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EQA of POCT within Primary Care and the High Street Pharmacist

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IEQAS Meeting
1st October 2009



POCT in the high street

- What are the drivers?
- What's being done and by whom?
- What's the laboratories' role?
- WEQAS POCT Schemes
- POCT EQA performance
- Performance surveillance, support and troubleshooting

In the UK

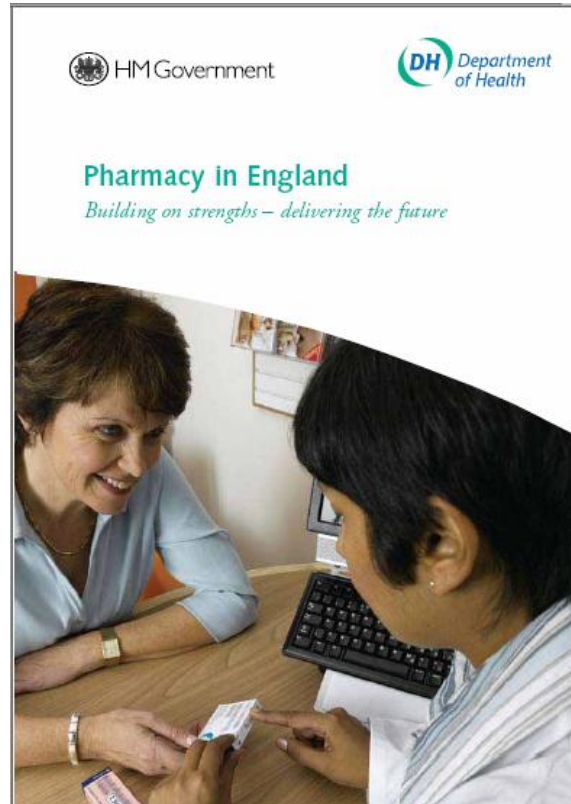
Carter Review – 21 references to POCT

Report of the Review of NHS Pathology Services in England
Chaired by Lord Carter of Coles



An Independent Review for the Department of Health

1st October 2009



Pharmacy White paper



Darzi Report





Royal
Pharmaceutical
Society
of Great Britain



PRESS RELEASE

7 September 2008

Pharmacy bodies pledge to work as one on White Paper

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“ What the politicians think

“Let me single out the benefit that will come to the individual citizen if the local pharmacy is able to offer services... such as blood tests and anything that will make it more convenient for the patient...”

Prime Minister Gordon Brown

“I would like pharmacists to be the first port of call for people who aren't sure about whether they need to see a doctor or not. Pharmacists know whether someone should be referred to a GP.”

Lib-Dem Shadow Health Secretary Norman Lamb

“Community pharmacists reach every part of the population and very often there are people who don't visit their general practitioner or the NHS very much at all. So if we want proactive public health measures, community pharmacists have got an enormous amount to offer.”

Conservative Shadow Health Secretary Andrew Lansley

- What's being done and by whom?

Long-term conditions: integrating community pharmacy

Diabetes

- Screening - Community pharmacists in Durham Dales PCT.
- Integrated diabetes service – Hillingdon PCT

CHD

- Monitoring -22 pharmacies in Greater Manchester.

Cancer

- Prevention & early detection

Pharmacy Case Studies

INTEGRATED DIABETES SERVICE

Ten community pharmacies in Hillingdon PCT were commissioned to provide a diabetes service which is integrated with other local services.

Evaluation showed that diabetes control improved in almost all patients receiving the pharmacy service.

In patients whose diabetes was uncontrolled at baseline, target levels were reached in half of the patients during the first year of the service.

Positive effects were also seen on blood pressure control and total cholesterol.

GMS project

- **Aim**

- Offer patients with diabetes and/ or Cardiovascular disease choice of attending pharmacy for clinical consultation and diagnostic testing instead of GP.

- **Objectives**

- Opportunity for new pharmacy contract – inform DH on valuation of contract.
- Assess whether pharmacies can deliver care for LTC
- Inform DH on contribution of POCT to the development of primary care facing lab med services.

- **The diagnostic service**

- BP, HbA1c, lipids, height, weight, lifestyle info for people with type2 diabetes and / or CHD.
- When August '06 to November '07

- **Outcome**

- Only 34% of patients took up choice for POCT

- **Benefits**

- Patients – improved choice of access, self empowerment and encouraged self management through immediate feedback of POCT results (47% felt care better, 50% same).
- -Pharmacist – Extended job role and greater satisfaction. Opportunities to support new pharmacy contract, increased income.
- GP- reduced workload

- **Barriers**

- Lack of GP engagement and confidence in the service
- Concerns over additional patient journeys (not complete repertoire)
- Small numbers of patients seen by each pharmacy - Lack of practice and confidence in quality of POCT
- Lack of IT infrastructure
- Governance issue

Impact of POCT

- Opportunities for decentralised testing, ease of use.
- Future roles for lab medicine in service delivery, performance management, developing infrastructure for QA
- Accreditation in primary care requires further consideration – ISO 22870- may not be suitable.

Pharmacy Enhanced Services from Rowlands Pharmacy

- Chlamydia Screening
- Heart failure clinics
- Anticoagulation clinics
- H. pylori “test & treat” Service
- Diagnostic services – Greater Manchester pilot
- Obesity & weight management
- Men’s PISTOP Health Checks. – BMI, BP, Chol, glucose. Part of a high profile PCT marketing campaign.

POCT in the high street – existing services

Lloydspharmacy – celebrating 5 years of testing for Diabetes

Lloydspharmacy



- Lloydspharmacy was the first pharmacy retailer to establish a FREE Diabetes Testing Service in 2003; since then, we have tested over 1 million people in the UK and nearly 60,000 of these were referred to their Doctor with high blood glucose readings.

Professional Services: **Diabetes**

3rd Step



Your blood glucose level will then be measured.

- This is measured through a simple test which involves a very small finger prick sample of blood
- A blood glucose monitor provides the test result



Cholesterol & Heart Check

Professional Services: Cholesterol and Heart Check

3rd Step



Your cholesterol will then be measured

- These are measured through a simple test which involves a finger prick sample of blood
- Your results are available after about five minutes

5th Step



The pharmacist will discuss your results with you. Dependent on the outcome of the results you may be invited to return for further measurements

- You will be offered lifestyle advice and advised on ways of reducing your chance of developing heart disease later in life
- If appropriate, the pharmacist may refer you to your doctor



Weight loss programme

cholesterol/ HDL

Health screen – glucose
/ cholesterol

Enhanced services

Anticoagulation monitoring

Over the counter sales

Pregnancy testing

Fertility testing

Ovulation tests

Celiac disease

Cholesterol testing

Bowel cancer testing FOB

Blood Glucose monitoring

Menopause test

Chlamydia test kit

What can the accredited laboratory provide?

