NTEC POCT Blood Glucose Analyzer (BGA) Refresher Training for BGA Link Nurses / Operators

Department of Chemical Pathology
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New Territories East Cluster

What is POCT?

- Laboratory test performed outside Pathology Laboratories
- Performed by non-laboratory professionals

Classification of Complexity of Testing for POCT/ Devices*

Complexity of Testing*	Level I	Level II
Description	Low complexity of testing	Moderate to high complexity of testing
Type of POCT/ Devices	1. Glucometers, e.g. Bayer Contour® TS system, Roche Accu-Chek® Performa system. 2. Haemoglobinometers, e.g. HemoCue® Haemoglobin system. 3. Blood ketone	All types of POCT/ devices NOT classified as Level I.
POCT Operator Requirement	Well-trained hospital staff, including ancillary staff.	Well-trained professional staff (doctors, nurses, medical technologists, other specialists).

Urine dipstick tests which are simple to perform with little potential for adverse medical consequence are exempted from compliancy to this Policy. However it should be noted that performance of these tests should adhere to the manufacturer's instructions. Exempted tests include urine test strips for glucose, protein, ketone, red blood cells, pH, bilirubin and urobilinogen.

* Factors considered include complexity of testing methodology, potential analytical interference, clinical importance, medical-legal implications, availability of positive patient identification, etc.

Risk of Using POCT

(D) Point-of-Care Device (POCT) Guidelines

A young girl presented to hospital with abdominal pain. Initial investigation using blood glucose monitor in the A&E revealed normal values, but subsequent investigation revealed patient with very high blood glucose suffering from diabetic ketoacidosis. Investigation revealed that the glucometer test strips were not properly stored and deteriorated

A number of similar incidents were reported and led to the formation of a Working Group (WG) formed by representatives from Co-ordinating Committee in Anaesthesia, Emergency Medicine, Paediatrics and Pathology to look into the issue of Point-of-care Testing (POCT). A survey on the current status of POCT use in HA was done in 1999, confirming that POCTs were commonly used, the commonest used were U dipstick and BGM. A set of guidelines was then developed by a Working Group and is posted on the HA intranet: (http://hohbfsmc2/bssd/bes/mdbb.html)

Hospital Authority. Risk Management Release Issue No. 4; 2001

Inaccurate Results, Why?

1. Pre-analytical factor
2. Analytical and post-analytical factor

- Environmental Factors (Pre-analytical)
- Patient Factors (Pre-analytical)
- Operator Factors (Analytical)
- Instrument / Reagent Factors (Pre-analytical)

Environmental Factors

- Light
- Air exposure
- Humidity
- Temperature

Clustered Cases of Hypoglycaemia …

- Data from POCT Server

Ward	Handset S/N	Fliers date	Time	Results	Strip Lot
A	XP0909A0211010	06-Mar-12	5:46:00 AM	1.7	461R5H
			5:52:00 AM	5.4	461R5H
B	XP0909A0211442	12-Apr-12	11:53:00 PM	1.4	461R5H
			11:58:00 PM	4.0	461R5H
B	XP0909A0211443	14-Apr-12	5:32:00 AM	1.8	461R5H
			5:34:00 AM	4.0	461R5H
			Recheck after meal		
			6:29:00 AM	1.3	461R5H
			6:31:00 AM	8.2	45K25H

Investigations

Analyser Check

No problem detected

Site Inspection

- Staff pre-opened the individually packed glucose strips well before testing on patient blood samples.
- What is the consequences?

Deterioration of Glucose Strips

Pre-opened glucose strips

Day	Low level	QC	High level	QC
0	2.6	2.9	17.7	18.8
1	2.4	2.4	13.7	14.1
2	1.9	2.1	10.9	10.4
3	1.6	1.4	7.2	6.2
4	1.2	1.2	3.7	3.0
5	**Saturday**			
6	**Sunday**			
7	<1.1	<1.1	2.8	2.4
8	<1.1	<1.1	1.4	1.7
9	<1.1	<1.1	1.1	<1.1
10	<1.1	<1.1	<1.1	<1.1
11	<1.1	<1.1	<1.1	<1.1

