Produce reports using validated results on common biochemistry investigations - CB-1-C-8

The Clinical Pathology Accreditation (CPA) body have standards that accredited laboratories must follow with regards to all policies and procedures. This includes standards for the preparation and process of reporting patient results. The specific protocols and policies vary between laboratories but all must follow the standards stated by CPA (1). The generation of patient results is also covered by CPA standards and involves ensuring investigations are completed under thorough internal quality control systems on well maintained and calibrated analysers and participate in external quality assessment schemes (1).

The actual generation and communication of pathology results can be through any of the following report mediums:

- Paper copy of report
- Telephoned report
- Faxed report
- Amended report
- Notification to the requester when an investigation is delayed

The fashion in which the report is communicated determines the applicable standards to the conveying of results.

In the instance of a physical report the following CPA standards should be followed at all times (1):

- The report should be comprehensible, unequivocal, and contain adequate information to allow the recipient to interpret the results.
- The report should be created in a fashion that is consistent with the needs of recipients and within conditions stipulated by local medical records systems.
- The report must contain the following items:
    - Laboratory name
    - Patient identifiers i.e. hospital number or NHS number.
    - Requesting clinician and source of request
    - Specimen type, date and time of collection
    - Time and date of report
    - Results (and any reason(s) for non-completion of any investigation(s))
    - Reference ranges - as appropriate
    - Interpretive comments - as appropriate
    - Highlighting abnormal results
    - Report status - as appropriate, e.g. copy, interim, amended or supplementary.
    - As applicable - identification of person(s) authorising report.
- Reports/letters issued based on results from referral laboratories should also include:
    - Identification of the referral laboratory
    - All the results
    - Interpretive comments from the referral laboratory
- An appropriate mechanism for the handling and communication of confidential patient results.
- Reports may be written or electronic.

In the instance of telephoned reports the following CPA standards should be used (1):

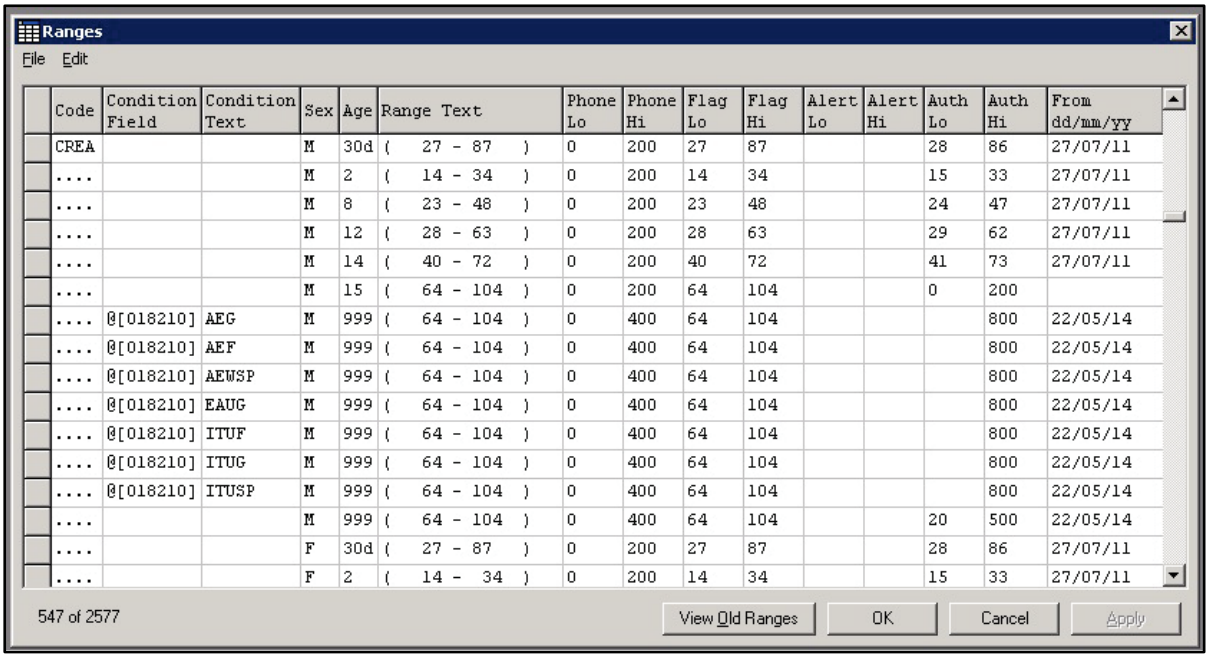
- An appropriate standard operating procedure (SOP) for communication of confidential patient results.

