WEQAS

Maintaining Quality in Laboratory Medicine

POCT Urinalysis Scheme Guide

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UKAS PROFICIENCY TESTING 4301

UKAS CALIBRATION 4301

Contents

1. Scheme details and repertoire

1.1 Analyte Range and Approximate concentration

Frequency: Bimonthly *Number of samples: 1*

Analyte	Range
Glucose	0 - 60 mmol/l
Ketones	0 - 20 mmol/l
Protein	0 -5 g/l
Haemoglobin	0 - 7500 ug/l
Specific Gravity	1.005 - 1.020
pH	6 - 8
Bilirubin	0 - 50 umol/l
Leucocytes	0 - 500 ul esterase / 1
Nitrites	0 - 40 umol/l
Microalbumin	0 – 1000 mg/l
Albumin/ Creat	<3.4 – >34 mg/mmol

2. Material integrity

The base material is human urine from "normal" volunteers, spiked with the appropriate analytes.

2.1 Stability

Glucose, protein, ketones and leucocytes are stable at room temperature for a week. Bilirubin and Haemoglobin are stable for 3 days if kept in the dark at 4° C. It is therefore advisable to analyse the samples immediately on receipt or store in the refrigerator.

2.2 Instructions for use

The sample should be treated as if it were a patient sample and must be analysed on the day that you receive it. If you are unable to assay the EQA sample on that day, it can be refrigerated but tested WITHIN THREE DAYS of receipt.

N.B. These samples are light sensitive and as such need to be protected from light until assay date.

1. Wear gloves and assay / handle the samples as if they were clinical samples.
2. Gently invert the sample 3 or 4 times to ensure adequate mixing.
3. Carefully remove lid.
4. Dip strip briefly into the sample and remove excess as you would a patient sample.
5. Ensure that the test area is completely covered.
6. Read the strip as per your normal method (visual reading / strip reader).
7. Record results according to your organisational policy.
8. Return results to your Point Of Care Coordinator/lead contact person.
9. 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 participate in the scheme.

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens

3. Reports

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, [**WI-QL2-WebUrinGudPt1 to 3].** Participants (both POCT co-ordinator and POCT user) are given unique username and passwords to enter data and retrieve reports on line.

The spiked values are used to determine the target value, verified whenever possible by quantitative analysis. For endogenous samples the result from quantitative analysis is used. When quantitative data is not available, interpretation is based on the response from the majority of participants.

Results are compared with all meters, and all Trusts.

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 Scoring

The individual results are compared against specific target values and the results converted to scores. The scores broadly reflect clinical importance and are based on the following:

A correct result (correctly identifying that the analyte is either present or absent and in agreement with target concentration range) is given a score of 0.

A sliding scale score of between 1 and 5 is assigned for an incorrectly identified concentration range, where 4 or 5 represented a gross misclassification of the result (negative for a strong positive). A positive for a negative is given a score of 2 to 5 depending on the degree of error. A negative result for a positive sample is given a score of 3 to 5 depending on the concentration of the positive sample.

The sensitivities of the test strips and the interpretation of each colour block is also taken into account in calculating the scoring.

			Target range						
Glucose	**Strip type**	**0**	**1-2**	**2-5**	**5-10**	**10-20**	**20-40**	**>50**	**mmol/l**
	Bayer	neg	no block	no block	5.5 (Trace)	14 (+)	28 (2+)	55-111 (3+ - 4+)	
	Roche	norm	no block	2.8 (Trace)	5.5 (+)	17 (2+)	no block	55 (3+)	
	BHR	norm	1.1 (Trace)	2.8 (+)	8.3 (2+)	no block	27.8 (3+)	55.5 (4+)	
	Menarini	norm	no block	2.8 (Trace)	5.6 (+)	11.1 (2+)	27.8 (3+)	55.5 (4+)	
	Steri-Lab	neg	no block	2.8 (Trace)	5.6 (+)	14 (2+)	28 (3+)	56 (4+)	