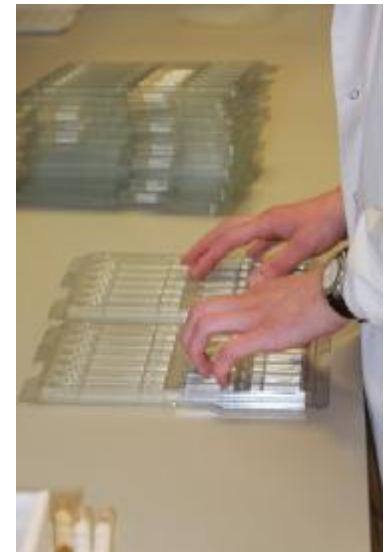
- Advice /Support
- Training / competence assessment
- Audit / EQA / Performance surveillance
- ? Governance / Certification

POCT EQA performance –WEQAS experience



About WEQAS

- EQA service initiated in 1968
- POCT EQA service providers since 1995.
- WEQAS provides POCT EQA to over 200 Trusts within the UK and Ireland.
- Over 25,000 samples are distributed each month.
- Website launched November 2002 to improve the EQA services to both POC coordinators and users.
- All Schemes are CPA (EQA) accredited incorporating ILAC G13:2000, and ISO Guide 43.



Accredited EQA scheme
Reference No: 004

POCT EQA Scheme design

- Customised – to meet the requirement of each client, i.e. sample provided per meter / per POCT site or per operator.
- The EQA programmes are designed for ward staff, primary care nurses, occupational health staff and pharmacists and covers: Training, external quality assessment and problem solving.



Programmes Currently available from WEQAS for POCT devices.

POCT devices covered in Lab based Schemes

- WeQas Pregnancy Testing
- WeQas Blood gas / co-oximetry
- WeQas Hct - iStat
- WeQas Bilirubin - bilirubinometer
- WeQas HbA1c
- WeQas Cardiac marker - Cardiac reader

POCT specific Schemes

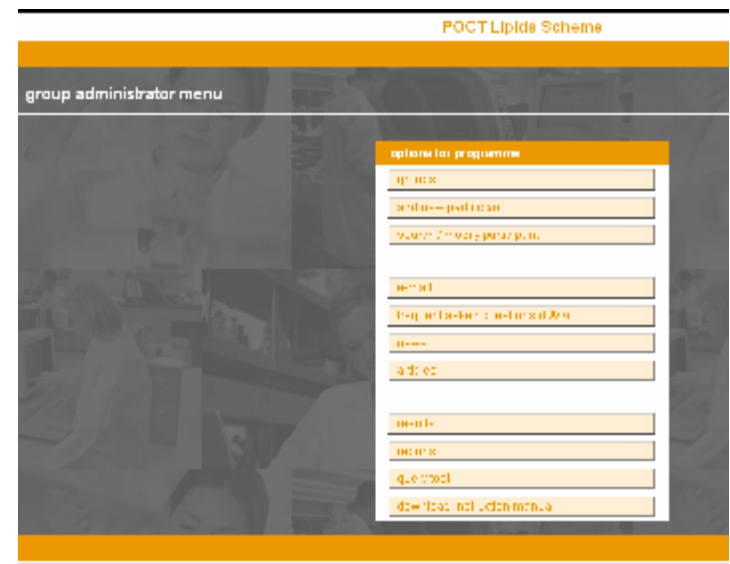
- WeQas POCT Glucose and Ketones
- WeQas POCT Urinalysis
- WeQas POCT Lipid and glucose
- WeQas Cardiac marker - Triage
- WeQas BNP – Triage
- WeQas POCT Hb
- WeQas POCT INR

1^oCARE / PHARMACY BASED SCHEMES

- **WeQas POCT Lipid & glucose** - includes Cholesterol, HDL, triglyceride and glucose.
- Sterile human serum covering pathological range is distributed bimonthly in 0.5 ml volumes.
- Cholesterol concentration range 3 – 8 mmol/l,
- Triglyceride 0.5 to 2 mmol/l,
- HDL 0.6 – 2 mmol/l,
- glucose from 2 –20mmol/l.

The Database

- User / site can upload data and download their reports
- Sub-group administrator is given access to all users in their Region.
- Group administrator given access to all users in their organisation.



Administrator Tools and Reports

Overall results - pie charts

Overall results - histogram

Overall results – excel table

Poor performers summary report

Poor performers letter

No results booked summary

No results booked letter

Cumulative Reports

Group Administrators

- Regional superintendent pharmacist or
- Laboratory POCT co-ordinator

Reports – target values can be mean/ median or ref value depending on Scheme.

Results - can be compared with all meters, same meters, within the group or within a subgroup.

Role of **performance surveillance** is devolved locally but monitored by WEQAS.



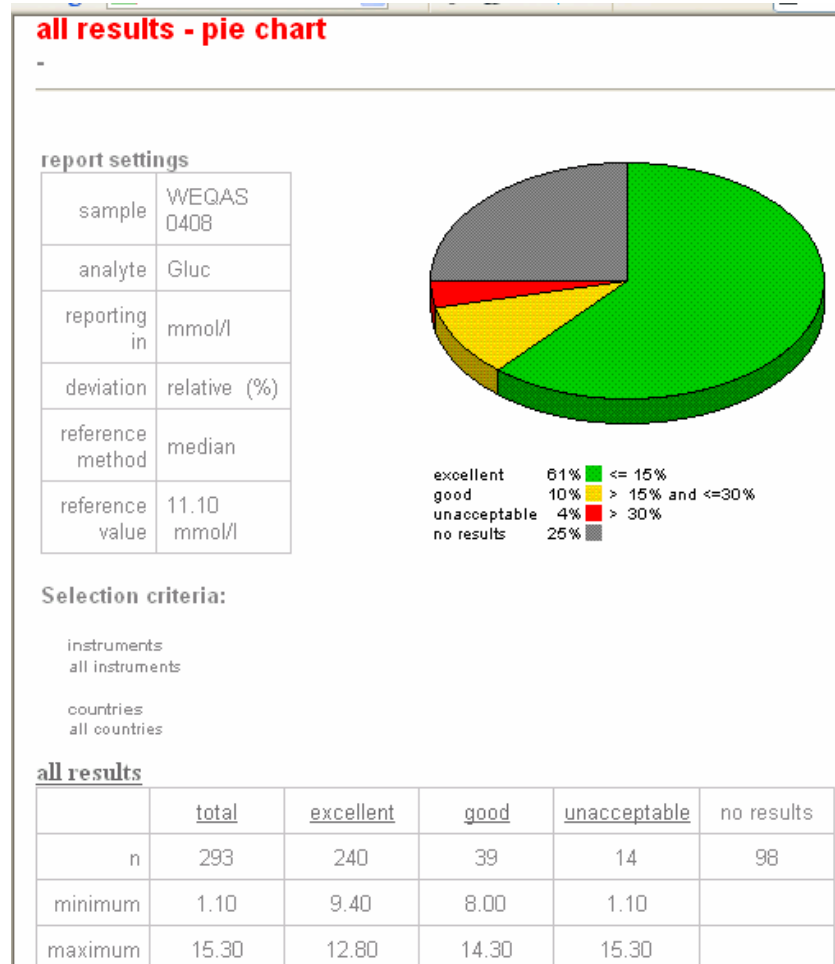
Analytical Quality Specifications

Analyte	WEQAS Lab TE	WEQAS POCT TE	Recommended TE
Chol	6%	24%	8.5%
HDL	+/- 0.2mmol/l	30%	11%
Trig	12%	24%	28%
Gluc	8%	30%	7%