- Adequate training for individuals who may give reports
- Assurance of the suitability of individuals receiving reports
- Mutual identification of the patient between reporter and receiver
- Confirmation of correct transmission
- Mechanism for recording the event
- Adherence to patient confidentiality
- Process for sending a follow up report.

The CPA standards state that interpretative comments added to reports should be concise, clear and unambiguous. This should only be performed by state registered personnel or trainees with very close supervision (1). The Association of Clinical Biochemistry (ACB) has given a set of guidelines for best practice when adding interpretative comments to reports (2). Key amongst these guidelines are:

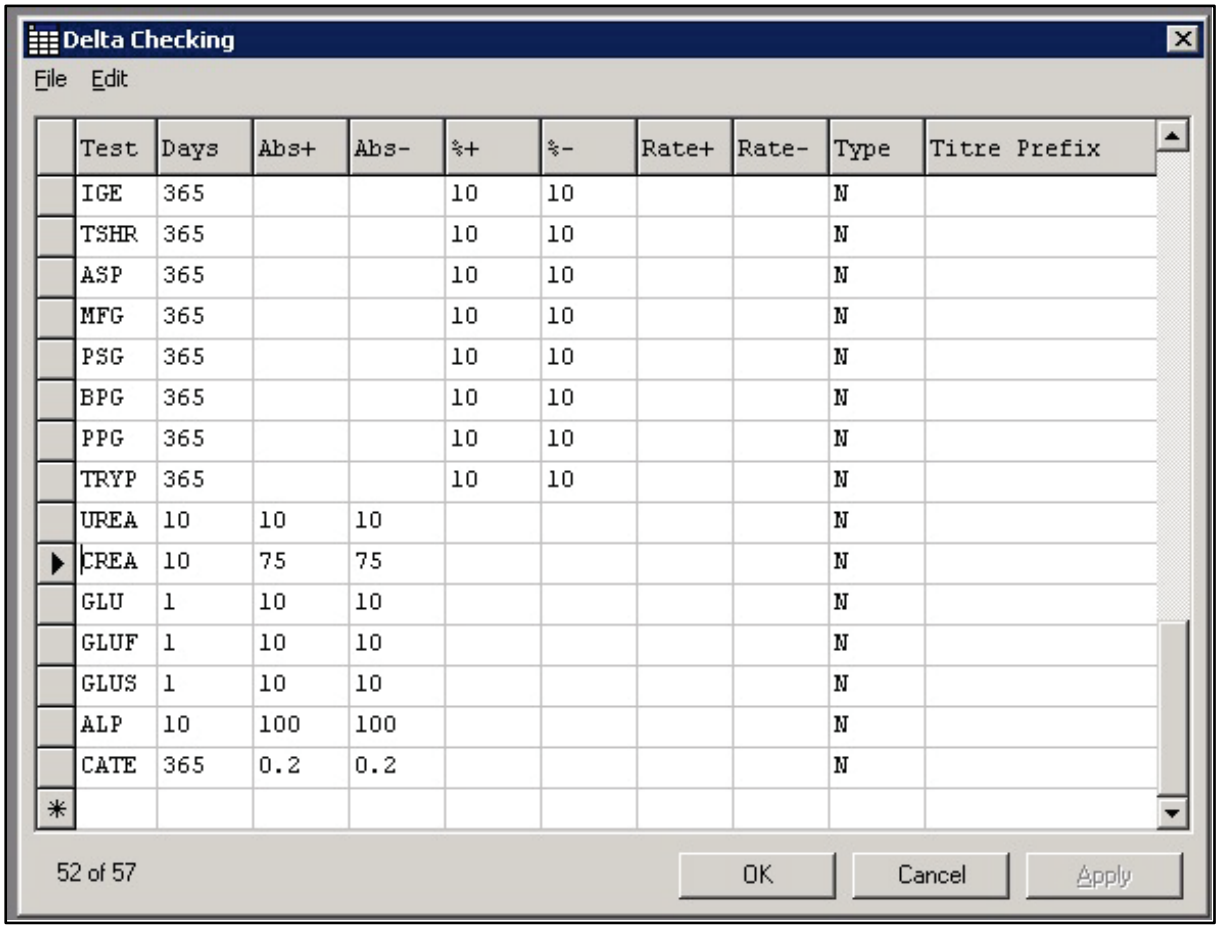
- Agreement between laboratories and service users on the tests that require interpretive comments and the criteria for adding them. This should be reviewed regularly.
- Persons adding interpretative comments should be sufficiently competent, adequately trained and peer-reviewed.
- Comments should be clear, succinct and unambiguous. Only added when there is clinical value.
- Language used in comments should be easily understandable and mindful of the potential of patients reading reports.
- Standardised comments must be agreed locally and/or internationally where appropriate and reviewed on a regular basis.
- In the instance of insufficient clinical details the requesting clinician should be contacted and patient clinical information clarified. If this is not practical/possible then interpretation should not be given and this reason stated clearly.
- Requesting of additional tests to help diagnoses and interpretation should only be done where this is within the remit of the original request and does not require further patient consent. If in doubt the requesting clinician and patient should be contacted to obtain consent. At RSCH once a patient's sample has been analysed and the results technically validated a small proportion of results that fail against authorisation limits (fig. 1), of which some are further subdivided by age, sex and clinical location are sent to an authorisation queue in the WinPath system. Results that fail delta check limits (fig. 2) will also be sent to the authorisation queues along with any text results and certain tests e.g. glucose tolerance tests (GTT). These authorisation queues are dealt with by the duty biochemist/duty doctor who are persons registered with the Healthcare Professions Council (HCPC), General Medical Council (GMC) or trainees with close supervision and have in-depth clinical knowledge relevant to interpreting results. The SOP for clinical authorisation can be found: BIO-SPS-SOP-002, standardised interpretive comments can be found: BIO-SPS-SOP-002 Appendix 1.