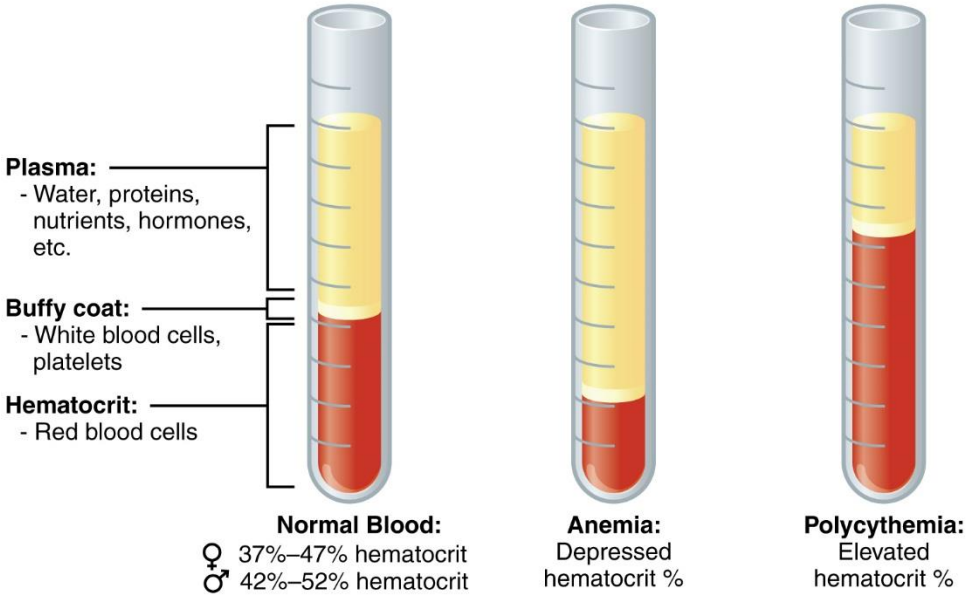
Freshly opened glucose strips

Day	Low level QC	High level QC
0	2.5	16.6
1	2.2	16.6
2	2.7	17.0
3	2.7	17.4
4	2.5	16.3
5	**Saturday**	
6	**Sunday**	
7	2.6	15.8
8	3.1	16.9
9	2.7	15.9
10	2.6	16.4
11	2.6	15.4

Handset S/N	XP0939A0211018
Strip Lot	46NC5H Exp 2013.07
QC Range (mmol/L)	Low level = 1.8 - 3.4 High level = 12.6 - 20.9
Ambient Temperature	24˚C

Patient Factors (I)

If the **plasma glucose conc.** in all specimen tubes being the same,



then the **whole blood glucose conc.** in the right specimen tube will be **about half** of that in the middle specimen tube

Effect of Haematocrits on [Glucose]

1. Neonates
   - – higher Hct → lower [glucose]

2. Patients with DKA
   - – higher Hct → lower [glucose]

3. Patients with anaemia in general
   - – lower Hct → higher [glucose]

Patient Factors (II)

Fasting state

- **Lipaemia** (high triglycerides) affects glucose (falsely ↓) POCT devices.

Sugars (Maltose)

- Affect method using ***Glucose Dehydrogenase-Pyrroloquinoline Quinone*** (**GDH-PQQ**) coupling reaction (falsely↑)

- **Icodextrin** – ingredient in CAPD fluid

- **Intragam® P** – ingredient in some intravenous preparations

Systolic blood pressure

- If **< 80 mmHg**, blood leaves finger tip and moves to central part of body
- In **hypotensive state**, finger-prick glucose < venous or arterial specimens

Drugs

Paracetamol (overdose: blood conc. 3542 – 4511 umol/L) **(fasely ↑/↓- depending on type of BGA)**

Metabolites

- **Uremia (falsely ↑)**

30 drugs tested on 7 glucometers (Am J Clin Pathol 2000; 113: 75 -86)

Operator Factors

Pre-analytical Errors

- Incorrect patient tested
- Delayed analysis
- Inappropriate amount of sample presented

Patient Preparation

- Sample artifacts (drip arm)

Results / Readouts / Raw Data Analysis

- Visual mis-interpretation
- Transcription error
- Interference not recognized

Blood glucose Instrument / Reagent Strip Factors

Reagent Strips

- Expired or deteriorated strips
- Improper reagent storage
- Lot-to-lot strip variability