Performance criteria – POCT Lipid

Analyte	Deviation	Interpretation	Colour
Cholesterol HDL Triglyceride Glucose	<12% deviation <15% deviation <12% deviation <15% deviation	Excellent	Green
Cholesterol HDL Triglyceride Glucose	12 – 24% deviation 15 – 30% deviation 12 – 24% deviation 15 – 30% deviation	Acceptable (Good)	Yellow
Cholesterol HDL Triglyceride Glucose	>24% deviation > 30% deviation > 24% deviation > 30% deviation	Unacceptable (poor) operator needs to evaluate technique/meter.	Red

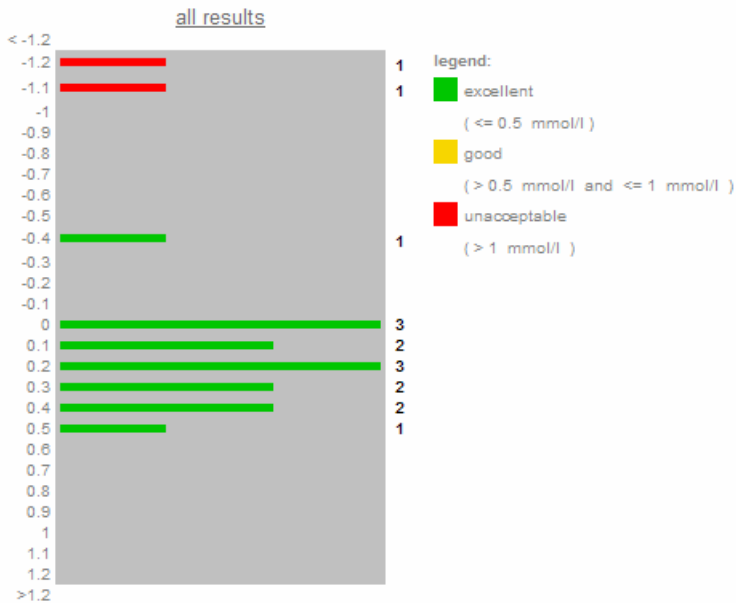
POCT Co-ordinator / Pharmacy Regional Manager – Pie chart overview



POCT Co-ordinator / Pharmacy Regional Manager bimonthly report

report settings		all results	
sample	WEQAS 0809	n	16
analyte	Chol	minimum	2.98
reporting in	mmol/l	maximum	4.59
deviation	absolute (resolution 0.1)	average	4.13
reference method	average	median	4.28
reference value	4.13 mmol/l	SD	0.50
		CV	11.9 %

Scale can be set to absolute (mmol/l) or % deviation.



Click on **All results** for table

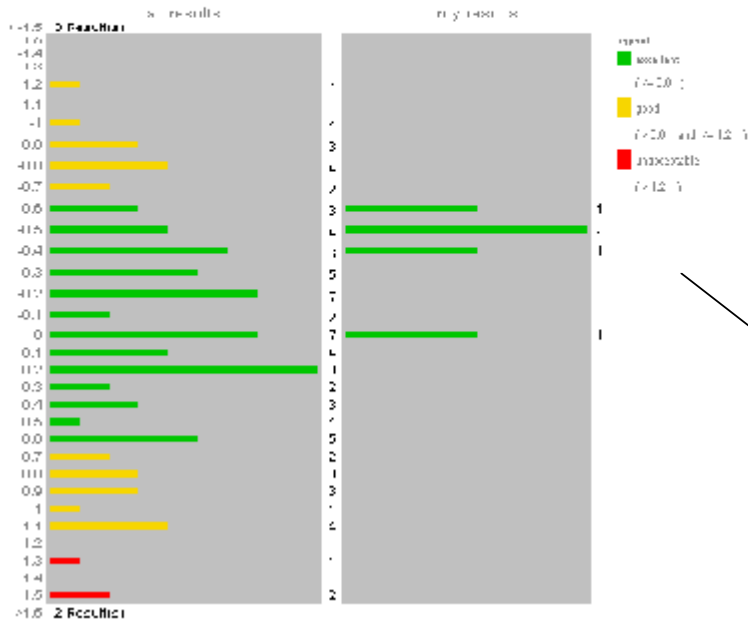
User reports

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Example of Pharmacist store Bimonthly Report.

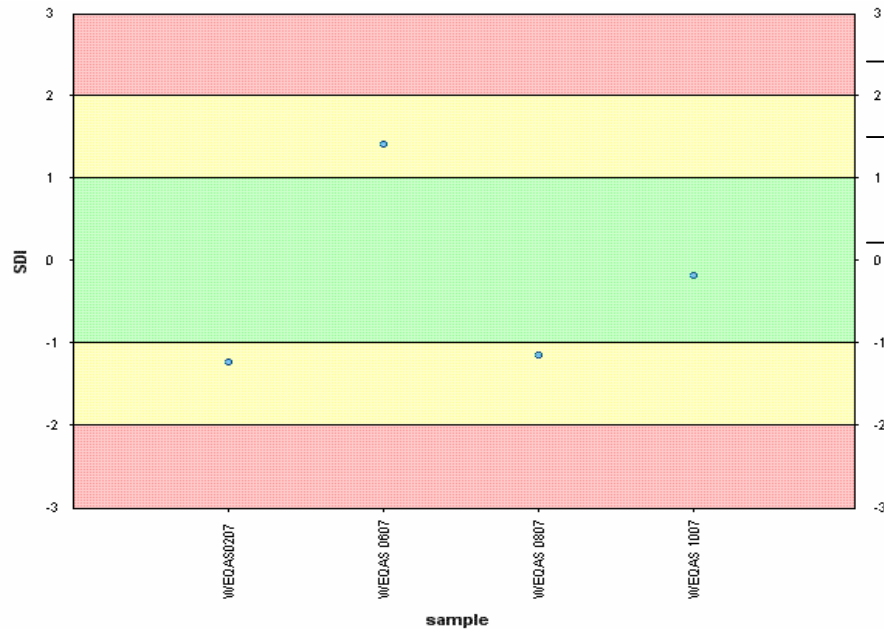
report settings		all results		my results	
store id	WPCAT-007		3		5
store name	Ch...	no. in m	2.27	no. in m	4.27
reporting to	no. in d	no. in m	7.07	no. in m	2.72
restriction	all sub results (in 7.1)	no. sig	5.7	no. sig	4.52
reference range l	no. sig	no. sig	5.73	no. sig	4.52
reference range u	5.03 no. in d	7.7	7.27	7.0	6.27
percentage	all results and my results	2.27	15.5%	2.0	4.3%