The results generated through laboratory investigations are reported to users in a regulated and confidential fashion. Those persons who are in a position to report laboratory results must have undertaken Information Governance training and clearly understand the need for confidentiality. Furthermore those telephoning results must have received appropriate training and read the SOP: Gen-SPS-SOP-24. The interpretation of results can only be given by HCPC/GMC registered, Clinical Scientists and Consultants.



Code	Condition Field	Condition Text	Sex	Age	Range Text	Phone Lo	Phone Hi	Flag Lo	Flag Hi	Alert Lo	Alert Hi	Auth Lo	Auth Hi	From dd/mm/yy
CREA			M	30d	(27 - 87)	0	200	27	87			28	86	27/07/11
....			M	2	(14 - 34)	0	200	14	34			15	33	27/07/11
....			M	8	(23 - 48)	0	200	23	48			24	47	27/07/11
....			M	12	(28 - 63)	0	200	28	63			29	62	27/07/11
....			M	14	(40 - 72)	0	200	40	72			41	73	27/07/11
....			M	15	(64 - 104)	0	200	64	104			0	200	
....	@[018210]	AEG	M	999	(64 - 104)	0	400	64	104				800	22/05/14
....	@[018210]	AEF	M	999	(64 - 104)	0	400	64	104				800	22/05/14
....	@[018210]	AEWSP	M	999	(64 - 104)	0	400	64	104				800	22/05/14
....	@[018210]	EAUG	M	999	(64 - 104)	0	400	64	104				800	22/05/14
....	@[018210]	ITUF	M	999	(64 - 104)	0	400	64	104				800	22/05/14
....	@[018210]	ITUG	M	999	(64 - 104)	0	400	64	104				800	22/05/14
....	@[018210]	ITUSP	M	999	(64 - 104)	0	400	64	104				800	22/05/14
....			M	999	(64 - 104)	0	400	64	104			20	500	22/05/14
....			F	30d	(27 - 87)	0	200	27	87			28	86	27/07/11
....			F	2	(14 - 34)	0	200	14	34			15	33	27/07/11

Figure 1 WinPath authorisation limits for creatinine subdivided by age, sex and clinical location



