental impacts are other issues which government tend to show concern regarding fake products, the time lag before any intervention takes place shows that health and environment are secondary considerations. It is also believed that in their bid to sustain industrial lead, developed countries impose standards which are not necessarily desirable.

Finally, the quantum of transactions involving fake products in every segment and every country is increasingly alarming. More agencies of governments are being established to fight counterfeiting and yet the trade is officially reported to be increasing annually.

1.1 Aim and Objectives

The main aim of this research work is to compare the efficacy of cutting-edge technology to High-Performance Liquid Chromatography (HPLC) which is the gold standard. And objectives of the study include the following:

1. To determine the efficacy of TruScan to that of Gold Standard (HPL).
2. To ascertain the effectiveness of detecting counterfeit medicines using cutting-edge technologies particularly Raman spectroscopy.

To assess the correlation between results obtained using the TruScan® (Raman spectrometer) and those from the Laboratory

II. LITERATURE REVIEW

According to Director General of NAFDAC, [3], he said “NAFDAC is the first medicine regulatory agency; we have become the first in the world to use the device to detect the quality of medicines, and actually set the space for the us food and drug administration as well as Germany, Sweden, Canada, to begin using the TruScan to check the incidence of fake medicine in their system”. On the reduction of the incidence of fake drugs in Nigeria, Orhii said within one year the agency had reduced the incidence to just about 5 percent in Lagos, Abuja, Kano and Kaduna.

According to [4] titled “probabilistic Evaluation-First Principles vs. Empirical”, in most direct terms, the Thermo Scientific™ TruScan™ not only acquires the Raman spectrum of a material of interest, but also determines – in real time- the uncertainty of that measurement. Uncertainty here is defined as how consistent and reliable we expect measured spectrum to be in similar or dissimilar sampling conditions or in terms more common on a smaller-scale “standard deviation”. TruScan technology is designed to account for in all measurements intrinsic variability factors, including sample characteristics, instrument telemetry, environment and others. Thermo Scientific engineers and chemotricians spent a great deal of time on system design- specifying terms, accounting for how they affect measurements and recognizing when they dominate. With Raman spectrum acquired the multivariate estimate of its uncertainty determine, TruScan systems have the statistical measures necessary to perform an objective and statistically relevant comparison of the measured data to any reference spectrum of a material resulting in a multivariate test of equivalence.

Again, [5], states that, with increased regulatory scrutiny, the rise of global supply chains and the drive toward lean manufacturing, pharmaceutical and biotechnology manufacturers must ensure the quality of materials throughout the process- from incoming raw material through finished products. The Thermo Scientific™TruScan™ Rm analyser provides

manufacturers with fast and accurate material identity verification with ease and convenience. They also explained that, the TruScan RM analyser is built with a state-of-the-art optical platform paired with a field-proven embedded chemometric engine. Our patented, multivariate residual analysis offers the most effective chemometric solution for material identification- with two spectral pre-processing options, which is easy to operate in challenging environments and sampling conditions. The TruScan^{RM} analyser also offers enhanced compliance features, as well as software and data management functions, designed to facilitate workflow and optimize efficient in tightly regulated environment. It has the benefits to obtain pass/fail results within seconds with an option for STRONG PASS/WEAK PASS and STRONG FAIL/WEAK FAIL results, method development is fast and simple, requiring minimal samples for creation of a robust model.

III. METHODOLOGY

Briefly Research Methodology is the systematic, theoretical analysis of the methods applied to a field of study. It comprises the theoretical analysis of the body of methods and principles associated with a branch of knowledge. Typically, it encompasses concepts such as paradigm, theoretical model, phases and quantitative and qualitative techniques. [6] as cited by Agburu defines research as "the systematic control of empirical and critical investigation of hypothetical proposition about presumed relations among natural phenomenal".

3.1 Techniques for Analysis

In categorical data analysis, different techniques can be used to show the relationship between two different variables (HPLC/Lab and TruScan). In the case of two-by-two (2x2) contingency table which has two rows and two columns. However, in correction for dichotomous analysis, also different techniques can be used for two dichotomous variables (TruScan and HPLC), this may still be presented in the form of two-by-two contingency table. Here the observed frequencies 0_{11} and 0_{22} are known as the frequency of agreement.

3.2 Sensitivity and Specificity Analysis

Sensitivity and Specificity Test: with regards to the first objective of this study on ability to ascertain the efficacy 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.