3.1 Interpretation

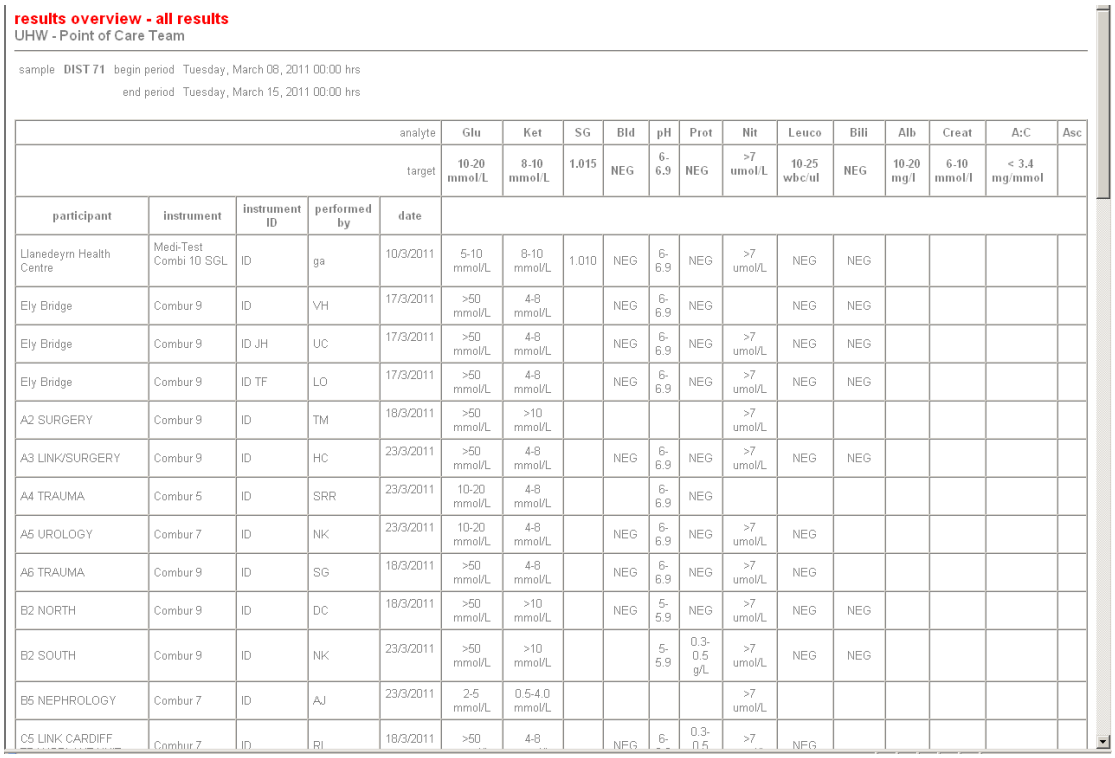
Interpretation		Colour
0-1	Good	Green
2-3	Acceptable	Yellow
>3	Unacceptable – operator needs to evaluate technique/strip.	Red

The scores are colour coded for ease of identification.

3.2Group Reports

Group administrators can select two types of report the results overview or scores.

