Maintaining Quality in Laboratory Medicine

POCT Glucose and Ketones Scheme Guide

Unit 6, Parc Ty Glas, Llanishen, Cardiff, UK, CF14 5DU
Tel: +44 (0) 2920 314750 Fax: +44(0) 2920 314760
Email: office@weqas.com website: www.weqas.com

UKAS PROFICIENCY TESTING 4301

UKAS CALIBRATION 4301

Contents Page

1. Scheme details and repertoire

Frequency: Monthly *Number of samples:* 1 dropper bottle per meter
Volume - 0.5ml volume supplied in sterile plastic dropper bottles.

Analyte	Range
Glucose	2 - 30 mmol/L
Ketones	0.6 – 6 mmol/L

2 Material

The base material is sterile tissue culture grade, new-born calf serum from BSE free herds. It has been tested negative for mycoplasma and adventitious viruses at source. Glucose and a red coloured dye is added to the base material, the serum is filtered to 0.2µm and gentamycin added to maintain sterility.

2.1 Stability

At 4°C the solutions are stable for 6 weeks in the unopened container.
At 20°C the solutions are stable for 4 weeks in the unopened container.
At -20°C the solutions are stable for 1 year in the unopened container.

Once opened the solutions should be used immediately

The following table shows the stability of two batches of the calf serum stored at room temperature for 40 days. Five aliquots were assayed on the days illustrated.

Batch 140499							
Date	**Day**		**Glucose**	**results**			**mean**
04-May	0	8.9	9.1	9.1	9.1	9	9
10-May	6	8.9	9	9.1	8.9	8.8	8.9
17-May	13	9.1	9.2	9.1	9.1	9.1	9.1
24-May	20	9.1	9.2	9.1	9.2	9.1	9.1
02-Jun	29	9	9	9	9.1	9.1	9.0
07-Jun	36	9.2	9.3	9.3	9.2	9.4	9.3

Batch 190599							
Date	**Day**		**Glucose**	**results**			**mean**
15-Jun	5	14.5	14.9	15	14.9	14.8	15
22-Jun	12	15	14.6	14.9	14.6	14.6	14.7
28-Jun	18	15	15.1	15	15	15	15.0
06-Jul	26	14.5	14.4	14.3	14.4	14.4	14.4
15-Jul	35	14.2	14.4	14.5	14.3	14.3	14.3
20-Jul	40	14.3	14.5	14.4	14.4		14.4

2.2 Instructions for use

Each POCT Co-ordinator will receive multiple samples for each POCT site / operator for both glucose and Ketones. Forms to record results from each site can be generated using the Distribution Letter in the Report module.

The sample must be used on the day you receive it. If you are unable to assay the EQA sample on that day, it can be refrigerated for up to two weeks.

1. If the sample has been stored in the fridge, allow the sample to come to room temperature prior to testing.
2. Wear gloves and treat the sample as if it were a clinical sample.
3. Mix the sample well by inverting 5 to 6 times – ensure there are no air bubbles in the sample.
4. Carefully remove the lid.
5. Gently squeeze the bottle to form a small drop onto a non-absorbent surface e.g. back of gloved hand.
6. Inoculate the strip as per the instructions in your meter user guide.
7. Analyse the sample following the standard operating procedure for your blood glucose meter.
8. Ensure the correct procedure is followed to ensure correct results.
9. Record the results according to your organisational policy.
10. Safely dispose of excess sample in accordance with local waste policy guidelines

The ward/operational site trainer should ensure that as many authorised users as possible participant in the scheme

Results should be returned to the POCT Co-ordinator for you organisation.

3 Statistical Analysis

POCT accreditation is assessed against ISO 15189:2012. WEQAS reports can greatly assist with your compliance to ISO standards. The standards require that the methods are verified prior to use, including traceability and uncertainty, assessed for trueness, precision and linearity and a QC programme used to monitor compliance.