Test	Days	Abs+	Abs-	%+	%-	Rate+	Rate-	Type	Titre Prefix
IGE	365			10	10			N	
TSHR	365			10	10			N	
ASP	365			10	10			N	
MFG	365			10	10			N	
PSG	365			10	10			N	
BPG	365			10	10			N	
PPG	365			10	10			N	
TRYP	365			10	10			N	
UREA	10	10	10					N	
CREA	10	75	75					N	
GLU	1	10	10					N	
GLUF	1	10	10					N	
GLUS	1	10	10					N	
ALP	10	100	100					N	
CATE	365	0.2	0.2					N	

Figure 2 WinPath authorisation delta limits for creatinine

When conveying results via telephone the following procedure should be followed:

- Staff must only give results to senior medical personnel or GP or nominated junior medical staff.
- Before giving any results the requester must give the patient's forename, surname, date of birth and Hospital/NHS number, details of requested tests and, if known, the date of sampling. Only if this exactly matches the details on WinPath can staff proceed to convey results.
- The giving of results must be recorded on WinPath in the telephone enquiry section along with the staff giving the results, the requesting clinician/source name and medical position and the date/time. Results should never be given to patients/patient representatives or other members of the public.
- Only authorised results should be given, in the event the requestor wants unauthorised results refer them to the Duty Clinical Scientist or Consultant staff.
- If at any point there is doubt about the person who is calling for results then request a department and telephone number in order to call them back or request a more senior clinician in order to give the results.

When conveying results via fax the following procedure should be followed:

- Faxing reports is not ideal and should follow the data protection principle 7 and Caldecott principle 4. Four patient identifiers should always be used.
- Faxes should only be sent to pre-programmed (speed dial) locations, which are checked for data security.
- All faxes should contain the SDRF 1 - SPS Fax Cover Sheet, which contains information about the sender, instructions about page numbers and a statement that there is confidential information.
- A record should be made on WinPath to show that the results have been faxed and where/who they have been faxed to.

Those results that require telephoning due to their urgency in clinical situations have been defined by the Royal College of Pathologists (RCP) (3), as seen below (fig. 3). However, there should be agreement between laboratories and service users on appropriate phone limits provided they are within those stated by the RCP. At RSCH these can be seen in the SOP: BIO-SPS-SOP-005 Appendix 1.

Example Report

Using creatinine measurements as an example, a report can be seen below (fig. 4) for an imaginary patient with a creatinine of 230µmol/L, which is above the normal reference interval. However, this value is not actionable in terms of an interpretative comment or phoning limits.