Click on **My results** to view your results as a table

	instrument	instrument ID	result ID	result
8	CardioChek Cholesterol	SN747218	C681	4.55
9	CardioChek Cholesterol	SN747619	C681	4.59
10	CardioChek Cholesterol	SN750292	C681	5.03
11	CardioChek Cholesterol	SN746313	C681	4.69
12	CardioChek Cholesterol	SN749995	C681	4.45

Example of Pharmacy Store Annual Report - Cholesterol



poor
good
Excellent

Can also
be run on
an ad hoc
basis

Performance is expressed as a Standard deviation index (SDI) where the SDI is calculated as total error (relative bias) from the target value / Standard Deviation.

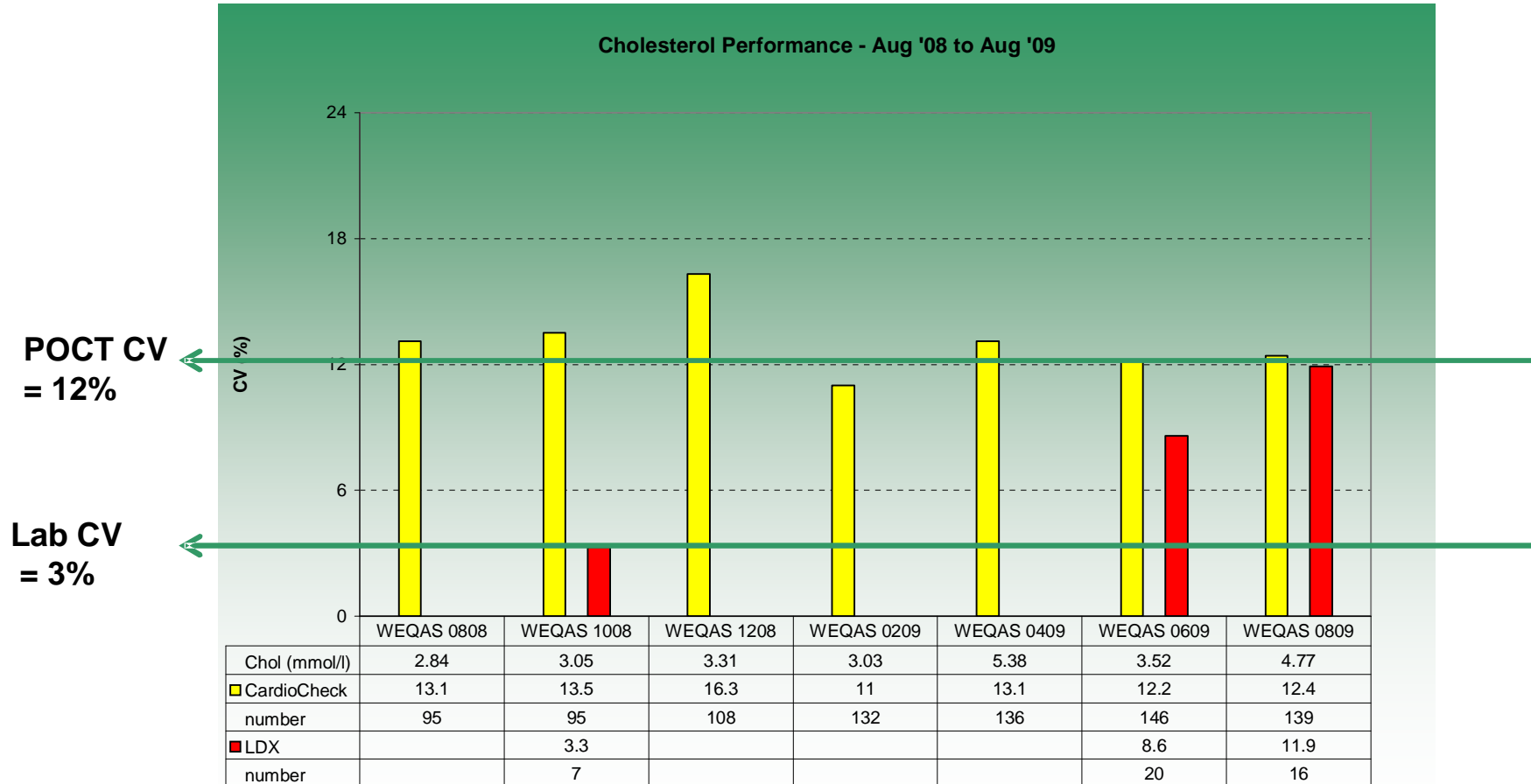
For cholesterol 1SDI = 12% (green area), 2SDI = 24% (yellow area), results in red are outside recommended target limits.