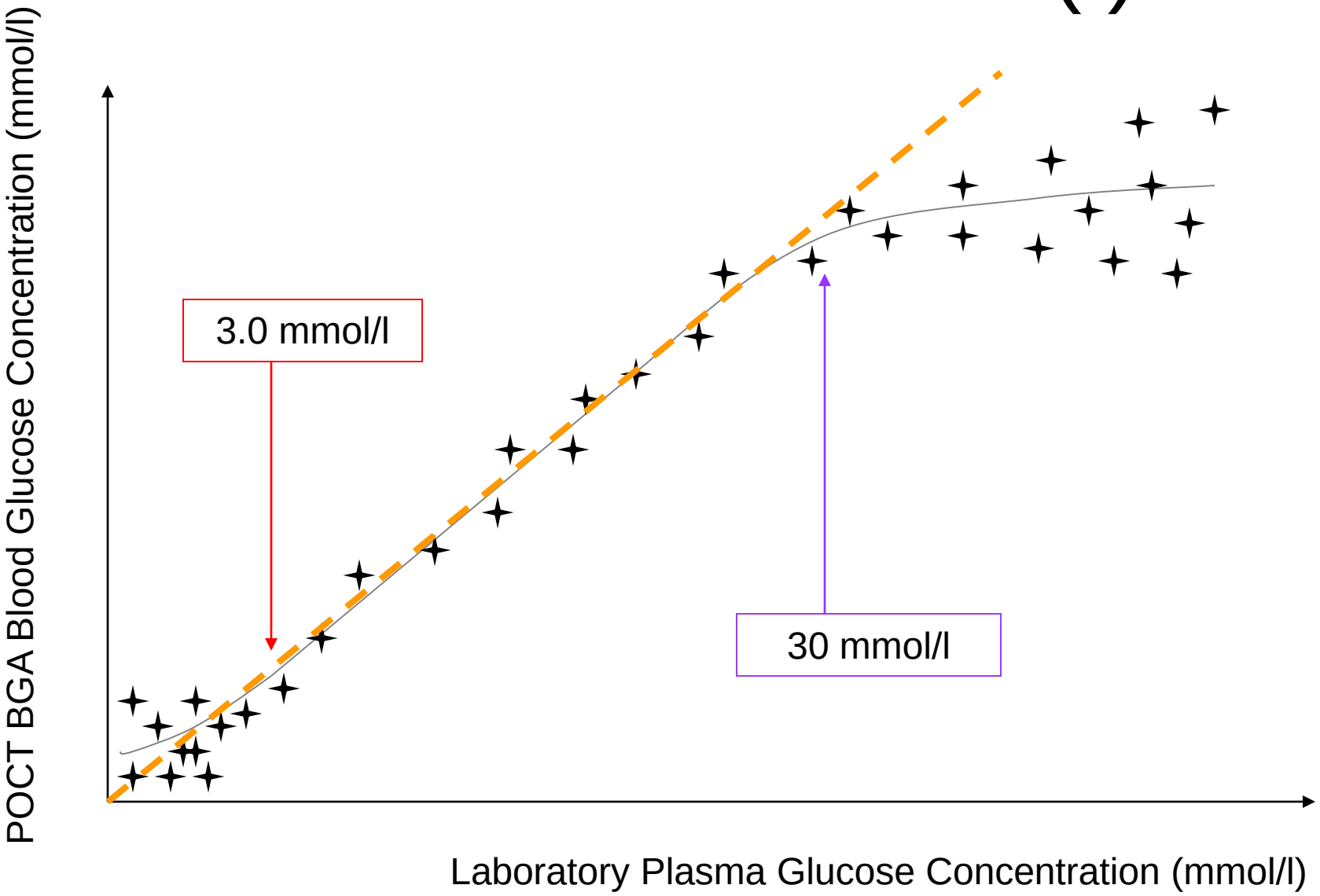
Instrument

- Instrument failure
- Internal QC data not verified prior to use

Calibration & Control Solutions

- Improper calibration
- Improper control storage
- Inadequate mixing of controls
- Non-linear reaction at extreme glucose values

Non-linear Reaction (I)

