

MAINTENANCE OF QUALITY IN THE LABORATORY

Dr Tom Hartley

Quality Manager : Royal Hobart
Hospital

Senior Research Fellow :
University of Tasmania
AUSTRALIA

Sponsor : Nancy Dale Scholarship, AACB

Objectives of Pathology Laboratory Quality Systems

- Results with Known Accuracy and Precision*
- On the Right Patient*
- Are Delivered to the Right Doctor*
- On Time*
- And you have Complete Audit Trail of every critical step of that Patient Pathology Request Episode through your Department should any queries arise from any quarter in the future.*

Alison Penny or Penny Alison ?

ROYAL HOBART HOSPITAL (A.P.A.)
48 LIVERPOOL STREET, HOBART 7000

PATHOLOGY REQUEST

Instrument No. A/3545
Phone (03) 6222 8416
Fax (03) 6222 8996

Lab. No. and Codes:	Ward:	U.R. Number	1 2 3 4 5 6
Date/Time Specimen Taken:	Specialist/Unit:	Surname: PENNY	Sex
Sample Type:	Collected By:	Other Names: ALISON	D.O.B: 12/10/53
Tests Requested Request details must be in doctor's own handwriting		Address:	Rel
Clinical Notes (Extra space on back of ...)		Date:	
Drug Assay Information: Drug:		Was or will the patient be, at the time of the service or when the specimen was obtained:	Y N
Time of last dose:		(a) a private patient in a private hospital, or approved day hospital facility,	
Pre-dose sample time:		(b) a private patient in a recognised hospital,	
Post-dose sample time:		(c) a Medicare (public) patient in a recognised hospital,	
To: Drs J. Burgess, D. Challis, L. Cooley, S. Donovan, P. Jessup, R. Kimber, J. McArdle, A. McGregor, K. Marsden, U. Ray, H. Rees		(d) an outpatient in a recognised hospital.	
		Medicare No:	
		or DVA No:	

SAH MFS 19335 11/06 F&P 66818 NOV06 M1

Practice Tip #1 : Use Positive Identification Procedures Everywhere

- In the Hospital or Doctor's Surgery use **three** points of ID when about to collect a specimen :
 - Surname
 - Given Name
 - Date of Birth and/or Hospital ID Number

Components of a TOTAL QUALITY SYSTEM

PREANALYTICAL

ANALYTICAL

POST ANALYTICAL

Components of a TOTAL QUALITY SYSTEM : PREANALYTICAL

- Draw A Process Map
- Assess the risks in Processes
- Institute Check Points at Critical Times that “Fail Safe”
- Record Time and Person ID as specimens move from one stage to the next – this gives you an Audit Trail.
- Document the Procedures in Unambiguous Language and Style
- Don't Rewrite Package Inserts or Instrument Manuals

Components of a TOTAL QUALITY SYSTEM : ANALYTICAL

- Use Statistical Quality Control within all Quantitative Procedures
- Use Quality Control Materials that are Independent of the Instrument Manufacturer
- Participate in External Quality Assurance Programmes
- Keep meticulous records of QC data, your assessments of those data, and all corrective actions made as a result of those assessments

Components of a TOTAL QUALITY SYSTEM : POST ANALYTICAL

- Set Up an Incident Reporting System
- Set up some Key Performance Indicators
- Audit and then Change
- Audit and then Change
- Audit and then Change
- Keep **all levels** Laboratory Staff Informed of the quality of the Service they are delivering

Components of a TOTAL QUALITY SYSTEM : PREANALYTICAL

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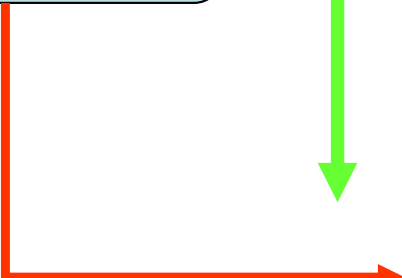
Components of a TOTAL QUALITY SYSTEM

PREANALYTICAL

PROCESS MAPPING

STEP ONE

Operator 1 Checks Details on Receipt



STEP TWO

Operator 2 DOES NOT Check Details on Receipt



STEP THREE

WHAT ARE THE RISKS ??