The Point of care Co-ordinator in each Trust is given a Group Administrator function and maintains the database for its own Trust. POCT Co-ordinators should refer to POCT web training guide for instructions on how to access the site, set up the database, enter results and print reports**.** Participants (both POCT co-ordinator and POCT user) are given unique username and passwords to enter data and retrieve reports on line.

The Target value default setting is the Median for the method. The performance criteria (limits of acceptable performance) are established by WEQAS and fixed. These Limits can be displayed on the report as either a percentage or absolute deviation from the Target value. The default is relative deviation (%); however the POCT Co-ordinator can select their preferred display option on the report. The performance criteria are detailed in section 3.2. Results are compared with meters of similar type, (the method) across all organisations. Group Administrators can also run

a Statistical report where results are confined to their own data subset. However, this should be used with caution for methods where the number of participants is low.

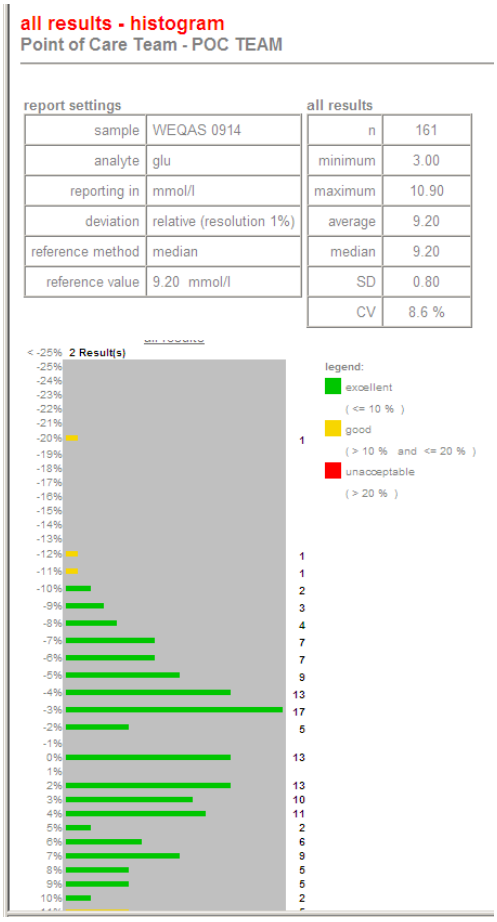
3.1 Reports

Group administrators can select from a range of reports
Overview reports- – All results table / histogram or pie charts.
The POCT user can select from Standard report (individual histogram reports), or a cumulative Levey –Jennings report.

3.1.1 Group Administrator Overview – "All results histogram"

The overall performance of each Trust is expressed as a table and a histogram. The limits of the histogram can be defined by the Trust POCT Co-ordinator with a default set at ± 25%. The POCT co-ordinator can immediately identify poor performers by selecting the red bars. The location and contact details are then displayed on the web. A full printout of the data is also provided as an Excel table by selecting 'All results' above the graph, an illustration can be seen on page 6 – All results table. The results are expressed as a percentage deviation from the target value and are colour coded to readily identify poor performers. The target value can be defined as mean / median or reference method.