report settings

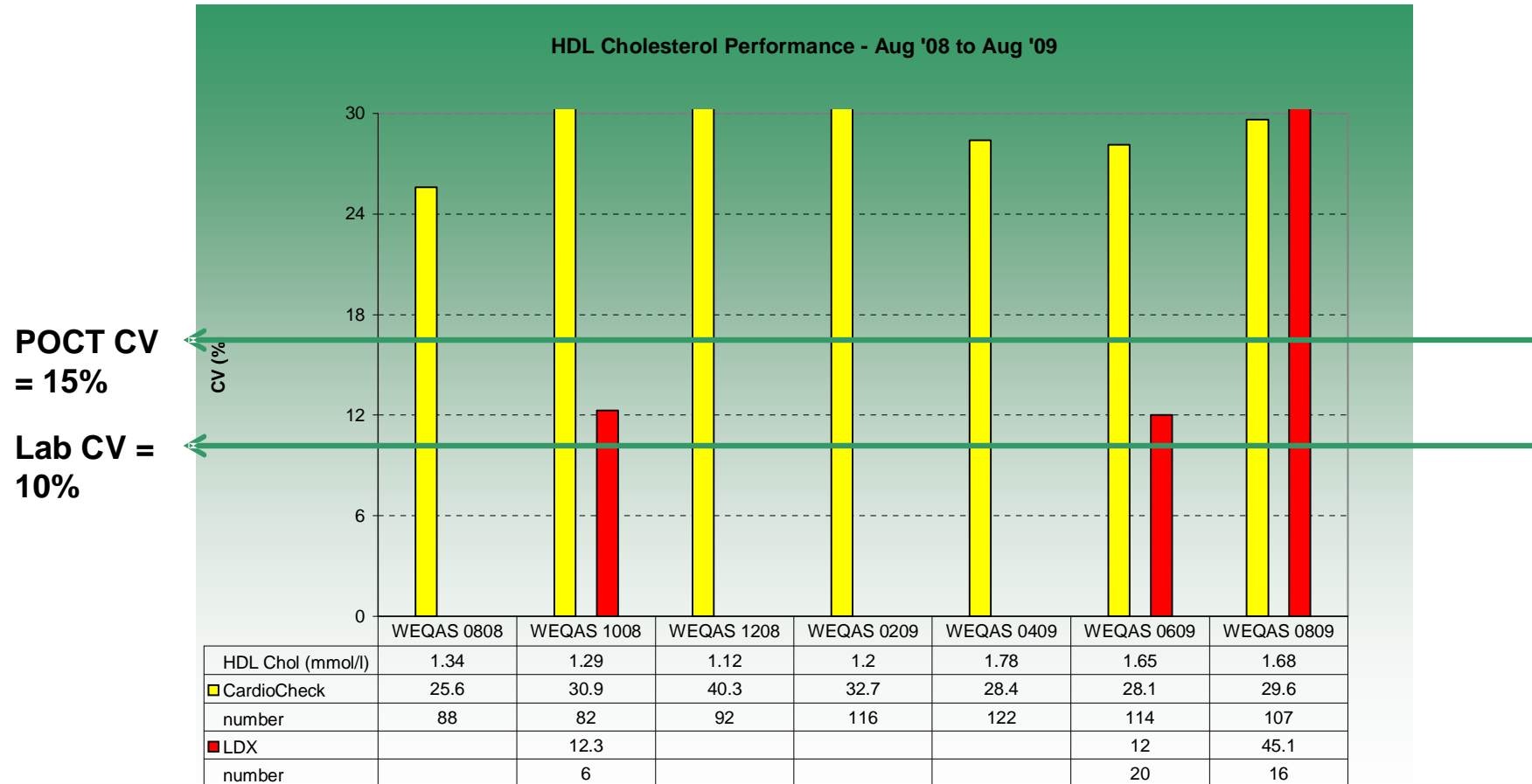
sample date range 1/1/2007 - 1/1/2008
your instrument(s) all instruments
reference value median
instruments all instruments
principles all principles
families all families
countries all countries
groups all

individual results					
	reference	your result	bias absolute	SD	SDI
	mmol/l	mmol/l	mmol/l	mmol/l	
WEQAS0207	6.42	5.72	-0.700	0.566	-1.2
WEQAS 0607	3.20	3.60	0.400	0.284	1.4
WEQAS 0807	3.74	3.19	-0.550	0.479	-1.1
WEQAS 1007	4.95	4.81	-0.140	0.776	-0.2