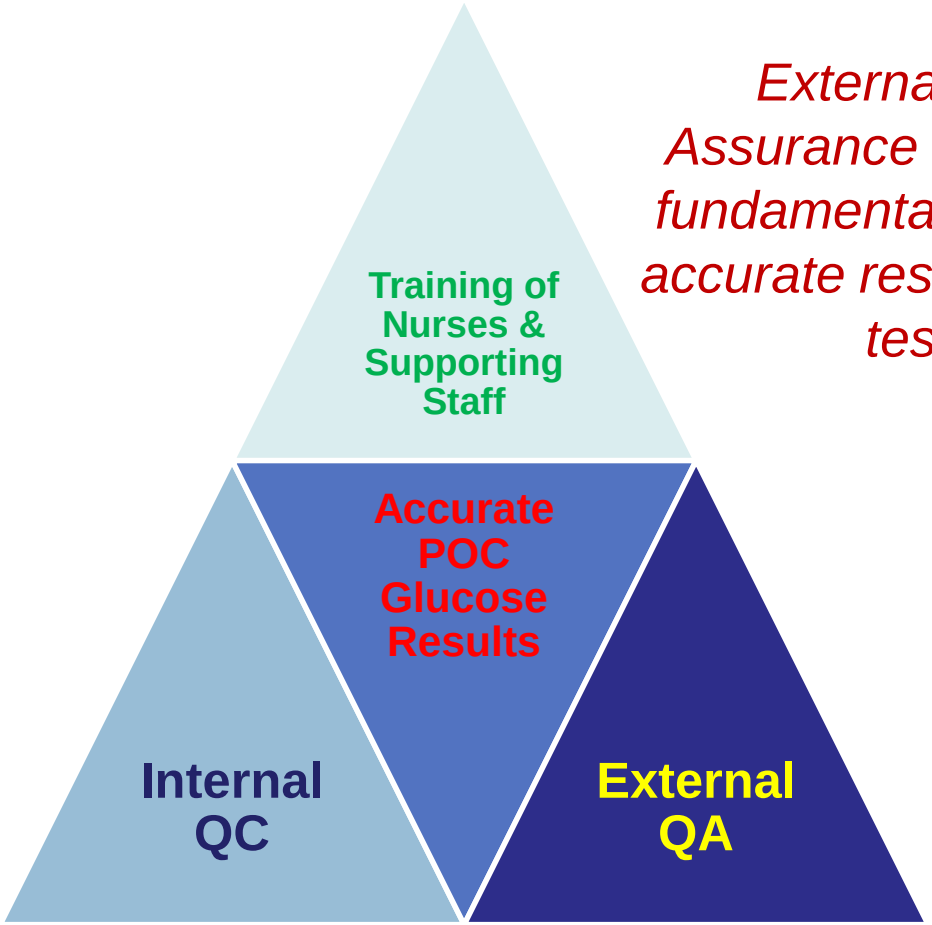


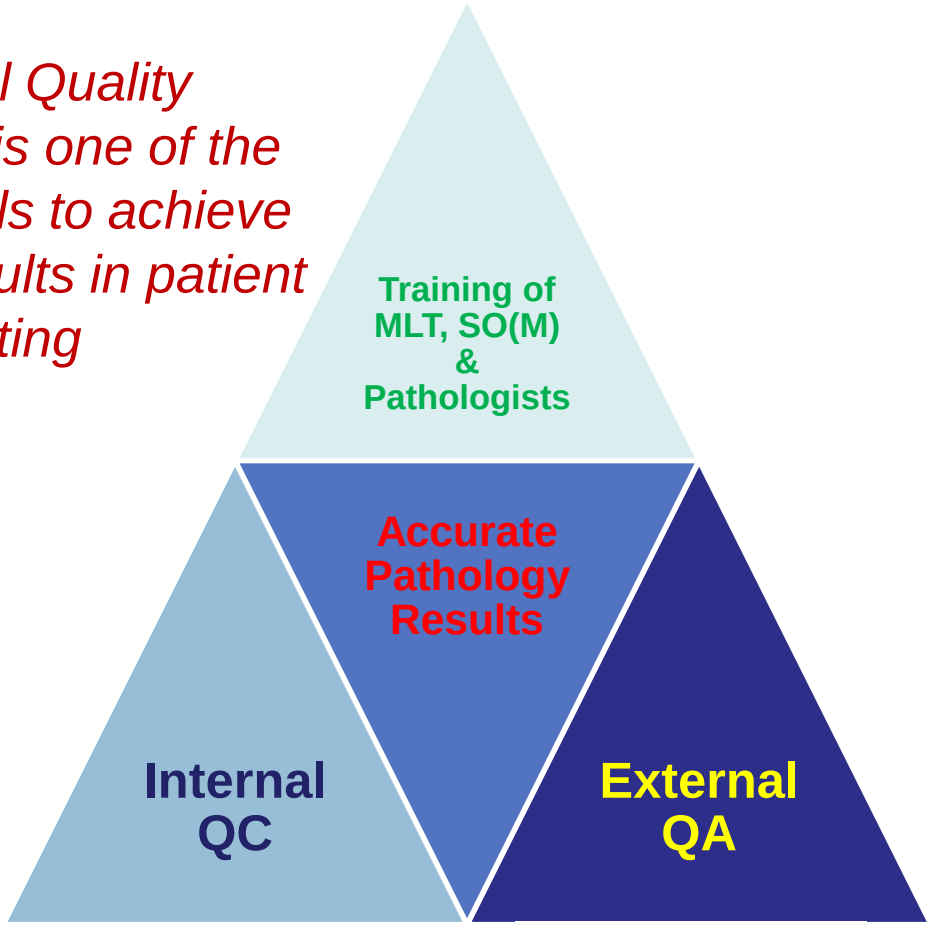
Non-linear Reaction (IV)