All results histogram



3.1.2 All results table

all results

back

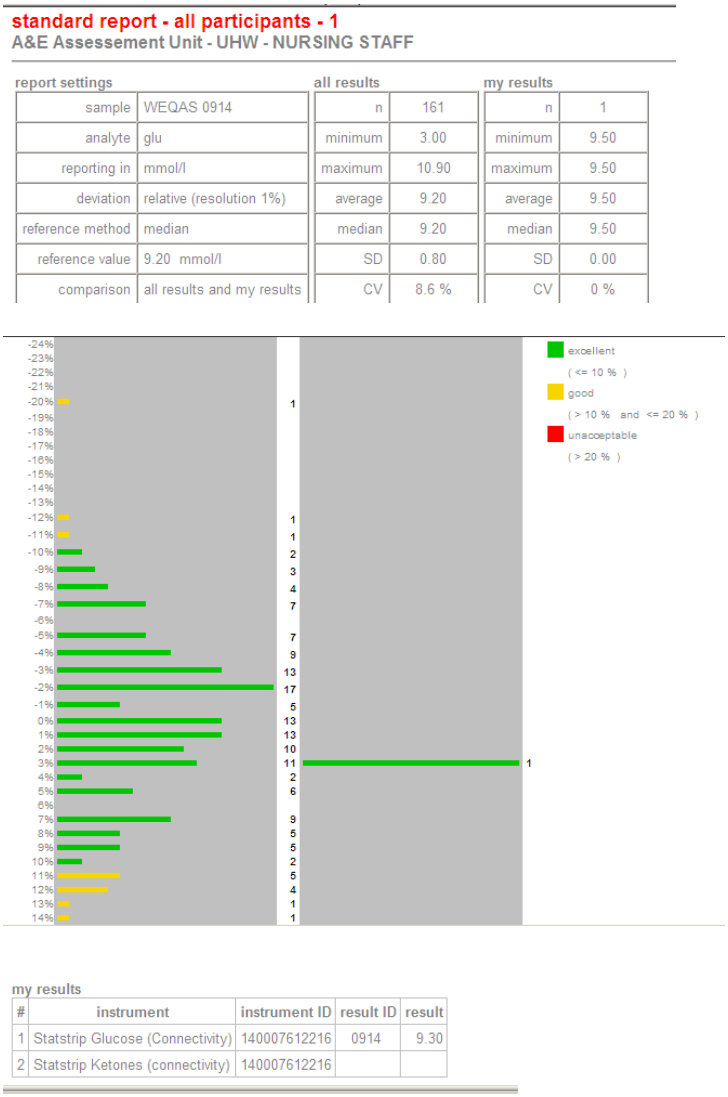
#	instrument	instrument ID	result ID	result	participant contact person	city country	subgroup	deviation from reference value	
								▽	all
1	Statstrip Glucose (Connectivity)	21100008610167	0914	3.00	Staff Clinic Rowena Griffiths	UNITED KINGDOM	Cardiff &Vale ULHB UHW	-68 %	unacceptable
2	Statstrip Glucose (Connectivity)	140025313309	0914	5.90	A&E Streaming Nurse in Charge	UNITED KINGDOM	Cardiff &Vale ULHB UHW	-36 %	unacceptable
3	Statstrip Glucose (Connectivity)	06074513168	0914	7.40	Colorectal Unit T2 Nurse In Charge	UNITED KINGDOM	Cardiff &Vale ULHB UHW	-20 %	good
4	Statstrip Glucose (Connectivity)	06060214006	0914	8.10	East 16 Llandough Nurse in Charge	UNITED KINGDOM	Cardiff &Vale ULHB LLANDOUGH	-12 %	good
5	Statstrip Glucose (Connectivity)	2100002410169	0914	8.20	Discharge Lounge Nurse In Charge	UNITED KINGDOM	Cardiff &Vale ULHB UHW	-11 %	good
6	Statstrip Glucose (Connectivity)	00004510134	0914	8.30	Adult Oncology Haemotology OPD Llandough	UNITED KINGDOM	Cardiff &Vale ULHB LLANDOUGH	-10 %	excellent
7	Statstrip Glucose (Connectivity)	02100000810112	0914	8.30	Haemophilia Centre Nurse In Charge	UNITED KINGDOM	Cardiff &Vale ULHB UHW	-10 %	excellent

3.1.3 Standard report (user report)

A typical report for glucose for a POCT ward is illustrated on page 7- see *Standard Report-All Participants.*

The left hand graph illustrated the deviation from the target value (median) for all results received for a Trust. The right hand graph illustrated the deviation from the target value for all results received for the POCT site (A/E Assessment Unit). This ward had 1 glucose meters – clearly identified by the coloured bar. This report can also be generated to compare users' results against the same meter type for all results (all Trusts), meters from one manufacturer, limit the data to within the Trust or within a subgroup.