	Passed	Failed	
Passed	True passed	False failed, type I error α	PPV=TP/TP+FF
Failed	False passed type II error β	True failed	NPV=TF/TF+FP
Total			

Sensitivity isgiven by $\frac{\text{TP}}{\text{TP+FP}}$ ---------- (3.3.1)

Specificity is given as $\frac{\text{TF}}{\text{TF+FF}}$ ---------- (3.3.2)

$\text{PPV} = \frac{\text{Tp}}{\text{TP+FF}}$ ---------- (3.3.3)

$\text{Npv} = \frac{\text{TF}}{\text{TF+FP}}$ ---------- (3.3.4)

$\text{Acc} = \frac{\text{TP+FF}}{\text{N}}$ ---------- (3.3.5)

Power of a test $= \frac{\text{TP}}{\text{TP+FP}} = 1 - \beta$ ---------- (3.3.6)

Matthew correlation coefficient (MCC)

$\text{MCC} = \frac{\text{TP x TF} - \text{FP x FF}}{\sqrt{\text{TP+FP)(TP+FF)(TF+FP)(TF+TP)}^2}}$ ---------- (3.3.7)

Where TP=True Passed/True Positive
FP=False Passed/False Positive
TF=True Failed/True Negative
FF=False Failed/False Negative

Power of a test: It is given by the formula: power=sensitivity=1-β

Efficiency is given by the formula as $\frac{\text{a+d}}{\text{N}}$

3.3 McNemar's Analysis

McNemar's test compares the proportions for two correlated dichotomous variables. These two variables may be two responses on a single individual or two responses from a matched pair (as in matched case-control studies).

However, each observation in the first group has a corresponding observation in the second group of either yes/no or pass/fail.

Control case

TruScan Results	Laboratory/HPLC Results		Total
	Passed	Failed	
Passed	0_{11}	0_{12}	$0_{11}+0_{12}$
Failed	0_{21}	0_{22}	$0_{21}+0_{22}$
Total	$0_{11}+0_{21}$	$0_{12}+0_{22}$	$N=0_{11}+0_{12}+0_{21}+0_{22}$

Model:$\chi^2 = \frac{(|O_{12}-O_{21}|-1)^2}{(O_{12}+O_{21})}$ ---------- (3.4.1)

Pairs with the same response from cases and controls (Yes/Passed-Yes/passed and No/Failed-No/failed) are called concordant pairs. Pairs with different responses (passed-failed and failed-passed) are called discordant pairs. McNemar's test statistic is the estimated

Odds ratio: Mc $=\frac{0_{12}}{0_{21}}$ ---------- (3.4.2)

Tests for two correlated proportions (McNemar's Test)

Npaire $= \frac{\{Z_{1-\frac{\propto}{s}}(OR+1)+ Z_{1-\beta}\sqrt{(OR+1)^2-(OR-1)^2PD\}2}}{(OR-1)^2PD}$ ---------- (3.4.3)

Where s is the number of sides to the test (one or two), OR= $\frac{012}{021}$, PD= 0_{12} +$0_{21,}$ and α and β are the usual error rate probabilities.

power test $= \sum_{R=r}^{N}\sum_{n12=0}^{IR}\frac{N!}{(N-R)!n12!(R-n12)!}(1-$ PD$)^{N-R}\left(\frac{D+PD}{2}\right)^{n12}\left(\frac{PD-D}{2}\right)^{R-n12}$ ---------- (3.4.4)

Where

PD= N_{12} +N_{21}D= N_{12}- N_{21}

N is total of all four cells (N_{11} + N_{12} + N_{21} + N_{22})

r is the smallest integer for which $\left(\frac{1}{2}\right)^{r} \leq \alpha$

IR is the largest integer such that $\sum_{j=0}^{IR}\binom{R}{j}\left(\frac{1}{2}\right)^{r} \leq \alpha$

3.4.1 Hypothesis Testing

H_0:There is no relationship between TruScan and Laboratory

H_1:There is relationship between TruScan and Laboratory

DF (h-1) (k-1)

Confidence level α=0.01

Decision Rule: reject null hypothesis (H_0) if $\chi^2 cal > \chi^2 0.01, (h-1)(k-1)$ otherwise there is no reason to reject it.

3.4 Kappa Agreement Index

Cohen's kappa measures the agreement between two raters who each classify N items into kmutually exclusive categories. The first mention of a kappa-like statistic is attributed to Galton (1892). The kappa statistic, κ, is a measure of the agreement between two raters of N subjects on k categories. Kappa agreement is defined as:

K $= \frac{Pr(o)-Pr(e)}{1-Pr(e)}$ ---------- (3.5.1)

Where Pr (0) is the probability of relative observed agreement among raters, P (e) is the hypothetical probability (expected) of chance agreement.