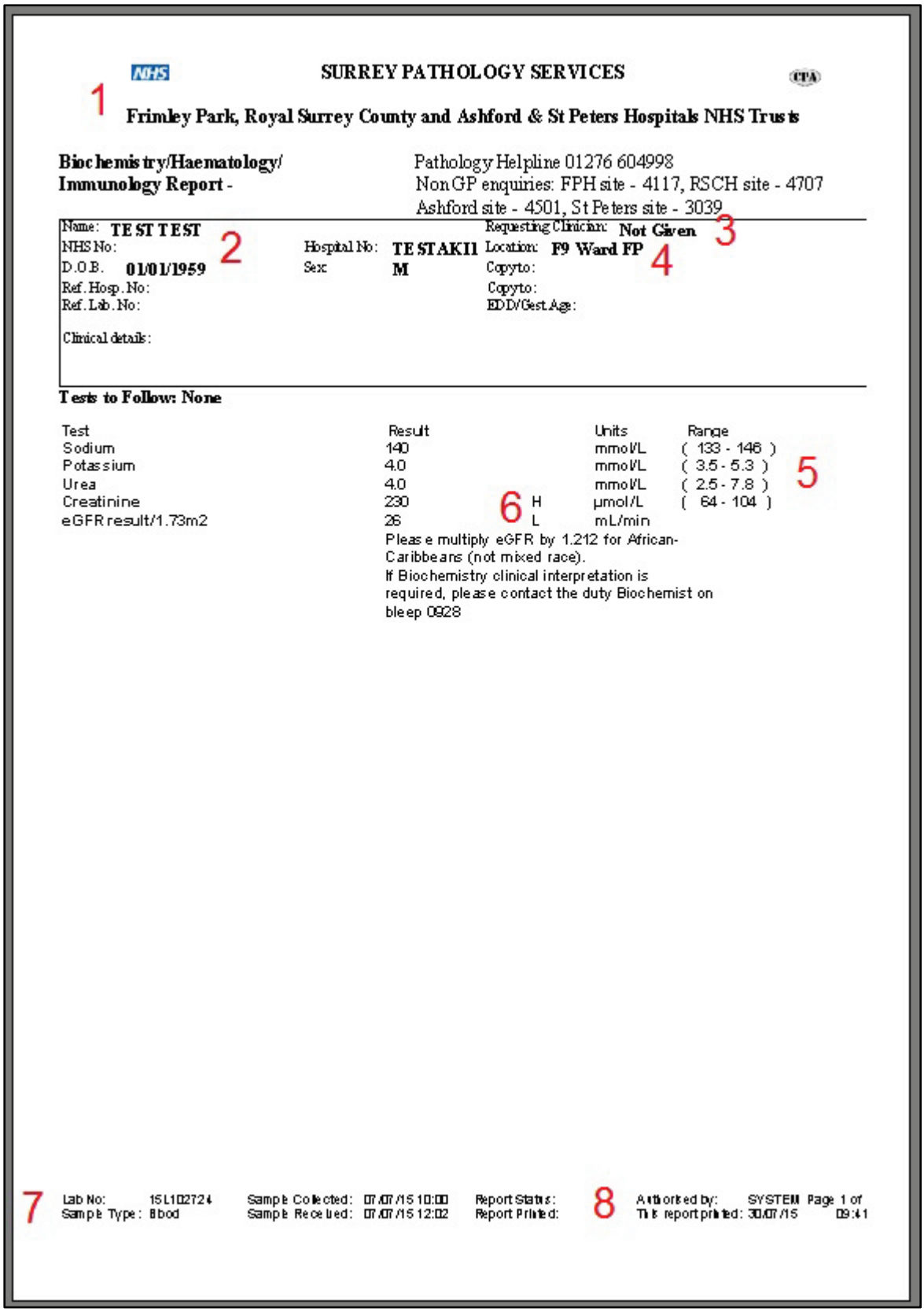
This patient was then seen a week later and a creatinine of 600µmol/L was observed (fig. 5). This value places this patient within the AKI stage 3 criteria (table .1). As such, NICE guidelines for AKI treatment/referral (4) should be adhered to and this result phoned to the requesting clinician as per RCP (fig. 3) and local phone limits.

Analyte (serum/plasma)		Action limits	
		Below	Above
Sodium	mmol/L	120	150
Potassium	mmol/L	2.5	6.5
Urea	mmol/L		30 (>10 if <16yr)
Creatinine	µmol/L		400 (>200 if < 16yr)
Glucose	mmol/L	2.5	25
Calcium adj	mmol/L	1.8	3.5
Magnesium	mmol/L	0.4	
Phosphate	mmol/L	0.3	
AST	U/L		15 x upper limit of normal (ULN)
ALT	U/L		15 x ULN
Total CK	U/L		>5000 unless ? MI
Amylase	U/L		5 x ULN
Carbamazepine	mg/L		25
Digoxin	µg/L		2.5
Theophylline	mg/L		25
Phenytoin	mg/L		25
Phenobarbitone	mg/L		70
Lithium	mmol/L		1.5
Triglyceride	mmol/L		>20
CRP	mg/L		>300
Troponin (I or T)			>local cut-off for MI

Figure 3 Out of hours critical phoning limits as outlined by the RCP. Taken from (3).

Stage	Serum creatinine (SCr) criteria	Urine output criteria
1	increase ≥ 26µmol/L within 48hrs or increase ≥1.5 to 1.9 X reference SCr	<0.5 mL/kg/hr for > 6 consecutive hrs
2	increase ≥ 2 to 2.9 X reference SCr	<0.5 mL/kg/ hr for > 12hrs
3	increase ≥3 X reference SCr or increase ≥354µmol/L or commenced on renal replacement therapy (RRT) irrespective of stage	<0.3mL/kg/hr for > 24hrs or anuria for 12hrs

Table 1 NICE criteria for acute kidney injury (AKI) staging. Taken from (4).