Standard Report – All participants



standard report - all participants - 1
A&E Assessement Unit - UHW - NURSING STAFF

report settings		all results		my results	
sample	WEQAS 0914	n	161	n	1
analyte	glu	minimum	3.00	minimum	9.50
reporting in	mmol/l	maximum	10.90	maximum	9.50
deviation	relative (resolution 1%)	average	9.20	average	9.50
reference method	median	median	9.20	median	9.50
reference value	9.20 mmol/l	SD	0.80	SD	0.00
comparison	all results and my results	CV	8.6 %	CV	0 %

my results

#	instrument	instrument ID	result ID	result
1	Statstrip Glucose (Connectivity)	140007612216	0914	9.30
2	Statstrip Ketones (connectivity)	140007612216		

3.2 Interpretation and performance criteria

On the left hand graph, ALL RESULTS, 161 users returned results for the Nova Statstrip connectivity meters, giving a range of results from 3.0 mmol/L (min) to 10.90 mmol/L (max). The average result was 9.2 mmol/L with a median of 9.20 mmol/L and a coefficient of variation (CV) of 8.6%. Any difference in these values gives an indication of the degree of skewness.
133 produced excellent results (green bars), 14 produced acceptable results (yellow bars) and 2 produced unacceptable results (red bars) which were outside the limits of the histogram graph at -36% and -68% deviation respectively.
The right hand graph, MY RESULT, (your individual site/ward), shows that this site returned a glucose of 9.5 mmol/L. This deviated by 3% from the Median and is denoted by a green bar. The minimum, maximum and coefficient of variation for multiple meters within a POCT site give an indication of the spread of results for that site.

Performance criteria

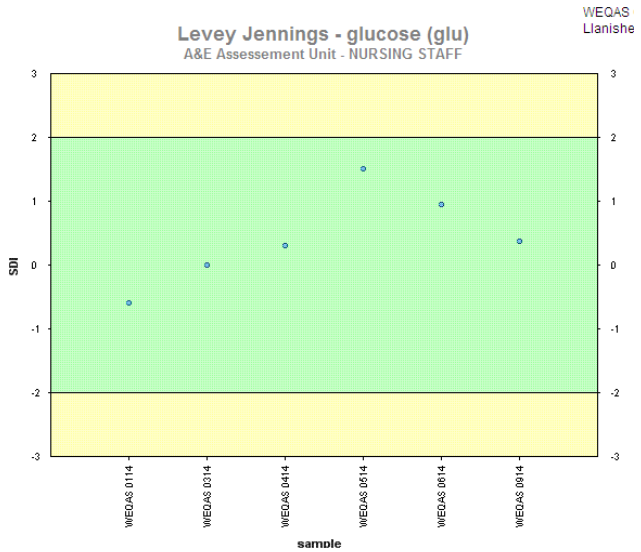
Analyte	Deviation	Interpretation	Colour
Glucose	<10%	Excellent	Green
	10 – 20%	Acceptable (fair)	Yellow
	> 20%	Unacceptable – operator needs to evaluate technique/meter.	Red
Ketones	<10%	Excellent	Green
	10 – 20%	Acceptable (fair)	Yellow
	> 20%	Unacceptable – operator needs to evaluate technique/meter.	Red

The scores are colour coded for ease of identification.

3.3 Cumulative report – e.g. glucose.

A typical Levey Jennings Report for A& E Resus Department over a 9 month period.

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.