If the raters are in complete agreement, then κ = 1. If there is no agreement among the raters other than what would be expected by chance (as given by p_e), κ ≈ 0.

3.5.1 Interpretation of Kappa Result

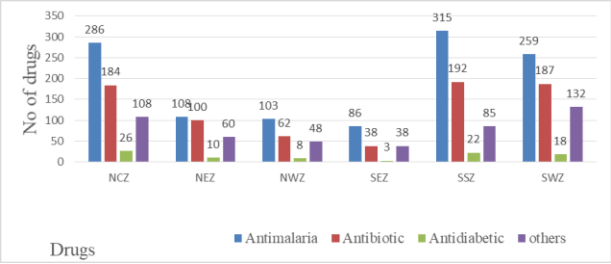
Perhaps the first was Landis and Koch, who characterized values < 0 as indicating no agreement and 0–0.20 as slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1 as almost perfect agreement. This set of guidelines is however by no means universally accepted; Landis and Koch supplied no evidence to support it, basing it instead on personal opinion. Fleiss's equally gave an arbitrary guidelines characterize kappa's over 0.75 as excellent, 0.40 to 0.75 as fair to good, and below 0.40 as poor.

IV. PRESENTATION OF DATA AND ANALYSIS

The data was analysed is a secondary data collected from the national agency for food and drug administration and control NAFDAC 2017.

4.1 Descriptive Analysis

Figure 4.1: The graph below show the number of drugs sampled from each geo-political zone of Nigeria.



The above graph shows that, Antimalaria drugs are more counterfeited than the rest in all the geo-political Zones of the country while Antidiabetic drugs are the least counterfeited.

4.2 Sensitivity and Specificity Analysis

The following presents the Sensitivity and Specificity analyses for each class of medicines using R-Language Software.

- Antimalaria

>xtab
truth
pred passed failed
Passed 812 33
Failed 141 201
>Sensitivity (pred, truth)
[1] 0.8520462
>Sensitivity (xtab)
[1] 0.8520462
>posPredValue(pred, truth)
[1] 0.9609467
>posPredValue(pred, truth, prevalence = 0.25)
[1] 0.668207
>specificity(pred, truth)
[1] 0.8589744
>negPredValue(pred, truth)
[1] 0.5877193
>negPredValue(xtab)
[1] 0.5877193
>negPredValue(pred, truth, prevalence = 0.25)
[1] 0.9457026

Antibiotic

>xtab truth
pred passed failed
passed 550 13
failed 47 109
>sensitivity(pred, truth)
[1] 0.921273
>sensitivity (xtab)
[1] 0.921273
>posPredValue(pred, truth)
[1] 0.9769094
>posPredValue(pred, truth, prevalence = 0.25)
[1] 0.7423962
>specificity(pred, truth)
[1] 0.8934426
>negPredValue(pred, truth)
[1] 0.6987179
>negPredValue(xtab)
[1] 0.6987179
>negPredValue(pred, truth, prevalence = 0.25)
[1] 0.971466

- Antidiabetic

>xtab
truth
pred passed failed
passed 68 0
failed 17 4
>sensitivity(pred, truth)
[1] 0.8
> sensitivity(xtab)
[1] 0.8
>posPredValue(pred, truth)
[1] 1>posPredValue(pred, truth, prevalence = 0.25)
[1] 1
>specificity(pred, truth)
[1] 1
>negPredValue(pred, truth)
[1] 0.1904762
>negPredValue(xtab)
[1] 0.1904762
>negPredValue(pred, truth, prevalence = 0.25)
[1] 0.9375

- Others

>xtab
truth
pred passed failed
passed 433 11
failed 31 8
>sensitivity(pred, truth)
[1] 0.9331897
> sensitivity(xtab)
[1] 0.9331897
>posPredValue(pred, truth)
[1] 0.9752252
>posPredValue(pred, truth, prevalence = 0.25)

[1] 0.3495051
>specificity(pred, truth)
[1] 0.4210526
>negPredValue(pred, truth)
[1] 0.2051282
>negPredValue(xtab)
[1] 0.2051282
>negPredValue(pred, truth, prevalence = 0.25)
[1] 0.9497655

The following presents the overall Sensitivity and Specificity analysis for all the medicines combined using R-Language application.