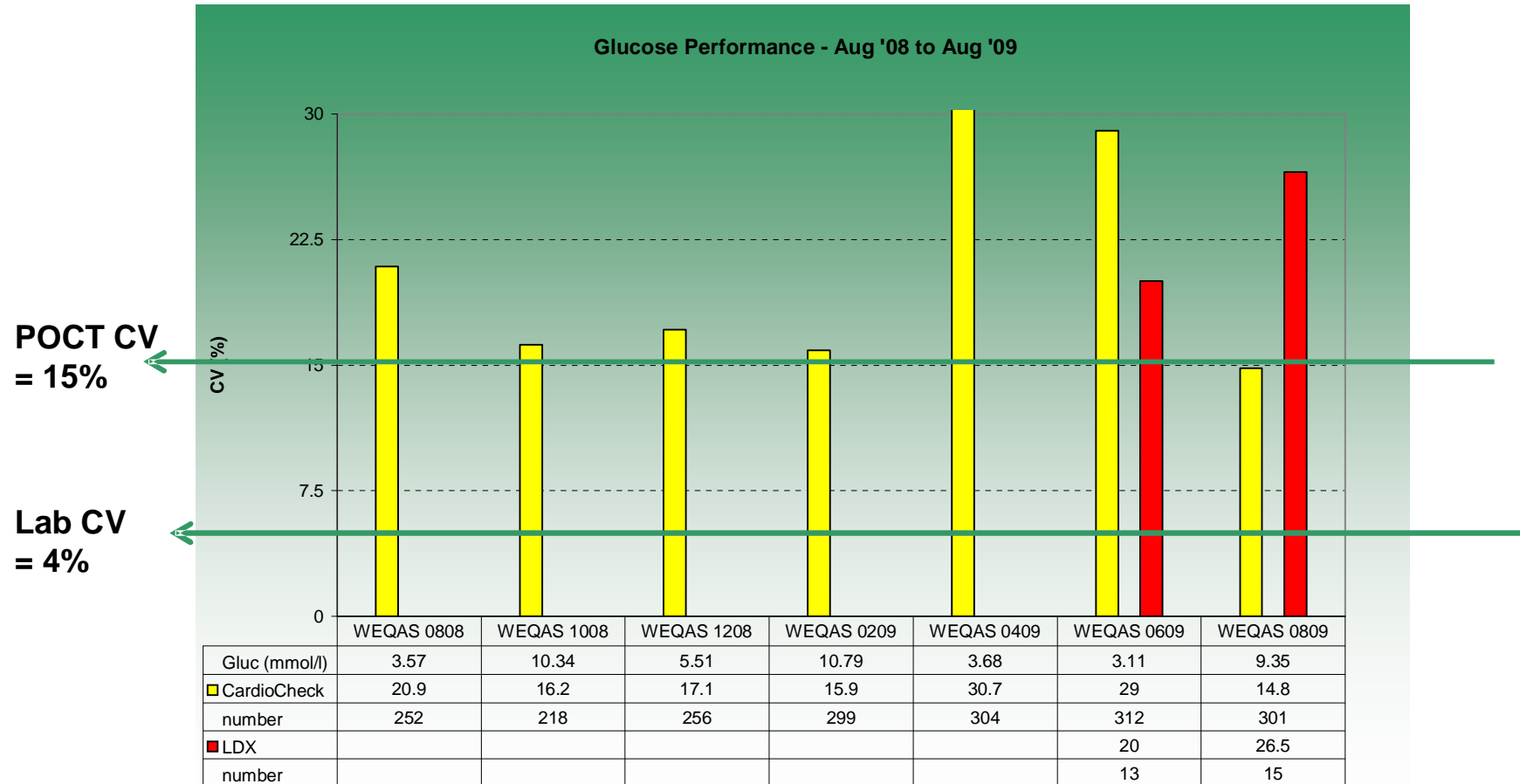
Performance –Cholesterol



Performance – HDL Cholesterol

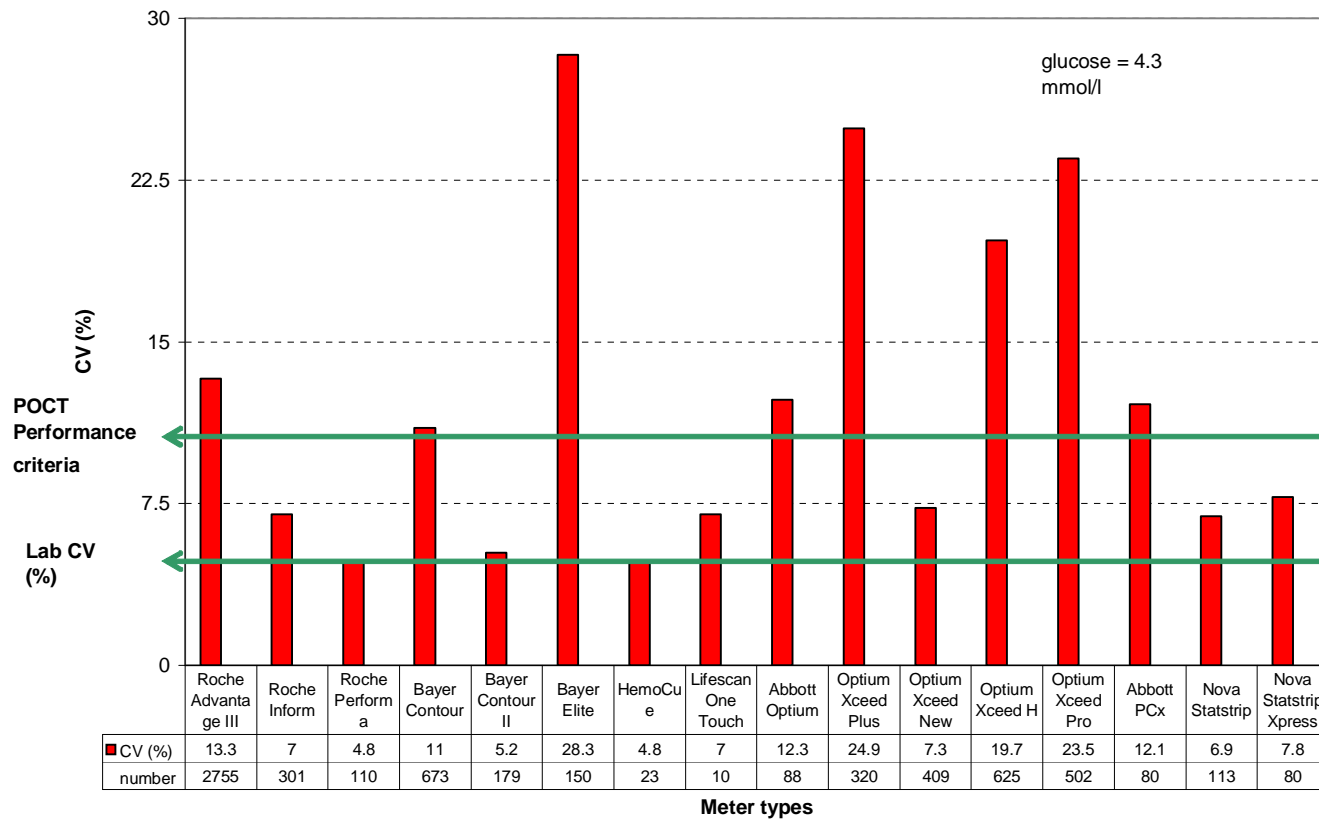


Performance – Glucose



Performance glucose – 2^o care

Glucose performance Aug '09



Performance surveillance, support and troubleshooting

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Focus & Simplify protocols

Action step

Visual aids

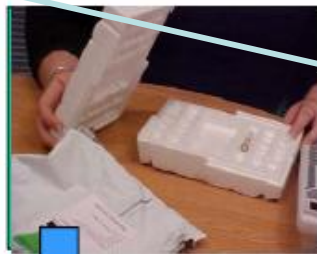


THE BOOTS' WAY: Complete an External Quality Assessment test for CardioChek PA

Perform an EQA test on samples from WEQAS

WHO: Pharmacist or trained member of staff
HOW LONG: 5-10 minutes
WHEN: Every 2 months, for each type of test performed on a CardioChek PA