Operator 1 : Alison Penny or Penny Alison ?

ROYAL HOBART HOSPITAL (A.P.A.)
48 LIVERPOOL STREET, HOBART 7000

PATHOLOGY REQUEST

Instrument No. A/3545
Phone (03) 6222 8416
Fax (03) 6222 8999

Lab. No. and Codes: _____ Ward: _____ U.R. Number: **1 2 3 4 5 6**

Date/Time Specimen Taken: _____ Specialist/Unit: _____ Surname: **PENNY** Sex: _____
Other Names: **ALISON** D.O.B.: **12/10/53** Marital Status: _____

Sample Type: _____ Collected By: _____ Address: _____ Rel: _____

Tests Requested
Request details must be in doctor's own handwriting

Date: _____

CLINICAL NOTES (Extra space on back of form)

PENNY ALISON
UR 123456

Was or will the patient be, at the time of the service or when the specimen was obtained:

	Y	N
(a) a private patient in a private hospital, or approved day hospital facility,		
(b) a private patient in a recognised hospital,		
(c) a Medicare (public) patient in a recognised hospital,		
(d) an outpatient in a recognised hospital.		

Medicare No: _____
or DVA No: _____

To: Drs J. Burgess, D. Challis, L. Cooley, S. Donovan, P. Jessup, R. Kimber, J. McArdle, A. McGregor, K. Marsden, U. Ray, H. Rees

SPH MRS 19335 11/06 F&P 66818 NOV06 M1

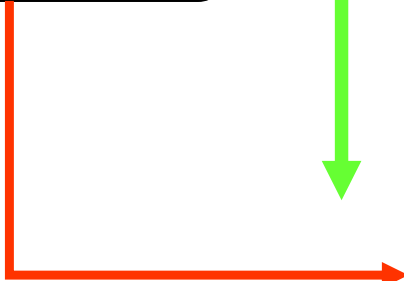
Operator 2 : Is that the Right Aliquot in My Tube ?