This sample was analysed by a certified POCT User. This report is for documentation only. The POC glucose result cannot diagnose hypoglycaemia. Please send a sample to the laboratory for confirmation if the POC glucose is <3.0 or >20 mmol/l.

How to Ensure Quality Performance?

External Quality Assurance is one of the fundamentals to achieve accurate results in patient testing

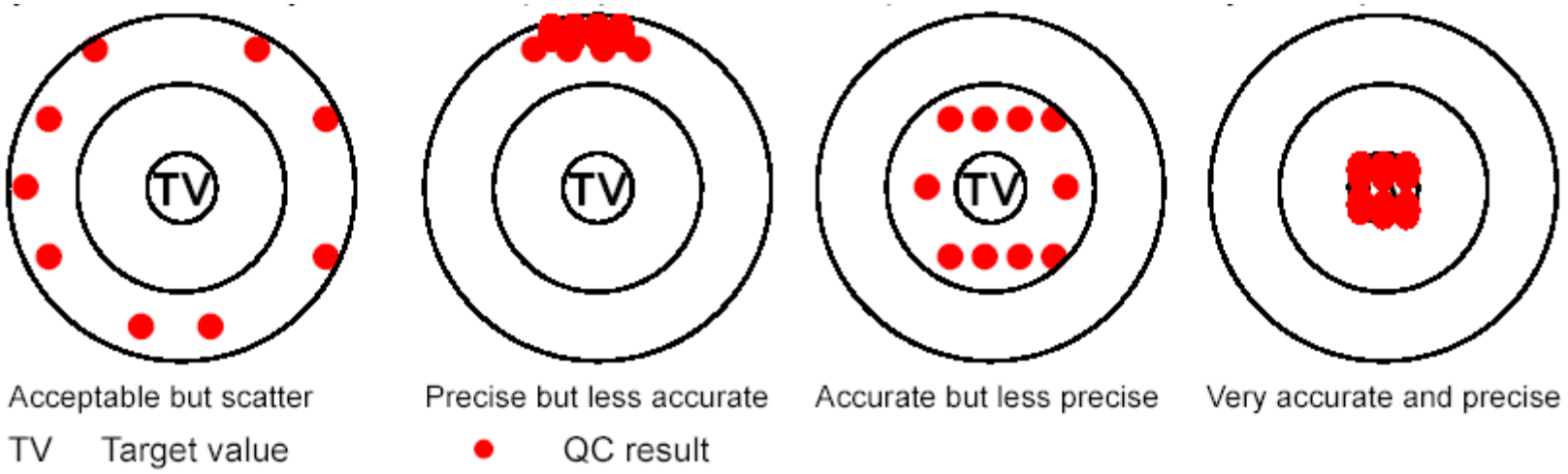




Internal QC – monitoring precision

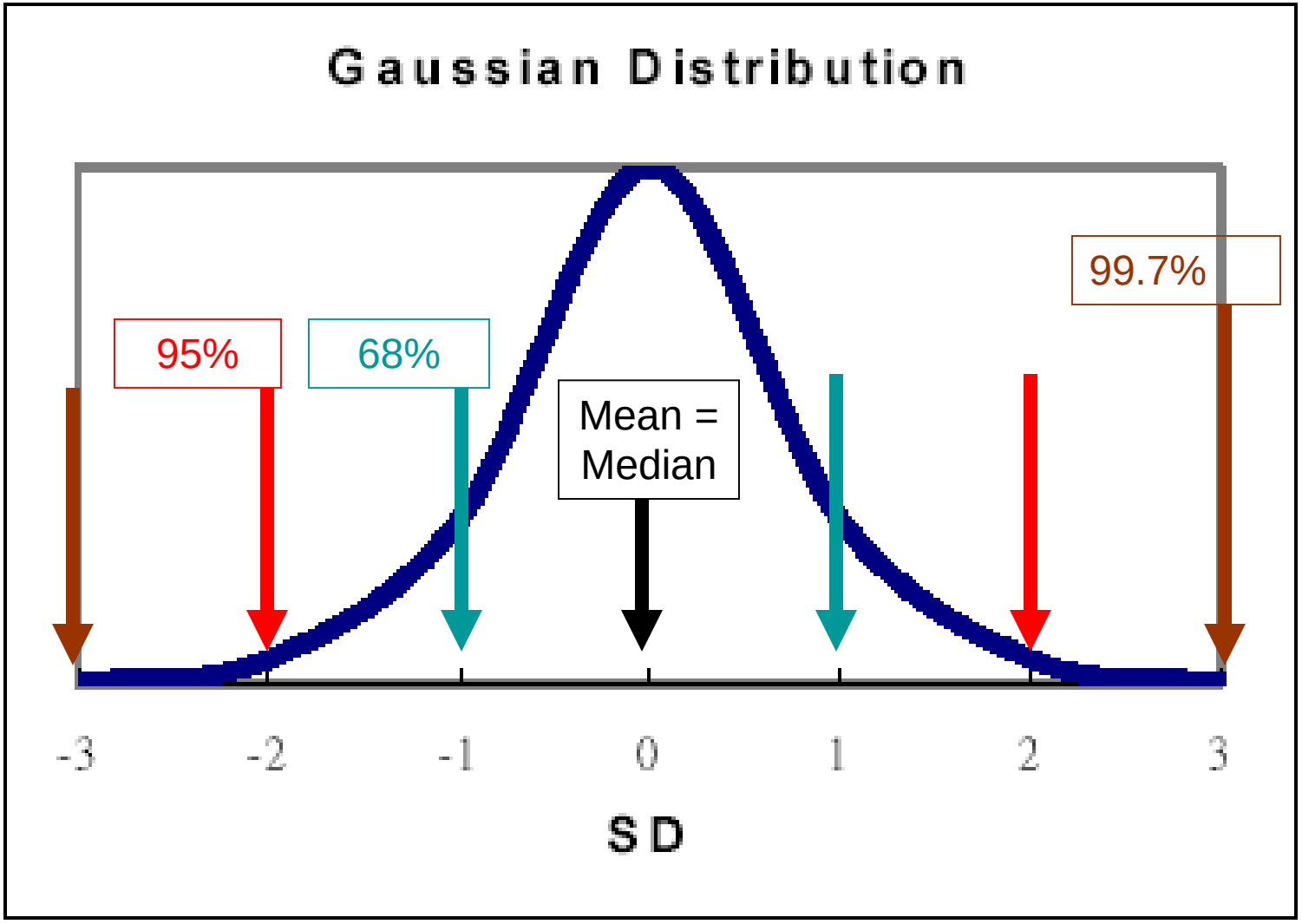
External QA – monitoring accuracy

Precision & Accuracy



4 2 3 1

Normal Distribution



Internal Quality Control

What is QC testing and why it should be done?

- QC testing are done routinely in laboratory and POCT wards to ensure analytical quality.
- QC result fall within its target range indicates the test is performed properly and there is no systemic error. The patient test result is acceptable for clinical management.
- Represent the random error across different operators, strip lots, time, etc

What is used for QC testing?

- Suitable materials with known value are used.

How is QC tested?

- It should be done as for patient sample. No special precaution is required.

When QC testing is required?

- According to HA POCT Guidelines, QC testing should be performed daily or before patient testing is done. But it should also be performed when:
  - When the BGA is dropped
  - When the battery of the BGA is changed
  - When the accuracy of the test result is questioned
  - When a new bottle/pack of strip is used
  - When QC testing fails

What should I do if my BGA keep failing to achieve acceptable QC?

