

# ENSURING QUALITY SYSTEMS AND STANDARDS IN LABORATORY SERVICES

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# Introduction

- Laboratory results are responsible for two-thirds of medical diagnosis in developed countries
- It is the responsibility of medical laboratories to meet the needs of patients and all clinical personnel responsible for patients care, including appropriate consultative services
- Primary function of ISO15189 in medical laboratory is to establish same standard throughout the world in order to overcome trade barriers
- Accreditation of PathCare Nigeria is a peer review by an independent organisation (SANAS), this was conferred in 2006 assuring that processes meet up to the minimum standard required to operate in all ISO accredited laboratories





# Method

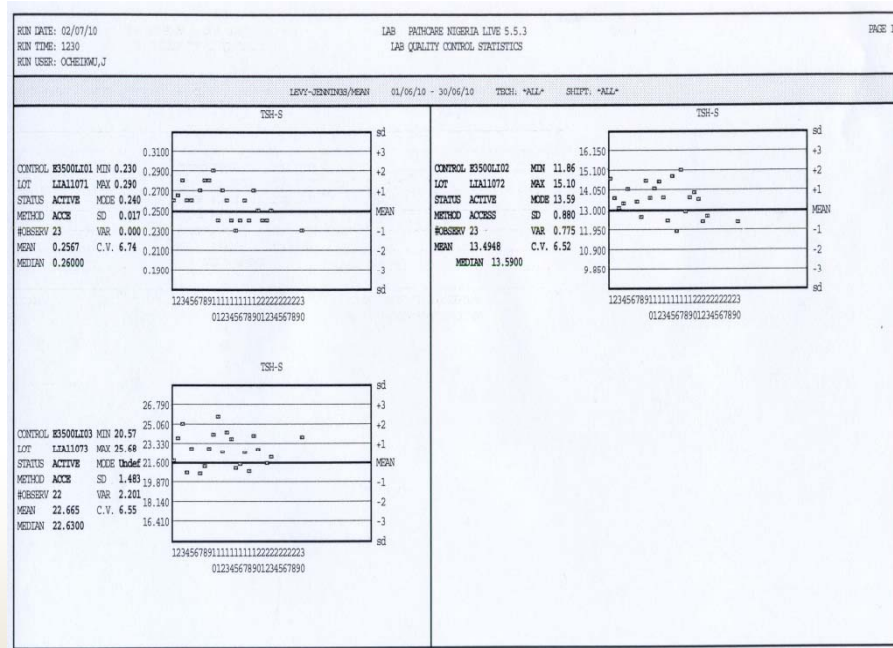
- A comprehensive review of literature identifying the laboratories accredited ISO15189 world-wide and its impact on health systems
- Identifying the importance of quality to Nigerian medical laboratories and the processes of ensuring proficiency in the system
- Analyse the PathCare Nigeria's quality management system utilising the '5Qs' framework. This '5Qs' framework encompasses Quality Assurance, Quality Control, Quality Improvement, Quality Indicator and Quality System



# Quality Parameters in PathCare

1. Quality Control
  - Internal Control – Daily Quality Control (DQC)
  - External Control – Inter-laboratory Quality Assurance (IQA) and/or External Quality Assurance (EQA)
2. Maintenance of instruments
  - Daily, weekly, fortnightly, monthly, biennial and bi-annual
3. Cold Chain
  - Control of Laboratory room temperature and control of working temperature of all instruments
4. Standard Operating Procedures (SOP)
5. Assured competence & continuous staff development
6. Audits
  - Daily, monthly and annual

# Daily Quality Control (DQC)



- This is a graph of the daily quality control done for the month of June for TSH
- The values have been plotted against the mean and as it shows we have consistently been around the mean, and within the allowable  $\pm 2$  SD range