**USE THESE
'CHANGEOVER'
OPPORTUNITIES TO
DOCUMENT AN
AUDIT TRAIL
.....How ?**

STEP ONE

Operator 1 Checks Details on Receipt



STEP TWO

**Operator 2
Check Data
Receipt**



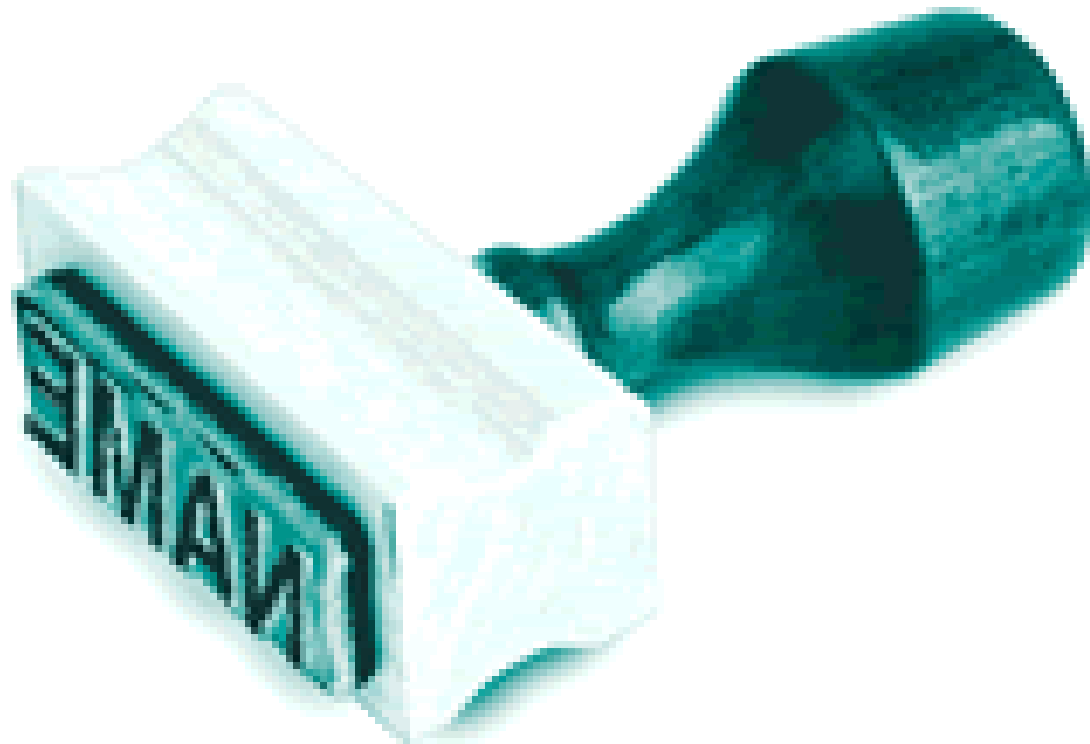
STEP THREE

Practice Tip #2 : Use a Time Date Stamp

SEIKO



Practice Tip #3 : Use Name Stamps





ANTREPATH

APA ROYAL HOBART HOSPITAL
43 LIVERPOOL STREET

Instrument No. A/3399

PATHOLOGY REQUEST

WARD/UNIT: Gastro 23
 JO: [Redacted] MI: [Redacted] 2
 RI: [Redacted] 16
 Ph: [Redacted] 3

TIME/DATE OF COLLECTION: 1120
17/10

07 / P / 154404

01-12-1967

Collected by: Andrew Foc...
 SAMPLE TYPE: [Redacted]

TESTS REQUESTED:
FBS, UEC, LETS, Cholesterol
Ca, ap, LDH, DAT, urea
heptaglobulin, iron studies
ferritin, B12, folate

TRT
~~CD~~

Was or will the patient be, at the time of the service or when the specimen was obtained:

	Y	N
(a) a private patient in a private hospital, or approved day hospital facility,		
(b) a private patient in a recognised hospital,		
(c) a Medicare (public) patient in a recognised hospital,		
(d) an outpatient in a recognised hospital.		

CLINICAL NOTES INCLUDING DRUG THERAPY:
Haemolysis
Recurrent iron deficiency

SELF DETERMINED

Medicare No. 6097 25482 11:40
 or DVA No. X2
X1W

Copies Required/Reports to be sent to: X 10

REQUESTING DOCTOR'S SIGNATURE: [Signature]

DATE: 12/17/67
 SURNAME: NZ INITIALS: KC
 ADDRESS:
 PROVIDER No.:

DR. D. POTTER

URGENT
 PHONE No:
 FAX No:
 HOSPITAL

RESULT ENQUIRIES (03) 6214-3058 or (03) 6222 7121
 HELPLINE (03) 6222 7935

Practitioner's Use Only

EDTA	WHITE	FAECES
COAG	GREY	SWAB
ESR	GREEN	OTHER
SST	2	URINE

Patient's Signature and Date: [Signature]
 Medicare Assignment (Section 20A of the Health Insurance Act 1973).
 By this declaration I offer to assign my right to benefits to the approved pathology practitioner who will render the requested pathology services.

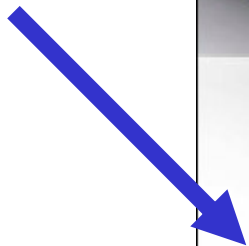
Privacy Note: The information provided will be used to assess any Medicare benefit payable for the services rendered and to facilitate the proper administration of government health programs, and may be used to update enrollment records. Its collection is authorised by provisions of the Health Insurance Act 1973. The information may be disclosed to the Department of Health and Ageing or to a person in the medical practice associated with this claim, or as authorised/required by law.