External Assessment for Glucometers in NTEC

A pair of artificial buffered solutions containing unknown amount of glucose will be prepared every month

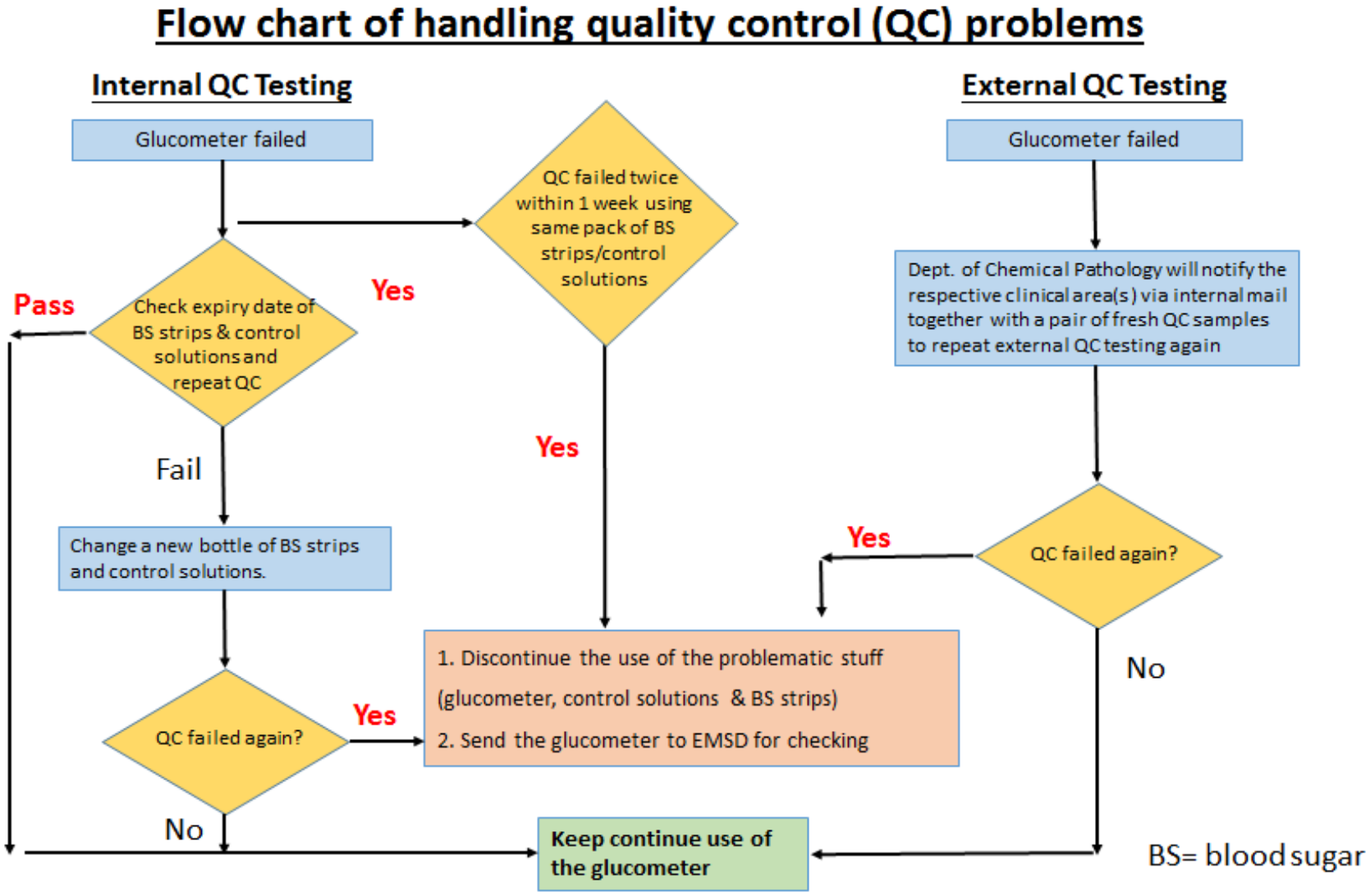
Reporting analysed EQAP sample results via a central NTEC EQAP Server

NTE Cluster
Point-of-Care Testing Glucometer External Quality Assurance Programme

Enveloped with two disposable pipettes and the reporting instruction for distribution to each ward or clinic in NTEC

Analysis of paired EQAP samples within two days of arrival

How to handle QC problem



The End

More information available at
iCHEMPATH@PWH