Levey Jennings - glucose (glu)

	reference mmol/l	your result mmol/l	bias absolute mmol/l	SD mmol/l	SDI
WEQAS 0114	21.00	20.10	-0.900	1.502	-0.6
WEQAS 0314	6.60	6.60	0.000	0.422	0.0
WEQAS 0414	14.00	14.30	0.300	0.960	0.3
WEQAS 0514	10.50	11.70	1.200	0.798	1.5
WEQAS 0614	7.70	8.50	0.800	0.841	1.0
WEQAS 0914	9.20	9.50	0.300	0.790	0.4

3.4 Method Summary Report

The method summary reports provide a peer group comparative performance analysis from the various manufacturers used in assaying EQA samples for a particular distribution. The information available can assist POCT co-ordinators managing a number of sites not only in comparing the analytical quality and performance, but also in the procurement of new equipment.

The method summary reports are available to download from the dedicated POC website.

Print Date:25/09/2014 POCT Glucose and Ketones Scheme Method Summary Report Dist WEQAS 0914

Analyte	Reporting in	Manufacturer	Instruments	Mean	n	SD	CV	Uncertainty
Glucose	mmol/l	Abbott	FreeStyle Precision Pro (Glucose)	11.2	63	0.690	6.2	0.087
			OPTIUM XCEED (Plus strips)	11.99	17	0.798	6.7	0.194
			OPTIUM XCEED (H Strips)	11.6	63	0.570	4.9	0.072
			OPTIUM XCEED (NEW H Strips& FreeStyle H Strips)	11.67	509	0.631	5.4	0.028
			XCEED (FreeStyle Optium strips)	11.77	90	0.770	6.5	0.081
			XCEED PRO (Xceed pro strips)	11.42	850	0.542	4.7	0.019
		Bayer	CONTOUR	9.59	324	0.673	7	0.037
			CONTOUR (5 secs)	7.99	279	0.337	4.2	0.020
		HemoCue	HemoCue	10.29	29	0.285	2.8	0.053
		Nova	Statstrip Glucose (Connectivity)	9.28	691	0.568	6.1	0.022
			Statstrip XPRESS Glucose	9.47	56	0.711	7.5	0.095
		Roche	Accu-Check Advantage III	9.75	35	0.793	8.1	0.134
			Accu-Check Aviva	9.8	17	0.367	3.7	0.089
			Accu-Check Inform II	10.04	1498	0.292	2.9	0.008
			Accu-Check Performa	10.02	2414	0.370	3.7	0.008
Ketones	mmol/l	Abbott	OPTIUM XCEED/FreeStyle (Ketones)	2.7	151	0.117	4.3	0.010
			XCEED PRO (Ketone Strips)	2.5	106	0.112	4.5	0.011
		Nova	Statstrip Ketones (connectivity)	1.8	96	0.147	8.1	0.015

3.5 Report Availability

Reports are available to print and distribute by the POCT co-ordinator at close of business on the “return by” date. Alternatively, users can download and print their own reports using their username and password.

4. Performance Surveillance

The role of performance surveillance is retained with each individual POCT Co-ordinator. Non compliance and poor performance reports and letters can be generated for each distribution. All group reports can be saved as an Excel file.

4.1 Non –Compliance report - *Distribution 0914*

	contact person	Department / Instrument ID	Location
1	Sarah Hand	ENT	A1 SOUTH/ENT
		83010682654	
2	Janet Scott Samuel	Surgery	A1 ENT OPD (SUITE 9)
		83012404405	
3	Beth Davies	Surgery - Ophthalmology	A1 North
		83011718703	
4	Charlotte Lloyd	Surgery	A2 North
		83011715635	

4.1.1 Non-Compliance Letter - *Distribution 0914*

Group Admin address

Beth Davies
Surgery - Ophthalmology
A1 North

Date: 01-09-2014

WEQAS Glucose/ Ketone POCT Scheme

Distribution: **Dist 0914**
Return date: **08/09/2014**

Meter ID
83011718703

Meter Type
Nova – Statstrip Glucose

Dear Colleague,

No results were received for the above meter / location for the current distribution.
To comply with current guidelines, participants should please ensure that at least 75% of their EQA results are returned.