Guidance



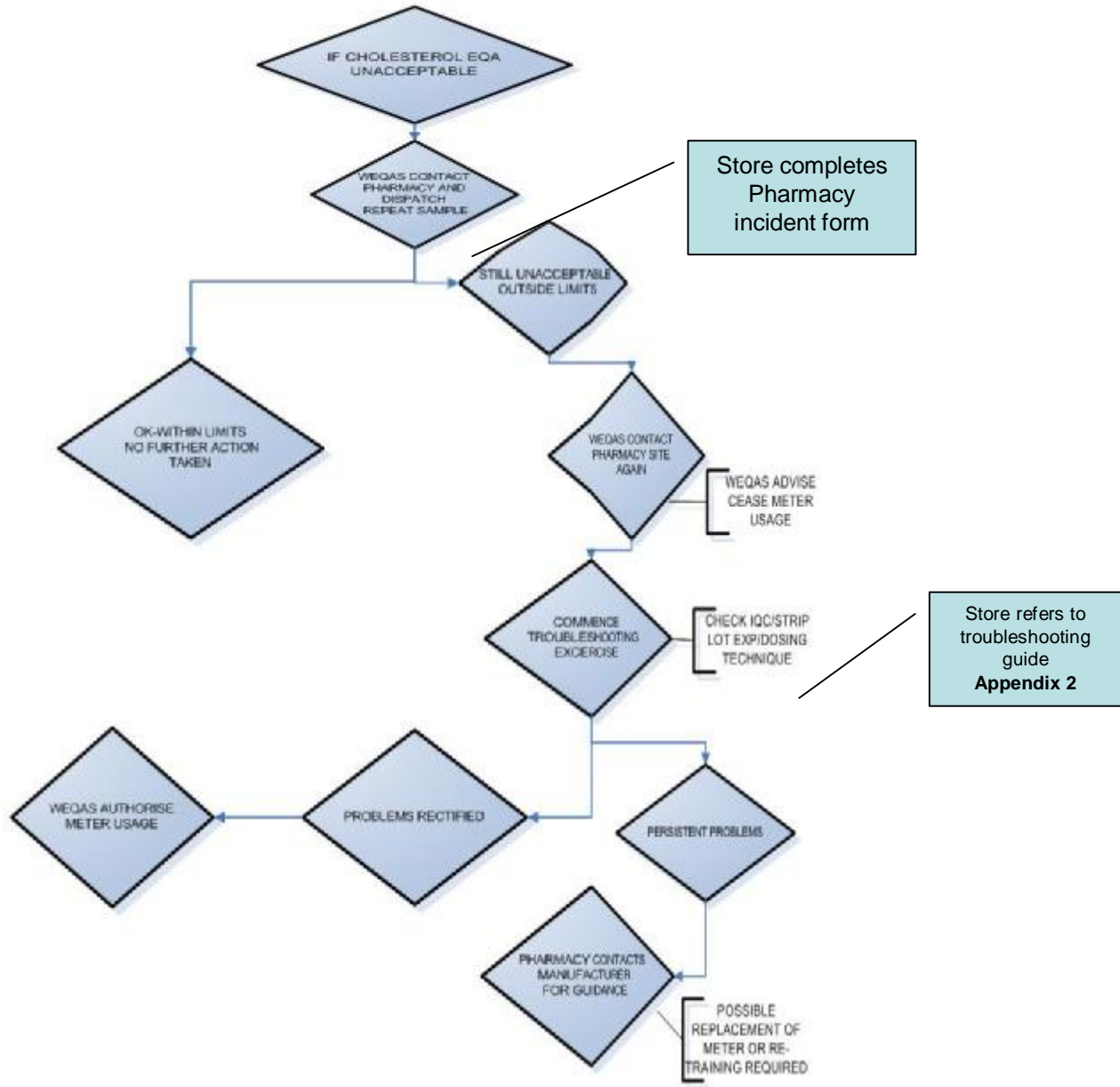
PROCESS STEPS

1. Receive sample in post from WEQAS, check sample to make sure it is intact.
2. Sample should either be used immediately or stored in the fridge, contact GPM if no-one available to perform EQA test within 7 days of date of dispatch, which can be found on the letter inside the package. Contact WEQAS (02920748188) if any concerns.
3. Wash your hands and collect the equipment that you will need to complete the test (hard surface wipes, CardioChek PA, test strips and memo chip, pipettes/capillary tube, clean damp gauze swab)
4. Put on gloves and wipe the CardioChek window with a clean damp gauze swab
5. Insert the relevant memo chip into the CardioChek PA and, with the ribs on the correct test strip facing upwards, guide the test strip into the analyser
6. Mix the sample well by slowly and gently inverting 5 to 6 times.
7. Remove the lid carefully and collect the precise sample of blood needed for the test by touching an appropriately sized pipette/capillary tube to the sample
8. Apply the sample to the blood application window on the test strip and check that the CardioChek display changes to 'testing'
9. Check the sample applied to the strip for air bubbles. If there are air bubbles present, carry out step 10 recording this observation on results table & then repeat steps 7-10, if enough sample left
10. Record results and complete the table on the results letter. Remove the test strip and

KEY POINTS

- ✓ If sample is stored in the fridge, remove sample from the fridge and allow it to come up to room temperature before performing EQA test. This should take half an hour
- ⚠ Although every effort is made to ensure the sample is free from any known infectious agent, samples should still be handled in the same way as finger-prick samples
- ✓ Ensure the correct memo chip and strip (with matching LOT numbers) are used for the correct sample eg Glucose chip and strip for the glucose sample
- ⚠ Take care to avoid creating bubbles in the sample whilst mixing
- ✓ CHOL + HDL panels require a 35-40µl sample of blood. CHOL + GLU panels require 25-30µl. GLUCOSE panels require 15µl
- ⚠ Once sample is opened it must be used immediately
- ⚠ Take care not to over or under fill pipettes
- ✓ Use a new pipette/capillary tube for any re-tests
- ⚠ When using the test strip which measures more than one analyte, press the right arrow key to scroll through each result.

CHOLESTEROL POCT EQA FLOWCHART



Store completes Pharmacy incident form

Store refers to troubleshooting guide Appendix 2

Troubleshooting Guide for CardioCheck meter

Problem	Probable cause	Solution
Unexpected results	Sampling errors <ul style="list-style-type: none"> Blood applied in more than one drop Insufficient blood Too much blood Blood applied to wrong side of strip. Hand cream or lotions on fingers Alcohol on finger. Faulty or incorrect pipette/ capillary used for blood collection device Air bubbles in capillary 	<ul style="list-style-type: none"> Check back of strip for even colouration. Please check that the correct amount of blood or EQA material is applied to the strip. 15ul for Gluc, 25-30ul for Chol + Gluc and 35 – 40ul for Chol + HDL. Please ensure that the fingers are thoroughly washed prior to sampling. Make sure that any alcohol has been thoroughly removed. Please ensure that the correct capillary is used for the right test Panel- see above There should be no air bubbles in capillary
	Strip errors <ul style="list-style-type: none"> Strip expiry date has passed. Storage conditions < 20°C or >30°C. anticoagulant not compatible with strip 	<ul style="list-style-type: none"> Replace strips Please store at room temperature. Discard if exposed to extremes of temperature. Please check with manufacturer. Fluoride oxalate should not be used with CardioCheck
	Meter errors <ul style="list-style-type: none"> Incorrect Memo code Chip Dirty optical system Defective LCD Meter stored improperly Low battery Use of result in stored memory 	<ul style="list-style-type: none"> Make sure the lot strip and Memo Code Chip match Clean opening by wiping with clean damp lint-free tissue or cloth. Ensure glass is free of dust or fingerprints Replace meter Make sure that the meter was not exposed to extremes of temperature Replace battery Please check that the reading relates to the last result.
	Interfering substances	<ul style="list-style-type: none"> High levels of Vitamin C may falsely decrease result for Chol +HDL+ Gluc Dopamine & α methyl dopa interfere with HDL test Hematocrit >50% may lower Cholesterol

POCT INR

Liquid stable, ready state material suitable for use on the Roche CoaguCheck XS and XS Plus,

Scheme details

- Frequency: Monthly
- Number of samples: 1 vial per POCT site
- Volume - 0.5ml volume supplied in sterile plastic dropper bottles.
- Analyte Range 2 – 8 Units

Easy to use

No reconstitution needed – use straight from the bottle.