# External Quality Assurance

**Immunoassay - EQA Report** THISTLE QA

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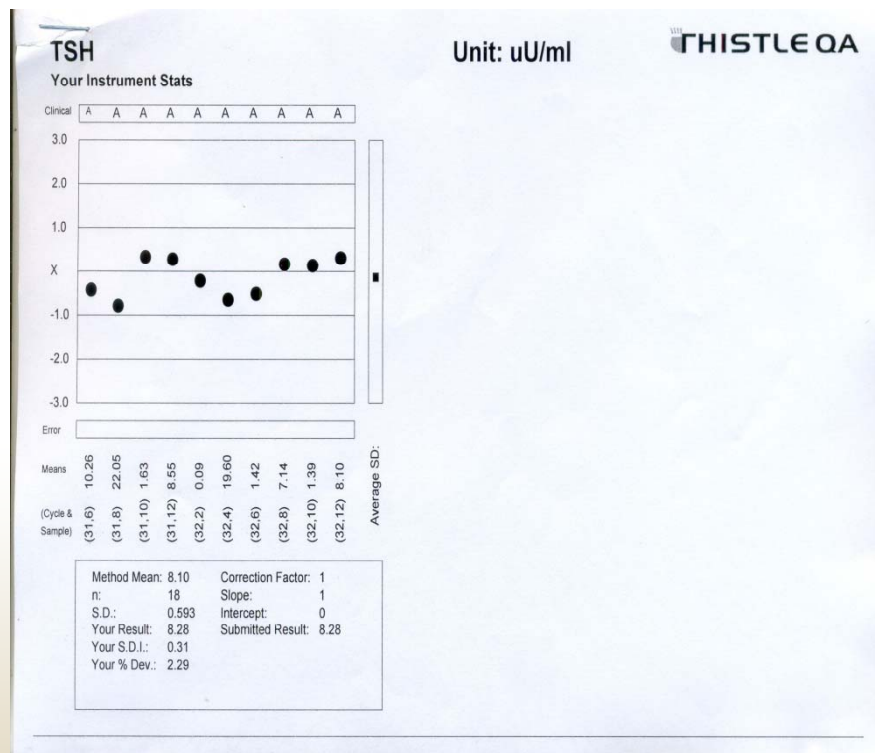
Participant: 2585 Pathcare - Nigeria Lagos  
 Cycle: 32 Material: Lyophilised Human Serum  
 Sample: 12 Sample Date: 31/05/2010

PERFORMANCE FOR THIS SAMPLE

Analyte	Your Result	Instrument Performance				Your	
		Mean	n	S.D.	S.D.I.	% D.	
Cortisol	749.21	761.1	8	37.96	-0.313	1.56	
Free PSA	15.34	15.21	3	0.664	0.196	0.85	
Free T3	16.19	16.68	14	1.004	-0.493	2.97	
Free T4	37.13	39.7	18	2.62	-0.996	6.56	
FSH	53.76	52.6	14	1.94	0.578	2.14	
hCG	131.96	143.0	20	9.36	-1.179	7.71	
LH	36.82	38.6	12	2.07	-0.839	4.51	
Oestradiol	1884.0	1909.1	14	146.57	-0.172	1.32	
Progesterone	69.15	78.987	11	7.035	-1.398	12.45	
Prolactin	859.66	896.9	13	58.69	-0.635	4.16	
Testosterone	23.98	22.673	11	0.981	1.333	5.77	
Total PSA	13.24	13.29	5	0.425	-0.118	0.38	
<b>TSH</b>	<b>8.28</b>	<b>8.10</b>	<b>18</b>	<b>0.593</b>	<b>0.312</b>	<b>2.29</b>	

- This is a print out of the external quality assurance run for the month of June. It is run by Thistle QA which is an independent and accredited proficiency testing body
- This print out shows the EQA for TSH (highlighted) which was run by several laboratories and the mean value stated. Our result has been compared to the mean and the standard deviation calculated. This is shown on the next page in a graphic form.

# External Quality Assurance



- ▶ This is a graph of the external quality assurance done in June for TSH
- ▶ This is done by sending the same sample to several participating laboratories
- ▶ All results are collated with the mean and SD deduced, which are used to judge individual laboratory's performance
- ▶ This graph shows PathCare's performance over the past 10 months, thus showing consistency within acceptable deviations



# Conclusion

- The pain-staking assurance of quality might be cumbersome, but results obtained are reliable trusted and acceptable world-wide
- Nigerian medical laboratories need to embrace quality by adopting ISO15189 which assures accuracy of diagnosis, thus, improving the efficiency of the health care system

***“quality will be remembered long after price is forgotten”***



Thank you.