SURREY PATHOLOGY SERVICES

1 Frimley Park, Royal Surrey County and Ashford & St Peters Hospitals NHS Trusts

Biochemistry/Haematology/ Immunology Report -

Pathology Helpline 01276 604998
Non GP enquiries: FPH site - 4117, RSCH site - 4707
Ashford site - 4501, St Peters site - 3039

Name: **TEST TEST** 2
NHS No:
D.O.B. **01/01/1959**
Ref. Hosp. No:
Ref. Lab. No:
Clinical details:

Hospital No: **TESTAKI1**
Sex: **M**

Requesting Clinician: **Not Given** 3
Location: **F9 Ward FP** 4
Copy to:
Copy to:
EDD/Gest Age:

Tests to Follow: None

Test	Result		Units	Range
Sodium	140		mmol/L	(133 - 146)
Potassium	4.0		mmol/L	(3.5 - 5.3)
Urea	4.0		mmol/L	(2.5 - 7.8)
Creatinine	230	H	µmol/L	(64 - 104)
eGFR result/1.73m2	26	L	mL/min	

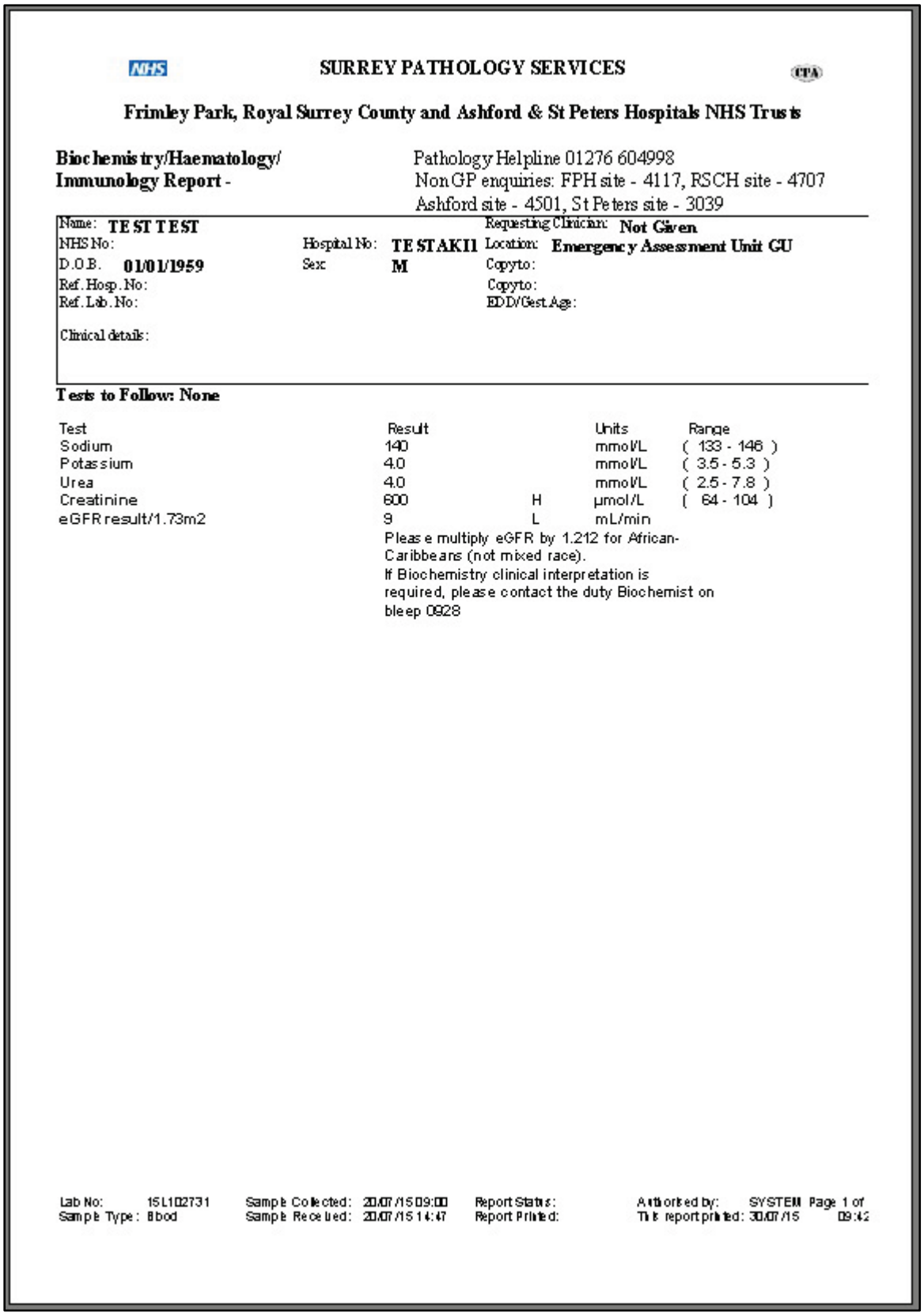
5 6

Please multiply eGFR by 1.212 for African-Caribbeans (not mixed race).
If Biochemistry clinical interpretation is required, please contact the duty Biochemist on bleep 0928

7 Lab No: 15L102724 Sample Collected: 07/07/15 10:00 Report Status:
Sample Type: Blood Sample Received: 07/07/15 12:02 Report Printed:

8 Authorised by: SYSTEM Page 1 of
This report printed: 30/07/15 09:41

Figure 4 Example report for an imaginary patient with an elevated creatinine value. Numbered annotations follow CPA guidelines for inclusive information on reports as follows: 1 - laboratory name, 2 – patient identifiers, 3 – requesting clinician, 4 - source of request, 5 – reference ranges, 6 – highlighting of abnormal results, 7 – laboratory number, sample type, collection time and received time and 8 – person authorising report and date/time of printing.



NHS

SURREY PATHOLOGY SERVICES

CPA

Frimley Park, Royal Surrey County and Ashford & St Peters Hospitals NHS Trusts

Biochemistry/Haematology/ Immunology Report -

Pathology Helpline 01276 604998
Non GP enquiries: FPH site - 4117, RSCH site - 4707
Ashford site - 4501, St Peters site - 3039

Name: **TEST TEST**
NHS No:
D.O.B. **01/01/1959**
Ref. Hosp. No:
Ref. Lab. No:
Clinical details:

Hospital No: **TESTAKI1**
Sex: **M**

Requesting Clinician: **Not Given**
Location: **Emergency Assessment Unit GU**
Copy to:
Copy to:
EDD/Gest Age:

Tests to Follow: None

Test	Result		Units	Range
Sodium	140		mmol/L	(133 - 146)
Potassium	4.0		mmol/L	(3.5 - 5.3)
Urea	4.0		mmol/L	(2.5 - 7.8)
Creatinine	600	H	µmol/L	(64 - 104)
eGFR result/1.73m2	9	L	mL/min	

Please multiply eGFR by 1.212 for African-Caribbeans (not mixed race).
If Biochemistry clinical interpretation is required, please contact the duty Biochemist on bleep 0928

Lab No: 15L102731
Sample Type: Blood
Sample Collected: 20/07/15 09:00
Sample Received: 20/07/15 14:47
Report Status:
Report Printed:
Authorised by: SYSTEM
This report printed: 30/07/15 09:42
Page 1 of

Figure 1 Example report for an imaginary patient with an actionable creatinine value, which is indicative of AKI compared to the previous value based on NICE criteria (4).

References

1. CPA. (2010). *Standards for the Medical Laboratory.* Available: http://www.ukas.com/Library/Services/CPA/Publications-CPA-accreditation/Standards%20for%20the%20Medical%20Laboratory.pdf Last accessed 29/01/15.
2. ACB. (2014). *Best Practice when providing interpretative comments on laboratory medicine reports*. Available: http://www.acb.org.uk/docs/default-source/committees/scientific/guidelines/acb/best-practice-when-providing-interpretative-comments-for-laboratory-medicine---final.pdf?sfvrsn=2 Last accessed 29/01/15
3. Freedman, D. (2010). *Out-of-hours reporting of laboratory results requiring urgent clinical action to primary care: Advice to pathologists and those that work in laboratory medicine*. Available: http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/G/g025_outofhoursreporting_nov10.pdf Last accessed 29/01/15
4. Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. London: National Institute for Health and Care Excellence 2013.