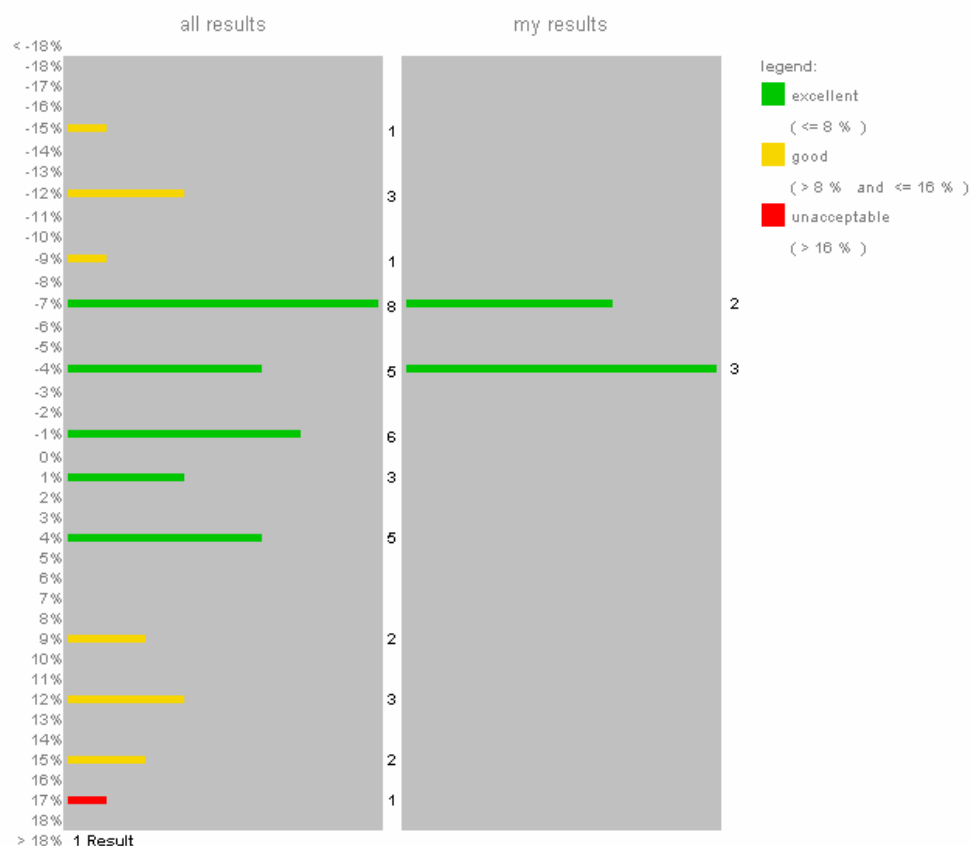


report settings		all results		my results	
sample	DIST 0309	n	41	n	5
analyte	INR	minimum	3.2	minimum	3.5
reporting in	units	maximum	4.5	maximum	3.6
deviation	relative (resolution 1%)	average	3.8	average	3.6
reference method	average	median	3.7	median	3.6
reference value	3.8 units	SD	0.3	SD	0.1
comparison	all results and my results	CV	8.7 %	CV	1.5 %

Typical participants report

my results

#	instrument	instrument ID	result ID	result
1	CoaguChek XS	UQ0008478	0309	3.5
2	CoaguChek XS	UQ0004743	0309	3.6
3	CoaguChek XS	UQ0004739	0309	3.6
4	CoaguChek XS	UQ0004720	0309	3.6
5	CoaguChek XS	UQ0009306	0309	3.5



Performance criteria

Deviation	Interpretation	Colour
<7.5% deviation	Good	Green
7.5 – 15% deviation	Acceptable (fair)	Yellow
> 15% deviation	Unacceptable – operator needs to evaluate technique/meter.	Red

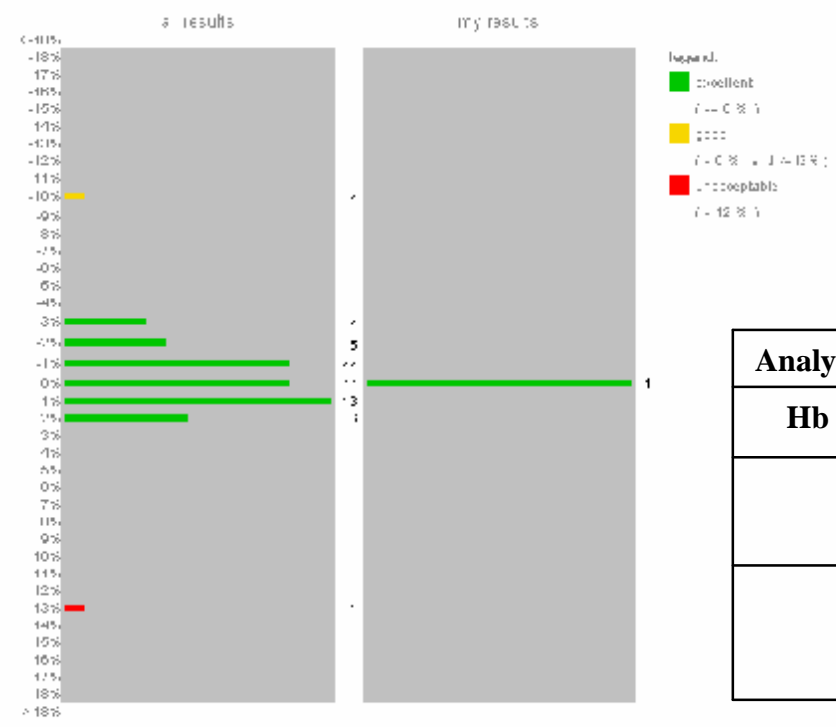
POCT Hb

Scheme details

- Frequency: Bimonthly
- Number of samples: 2 vials per POCT site
- Volume - 1ml volume supplied in sterile plastic tubes.
- Analyte Range - 4 – 20 g/dl
- Material - purified stroma free bovine haemolysate.

Typical Bimonthly Report

report settings		all results		my results	
sample	HUC sample 1	n	50	y	1
analyte	Hb	minimum	11.7	minimum	11.5
reporting	g/dl	maximum	12.4	maximum	11.5
deviation	relative (resolution 1%)	average	11.5	average	11.5
reference method	median	median	11.5	median	11.5
reference value	11.5 g/dl	SD	0.3	SD	0.1
comparison	all results and my results	CV	2.6%	CV	0.9%



Performance criteria

Analyte	Deviation	Interpretation	Colour
Hb	<6% deviation	Good	Green
	6 – 12% deviation	Acceptable (fair)	Yellow
	> 12% deviation	Unacceptable – operator needs to evaluate technique/meter.	Red

my results			
#	Instrument	Instrument ID	result
1	Hemocue 231	C71C012136	11.3

Thank you for listening

WEQAS POCT Team

Seetal Sall – POCT Manager

Nicky Blount

Margaret Perkins

Jenny Allen

Kate Sannino

www.weqas.com