> library ("epiR", lib.loc="~/R/win-library/3.4")
Loading required package: survival
Package epiR 0.9-93 is loaded
Type help (epi.about) for summary information
Warning message:
package 'epiR' was built under R version 3.4.4
> table1<-as.table(matrix(c(1863,57,236,322),nrow = 2,byrow = TRUE))
>epi.tests(table1)

Table 4.1 summary of sensitivity and specificity results of R-Language software

Point estimates and 95 % CIs:

Apparent prevalence 0.77 (0.76, 0.79)
True prevalence 0.85 (0.83, 0.86)
Sensitivity 0.89 (0.87, 0.90)
Specificity 0.85 (0.81, 0.88)
Positive predictive value 0.97 (0.96, 0.98)
Negative predictive value 0.58 (0.53, 0.62)
Positive likelihood ratio 5.90 (4.64, 7.50)
Negative likelihood ratio 0.13 (0.12, 0.15)

Based on the results above, the device has 90% to detect the efficacy (high quality) of the drugs on the spot and 88% to detect a drug that is of low quality (counterfeited) when indeed it is counterfeit.

For efficiency and correlation between TruScan and laboratory results, see appendix 4.

Sensitivity and Specificity test for overall results

$$\text{efficiency} = \frac{1863 + 322}{2478} = 0.88176 = 88\%$$

$$\text{sensitivity} = \frac{1863}{1863 + 236} = 0.8876 = 89\%$$

$$\text{specificity} = \frac{322}{322 + 57} = 0.8496 = 85\%$$

From the analysis showing above, the cutting-edge technology (TruScan) has 88% efficiency of what HPLC which is the gold standard could do. Also the device has the ability of 89% to detect that the product has passed when indeed it passed; again, it has 85% confirmatory that the drugs failed the Test when HPLC has already stated.

Table 4.2: Summary of Sensitivity and Specificity Test using TruScan and HPLC results

	LAB/HPLC RESULTS									
TRUSCAN RESULTS		Antimalaria		Antibiotic		Antidiabetic		Others		
		Passed	Failed	Passed	Failed	Passed	Failed	Passed	Failed	TOTAL
	Passed	812	33	550	13	68	0	433	11	1920
	Failed	141	201	47	109	17	4	31	8	558
	Sensitivity	85%		92%		80%		93%		
	Specificity	86%		89%		100%		42%		
	Prevalence Index	85%		92%		81%		91%		

Source: NAFDAC PID/Lab Directorates, 2012.

4.3 Mc Nemar's Test for Association of the Devices
To test for McNemar; Jamovi software analysis was used as thus

Table 4.3: Paired Samples Contingency Tables

Contingency Tables

	Labrslt_R		
Truscanrslt_R	Failed	Passed	Total
Failed	322	236	558
Passed	57	1863	1920
Total	379	2099	2478

McNemar's Test

	Value	df	P
χ^2	109	1	< .001
χ^2 continuity correction	108	1	< .001
N	2478		

4.4.1 Hypothesis Testing

H_0:There is no relationship between TruScan and Laboratory

H_1:There is relationship between TruScan and Laboratory

DF (h-1) (k-1)

Confidence level α=0.01

Decision Rule: reject null hypothesis (H_0) if $\chi^2 cal > p-value$ otherwise there is no reason to reject it.

Based on the analysis carried out using Jamovi software above, since the $\chi^2 cal > p-value$ (i.e. $\chi^2 = 108.14 > p = 0.001$)at α=0.01, we reject the null hypothesis and conclude that there exist a relationship between TruScan and HPLC which is the gold standard.

4.4.2 Use of SPSS Software Analysis for Kappa Agreement

Table 4.3: Truscanrslt_R * Labrslt_R * Drugclass_RCross tabulation

Count

Drugclass_R		Labrslt_R		Total
		Failed	Passed	
Antibiotic	Truscanrslt_R Failed	109	47	156
	Passed	13	550	563
	Total	122	597	719
Antidiabetic	Truscanrslt_R Failed	4	17	21
	Passed	0	68	68
	Total	4	85	89
Antimalaria	Truscanrslt_R Failed	201	141	342
	Passed	33	812	845
	Total	234	953	1187
Others	Truscanrslt_R Failed	8	31	39
	Passed	11	433	444
	Total	19	464	483
Total	Truscanrslt_R Failed	322	236	558
	Passed	57	1863	1920
	Total	379	2099	2478