3.2.1 Results Overview

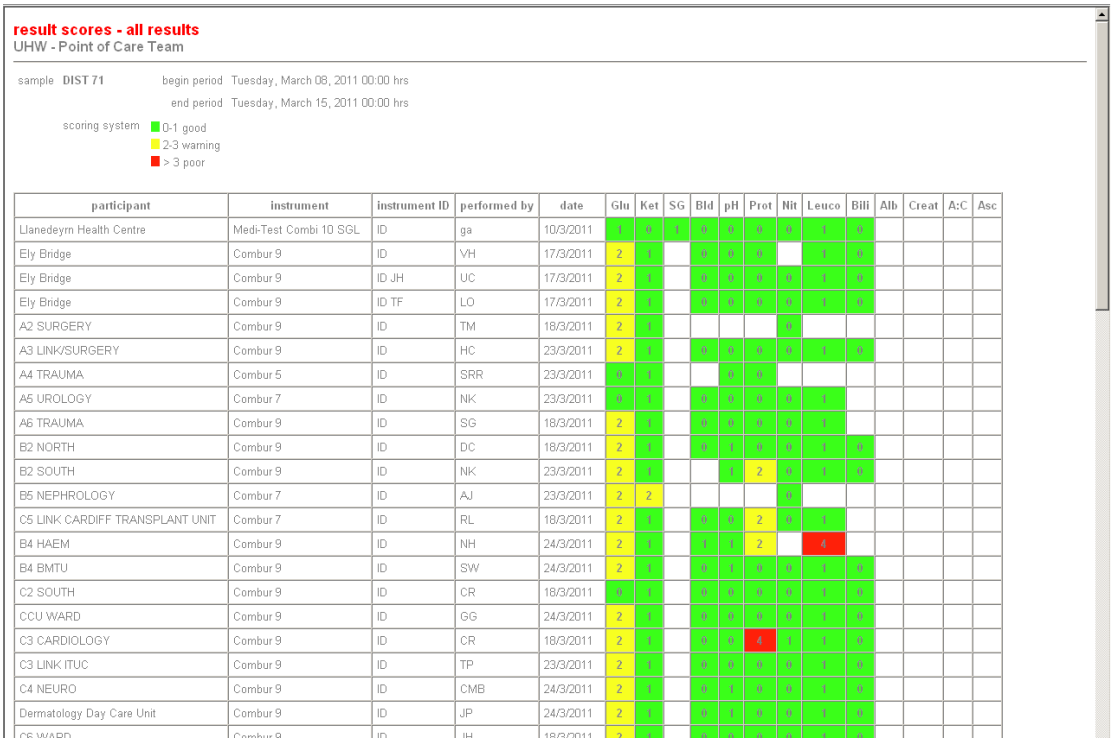


results overview - all results
UHW - Point of Care Team

sample **DIST 71** begin period Tuesday, March 08, 2011 00:00 hrs
end period Tuesday, March 15, 2011 00:00 hrs

					analyte	Glu	Ket	SG	Bld	pH	Prot	Nit	Leuco	Bili	Alb	Creat	A:C	Asc
					target	10-20 mmol/L	8-10 mmol/L	1.015	NEG	6-6.9	NEG	>7 umol/L	10-25 wbc/ul	NEG	10-20 mg/l	6-10 mmol/l	< 3.4 mg/mmol	
participant	instrument	instrument ID	performed by	date														
Llanedeyrn Health Centre	Medi-Test Combi 10 SGL	ID	ga	10/3/2011	5-10 mmol/L	8-10 mmol/L	1.010	NEG	6-6.9	NEG	>7 umol/L	NEG	NEG				
Ely Bridge	Combur 9	ID	VH	17/3/2011	>50 mmol/L	4-8 mmol/L		NEG	6-6.9	NEG		NEG	NEG				
Ely Bridge	Combur 9	ID JH	UC	17/3/2011	>50 mmol/L	4-8 mmol/L		NEG	6-6.9	NEG	>7 umol/L	NEG	NEG				
Ely Bridge	Combur 9	ID TF	LO	17/3/2011	>50 mmol/L	4-8 mmol/L		NEG	6-6.9	NEG	>7 umol/L	NEG	NEG				
A2 SURGERY	Combur 9	ID	TM	18/3/2011	>50 mmol/L	>10 mmol/L					>7 umol/L						
A3 LINK/SURGERY	Combur 9	ID	HC	23/3/2011	>50 mmol/L	4-8 mmol/L		NEG	6-6.9	NEG	>7 umol/L	NEG	NEG				
A4 TRAUMA	Combur 5	ID	SRR	23/3/2011	10-20 mmol/L	4-8 mmol/L			6-6.9	NEG							
A5 UROLOGY	Combur 7	ID	NK	23/3/2011	10-20 mmol/L	4-8 mmol/L		NEG	6-6.9	NEG	>7 umol/L	NEG					
A6 TRAUMA	Combur 9	ID	SG	18/3/2011	>50 mmol/L	4-8 mmol/L		NEG	6-6.9	NEG	>7 umol/L	NEG					
B2 NORTH	Combur 9	ID	DC	18/3/2011	>50 mmol/L	>10 mmol/L		NEG	5-5.9	NEG	>7 umol/L	NEG	NEG				
B2 SOUTH	Combur 9	ID	NK	23/3/2011	>50 mmol/L	>10 mmol/L			5-5.9	0.3-0.5 g/L	>7 umol/L	NEG	NEG				
B5 NEPHROLOGY	Combur 7	ID	AJ	23/3/2011	2-5 mmol/L	0.5-4.0 mmol/L					>7 umol/L						
C5 LINK CARDIFF	Combur 7	ID	RI	18/3/2011	>50	4-8		NEG	6-	0.3-0.5	>7	NEG					

3.2.2 Results Scores



result scores - all results
UHW - Point of Care Team

sample **DIST 71** begin period Tuesday, March 08, 2011 00:00 hrs
end period Tuesday, March 15, 2011 00:00 hrs
scoring system 0-1 good
2-3 warning
> 3 poor