4.2 Poor performance Report – *Distribution 0914*

instrument	instrument ID	result ID	result	participant contact person	deviation from reference value	
Nova Statstrip Glucose	211008610167	0914	3.00	Staff Clinic R. Griffiths	**-68%**	**unacceptable**
Nova Statstrip Glucose	140025313309	0914	5.9	A&E streaming Nurse in Charge	**-36%**	**unacceptable**

4.2.1 Poor performance Letter – *Distribution 0914*

Group Administrator Address

Sister
A&E Streaming

Date: 02-10-2014

WEQAS Glucose/ Ketone Scheme

Distribution: **Dist 0914**
Return date: **08-09-2014**

Meter ID: 140025313309
Meter Type: Nova Statstrip Glucose

Result: 5.9 mmol/L
Deviation from reference value: -36 %

Dear Colleague,

Your results for the above Distribution are outside the limits of acceptable analytical performance.
Please contact me as soon as possible to discuss these results.

4.3 Referral to National Quality Assurance Advisory Panel.

As programme administrator WEQAS oversee how each Trust performs in relation to each other, however within each Trust, the POCT Co-ordinator oversees individual ward / operator performance. WEQAS maintains and monitors the monthly CV's for each Trust (or Group). The worst performing Trusts are reported to the Panel (outside 95th percentile).

5 Communication and participant feedback

5.1 POCT Helpline

WEQAS Laboratory Manager: Samantha Jones
WEQAS POCT Scheme Manager: Nicky Blount.

POCT enquiries: Telephone 02920 314755
e-mail: weqas.poct@**wales.nhs.uk**

Participants can at any time during the working day (8.30 to 5.00 p.m. Mon to Fri) ring up for advice on their quality assessment. The POCT staff that have experience in, and information relating to many different methods, are there to discuss problems and aid in the interpretation of QA data. This troubleshooting and educational activity is an important part of the Service. A telephone log is kept of each call and all calls are answered as soon as possible.

5.2 Complaints procedure

Participants can contact us through our website, fax, e-mail or by telephone. All complaints are logged and actioned within 24hrs. If a non compliance can not be rectified within this period the participant is informed. The Communication log / non-compliance reports are audited monthly. The results of these audits are documented and brought to the attention of the relevant section head. You can also contact Michele Thomas our Quality Manager directly on 02920 744544.

6 Glossary

The definitions given below are from the document "MDA Purchase Management and Use of IVD Point of Care Test Devices".

POCT is defined as, any pathology test performed for a patient by a healthcare professional outside the traditional centralised laboratory.

Quality Assurance (QA)
Quality assurance is an essential component of POCT and includes all the measures taken to ensure that investigations are reliable. These will include, correct identification of patient, test selection, obtaining a satisfactory specimen, analysing it applying IQC and EQA, recording the results promptly and correctly, interpreting the result accurately, taking appropriate action, and documenting all procedures for reference. Utilising both: **internal quality control and external quality assessment** procedures can help ensure reliable results, but only if they are applied rigorously.

Internal Quality Control (IQC)
This is a means of checking that patient results are reliable before they are issued. The analysis of an appropriate control material (often supplied by the manufacturer of the POCT device) before analysing a set of specimens can provide reassurance that the system is working correctly**.** The user knows the value and limits of acceptance for the IQC material. It is essential that the results of QC are recorded appropriately.

External Quality Assessment (EQA)
EQA involves the analysis of samples with unknown values from an external source. Results are then subject to peer group assessment and statistical analysis to compare results across different sites. EQA schemes may be operated by the manufacturer or by external bodies such as the WEQAS (Wales External Quality Assessment Scheme). The hospital laboratory should be able to recommend appropriate EQA and may be able to act in this capacity itself in relation to POCT in the hospital and primary care settings.

Users of POCT have a duty to participate in an EQA scheme and perform adequately as part of clinical governance.

Clinical governance
The Government's white paper A First Class Service defines clinical governance as 'a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'. (It is about the systems the organisation has for ensuring high quality care.)