Table 4.4: Symmetric Measures

Drugclass_R			Value	Asymptotic Standardized Error[a]	Approximate T[b]	Approximate Significance
Antibiotic	Measure of Agreement	Kappa	.733	.032	19.894	.000
	N of Valid Cases		719			
Antidiabetic	Measure of Agreement	Kappa	.264	.109	3.683	.000
	N of Valid Cases		89			
Antimalaria	Measure of Agreement	Kappa	.606	.026	21.519	.000
	N of Valid Cases		1187			
Others	Measure of Agreement	Kappa	.235	.079	5.555	.000

	N of Valid Cases		483			
Total	Measure of Agreement	Kappa	.618	.020	31.621	.000
	N of Valid Cases		2478			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Kappa's agreement was equally used and the results show that the cutting-edge technology (TruScan) has 62% substantial agreement with HPLC which is the gold standard.

V. FINDINGS, RECOMMENDATIONS AND CONCLUSION

5.1 Findings

In objective 1, the sensitivity test show that TruScan device has 89% to detect the efficacy (high quality) of the medicines on the spot and 85% to detect a medicine that is of low quality (counterfeit) when indeed the medicine is fake, therefore it is efficient to use in a regulatory Organisation or Industry.

In objective 2, the sensitivity test show that TruScan device has 89% to detect the efficacy (high quality) of the medicines on the spot and 85% to detect a medicine that is of low quality (counterfeit) when indeed the medicine is fake, therefore it is efficient to use in a regulatory Organisation or Industry.

In objective 3, for an association or correlation between TruScan and HPL (Gold standard) two methods of analysis were employed to ascertain the relationship between the devices. First McNamara's Test was used and the result indicates that there is a relationship between TruScan and HPL (Gold standard). Secondly, Kappa's agreement was equally used and the result shows that TruScan has 62% substantial agreement with HPL (Gold standard).

RECOMMENDATIONS

In view of the above, I wish to recommend that;

There should be a Public enlightenment campaign on the use of TruScan in regulatory organisation such as National Biotechnology Development Agency NABDA and NAFDAC

Based on the nature of our porous borders, all securities organisations (i.e. Nigerian Police, NDLEA, Nigeria Customs Service, Nigeria Immigration Service) should endeavour to purchase at least one TruScan for their enforcement activities

Registration of regulated products should make mandatory before circulation into markets and citizen should endeavour to check for NAFDAC Reg. No.

Enforcement of compliance of local manufacturers of cGMP.

The Federal Government should enact laws that will impose stiffer penalties on counterfeiters of medicines and other regulated products.

Our porous borders should be proper guarded by security forces i.e. police, NDLEA, Nigeria Customs Service, Immigration with NAFDAC having offices at these borders.

Registration of regulated products should make mandatory before circulation into markets.

Enforcement of compliance of local manufacturers of cGMP.

The Federal Government should enact laws that will impose stiffer penalties on counterfeiters of medicines and other regulated products.

CONCLUSION

In conclusion, counterfeiting of medicines have been recognise as one of the major reasons why some diseases in the developing world have become resistant to treatment. NAFDAC has currently employed a multi-dimensional, well-coordinated approach to tackle the issue of counterfeiting in the country and is spearheading global efforts in the use of cutting-edge technologies such as Raman spectrometer (TruScan).

Considering the usefulness of the TruScan as an on-the-spot anti-counterfeiting tool as evidenced based in the survey, despite the fact that TruScan is expensive ($62,000) per one, every state should be equipped with the device to facilitate thorough and effective mop up of spurious medicines from the nooks and crannies of every state and Local Government Area in Nigeria.

APPENDIX 1

Sample showing the results of TruScan and HPLC which is the gold standard using SPSS version 23.0

	LABORATORY/HPLC RESULTS									
TRUSCAN		Antimalaria		Antibiotic		Antidiabetic		Others		
		Passed	Failed	Passed	Failed	Passed	Failed	Passed	Failed	TOTAL
	Passed	812	33	550	13	68	0	433	11	1920
	Failed	141	201	47	109	17	4	31	8	558
	Total	953	234	597	122	85	4	464	19	2478

Source: NAFDAC Lab/PID

APPENDIX 2

The overall results of TruScan and Lab/HPLC using SPSS version 23.0

	LABORATORY RESULTS			
TRUSCAN RESULTS		Passed	Failed	Total
	Passed	1863	57	1920
	Failed	236	322	558
	Total	2099	379	2478

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