participant	instrument	instrument ID	performed by	date	Glu	Ket	SG	Bld	pH	Prot	Nit	Leuco	Bili	Alb	Creat	A:C	Asc
Llanedeyrn Health Centre	Medi-Test Combi 10 SGL	ID	ga	10/3/2011	1	0	1	0	0	0	0	1	0				
Ely Bridge	Combur 9	ID	VH	17/3/2011	2	1		0	0	0		1	0				
Ely Bridge	Combur 9	ID JH	UC	17/3/2011	2	1		0	0	0	0	1	0				
Ely Bridge	Combur 9	ID TF	LO	17/3/2011	2	1		0	0	0	0	1	0				
A2 SURGERY	Combur 9	ID	TM	18/3/2011	2	1					0						
A3 LINK/SURGERY	Combur 9	ID	HC	23/3/2011	2	1		0	0	0	0	1	0				
A4 TRAUMA	Combur 5	ID	SRR	23/3/2011	0	1			0	0							
A5 UROLOGY	Combur 7	ID	NK	23/3/2011	0	1		0	0	0	0	1					
A6 TRAUMA	Combur 9	ID	SG	18/3/2011	2	1		0	0	0	0	1					
B2 NORTH	Combur 9	ID	DC	18/3/2011	2	1		0	1	0	0	1	0				
B2 SOUTH	Combur 9	ID	NK	23/3/2011	2	1			1	2	0	1	0				
B5 NEPHROLOGY	Combur 7	ID	AJ	23/3/2011	2	2					0						
C5 LINK CARDIFF TRANSPLANT UNIT	Combur 7	ID	RL	18/3/2011	2	1		0	0	2	0	1					
B4 HAEM	Combur 9	ID	NH	24/3/2011	2	1		1	1	2		4					
B4 BMTU	Combur 9	ID	SW	24/3/2011	2	1		0	1	0	0	1	0				
C2 SOUTH	Combur 9	ID	CR	18/3/2011	0	1		0	0	0	0	1	0				
CCU WARD	Combur 9	ID	GG	24/3/2011	2	1		0	0	0	0	1	0				
C3 CARDIOLOGY	Combur 9	ID	CR	18/3/2011	2	1		0	0	4	1	1	0				
C3 LINK ITUC	Combur 9	ID	TP	23/3/2011	2	1		0	0	0	0	1	0				
C4 NEURO	Combur 9	ID	CMB	24/3/2011	2	1		0	1	0	0	1	0				
Dermatology Day Care Unit	Combur 9	ID	JP	24/3/2011	2	1		0	1	0	0	1	0				
C6 WARD	Combur 9	ID	JH	18/3/2011	2	1		0	0	0	0	1	0				

3.3 Standard user report


C3 CARDIOLOGY - LINK NURSE
Sample DIST 71
Your instrument(s) ID - Roche - Combur 9
Groups all groups
scoring system
0 - 1 good
2 - 3 warning
> 3 poor
Glu
Ket
SG
Bld
pH
Prot
Nit
Leuco
Bili
Alb
Creat
A:C
number of results

3.4 Report Availability

Reports are available to print and distribute by the POCT co-ordinator on the "report" date, as set within the POC website. 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 Letter - *Distribution 58*

Quality Laboratory
Cardiff & Vale UHB
Unit 6
Parc Ty Glas
Llanishen
Cardiff
CF14 5DU

A & E Department
St. Elsewhere
High St.

Date: 23-2-2009

WEQAS Urine POCT Scheme

Distribution: **DIST 58**
Return date: 23-03-09
Meter ID 123456
Meter Type Clinitek Status (8SG)

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 Letter – *Distribution 57*

Quality Laboratory
Cardiff & Vale UHB
Unit 6
Parc Ty Glas
Llanishen
Cardiff
CF14 5DU

A & E Department

St. Elsewhere

High St.

Date: 30-12-2008

WEQAS Urinalysis Scheme

Distribution: **Dist 57** Return date: **21-12-2008**

Meter ID: 123456
Meter Type: Clinitek Status (8SG)

Result:

Glu	Ket	SG	Bld	pH	Prot	Nit	Leuco	Bili	Alb	Creat	A:C

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 (NQAAP).

When the individual / site performance is outside the performance criteria on 2 out of 3 consecutive occasions, the individual will be offered help by the WEQAS organisers. Failure to respond to this contact or to improve performance will lead to a further contact by the organisers. Persistent poor performance for that analyte will result in referral to the National Quality Assessment Advisory Panels.

The function of the Panel is to ensure that the quality of diagnostic, analytical services is of suitable quality to meet clinical needs. The WEQAS Scheme organiser submits quarterly reports on participant numbers, new developments and overall Scheme performance including individual group performance to the Panel.

Further information on the role of the Panel is provided on our website.

Referral criteria

When the performance of a site has not improved after two contacts by the organisers.

When the site has failed to submit a minimum of 75% of the distributions per annum.

Arrangements for any proposed changes in standards and notification of poor performers to the panel will be agreed with the WEQAS Steering Committee.

5 Communication and participant feedback

5.1 POCT Helpline

WEQAS Laboratory Manager : Samantha Jones,
WEQAS POCT Scheme Manager : Nicola 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, who 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 Michelle Thomas our Quality Manager directly on 02920 3144544