Practice Tip #4 : Use A Feed Through Style Scanner and Its 'Free' Image Database Software

Kodak Document Imaging Products



RHH



Kodak
i30 and i40 Scanners



Practice Tip #5 : Use Your Computer System to Log User and Time Data

Registered By

When

Logged in User

◆ PLS32 - tfh

Search for :229598

DOB: 17/08/1943
 Hy: 7010
 Hosp/Urno: RHH/229598
 6/5 Notes : Emerg Blood Merged

BB Group: 13/06/2000 00:52

Req# : 07/P/160416	Ext# :	Site: Main	Coll : 29/10/2007:10:55
Ward : RHH	GS-S	Collect : RHH	Alert : :
Doc : TuA1	Unit : SurgC		
Copy :			
Cond : I	Gest Wks : :	Ph# :	

Clinical Notes : Not Provided

TESTS ORDERED

FBC	6	CRProt	Cl	Urea	Bio
SPEC	Pink	1	SST	1	
REGU					

BILL

Category	M	Date	Amount
Notes			Int# : 207433
			KHOPE 29/10/2007 12:07

Delete Modify Price Results History Lookup !Samples Benchmark Quit

DOCUMENTATION & Document Control

- Document the Procedures in Unambiguous Language and Style – make sure they match the Process Map
- Don't Rewrite Package Inserts or Instrument Manuals
- Use a Unique Number on every document

Too Brief versus Explicit

- Pipette 250 μL of standards, QCs and samples into the test tubes.
- Add 50 μL of the first colour reagent to each tube
- Set up and label 5 test tubes for the blank and standards : 0, 10, 20, 30, 100 $\mu\text{mol/L}$
- Set up sufficient test tubes for the specimens and label each with its corresponding Lab. Number.
- Pipette 250 μL of distilled water into the 0 tube
- Pipette 250 μL of the 10, 20, 30 , 100 IU $\mu\text{mol/ L}$ standard into its correspondingly labelled tubes
- Pipette 250 μL of each of the specimens into its correspondingly labelled test tube
- Pipette 50 μL of colour reagent 'A' to all tubes.

Practice Tip #6 : Download the Methods from the Manufacturer's Website as Adobe pdf Files.

The Use a PDF editor to add your own Document Control Information.

The screenshot displays the CAD-KAS PDF Editor 2.3 application window. The interface includes a menu bar (File, Edit, View, Menu style, Language, Help), a toolbar with various editing tools (Pointer, Zoom, Hand, Annotations/Forms, Text, Text block, Pictures, Graphics), and a status bar showing page information (Page 1 of 0, Rotation: 0 degrees, Zoom: 100). A toolbar below the status bar contains icons for 'Open PDF file', 'Edit', 'Pages', 'Bookmarks', and 'Save PDF file'. An orange banner at the top of the workspace reads: 'Open PDF file - select the PDF file and double click on it'. On the left, a 'Favorite folders' list includes 'V:\original_files' and 'D:_Toms\TQI'. Below this is a file explorer showing a tree view of folders and files. An 'Info.' dialog box is open in the center, displaying the CAD-KAS logo, the application name 'CAD-KAS PDF Editor', and version 'Version 2.3.0.0'. The dialog also contains copyright information: 'Copyright (c) 2002-2004 by Christian A.D. Kassler. This is a CAD-KAS computersoftware production (info@cadkas.de)'. The release date is listed as 'Release (mm/dd/yyyy) : 11/24/2004'. An 'OK' button with a green checkmark is at the bottom of the dialog. In the background, a file list is visible with columns for file name, size, type, and modified date.

File Name	Size	Type	Modified
4264_CA_1500__Da...	534 KB	Adobe Acrobat 7.0 Doc...	13/11/2007 2:
4265_STAGO__STA...	983 KB	Adobe Acrobat 7.0 Doc...	13/11/2007 2:
4266_STAGO__LIAT...	1,013 KB	Adobe Acrobat 7.0 Doc...	13/11/2007 2:
6991_TEL_AML1_ES...	528 KB	Adobe Acrobat 7.0 Doc...	30/01/2007 1:
6994_Package_Insert...	416 KB	Adobe Acrobat 7.0 Doc...	30/01/2007 2:
6995_Package_Insert...	377 KB	Adobe Acrobat 7.0 Doc...	30/01/2007 2:



ALKALINE PHOSPHATASE
List No. 7D55-20 and 7D55-30
30-3086/R3

AEROSET®

c8000™

ALKALINE PHOSPHATASE

Document ID No. 4111
Issued: 13.11.2006

This package insert contains information to run the Alkaline Phosphatase assay on the AEROSET System and the ARCHITECT® c8000 System.

NOTE: Changes to AEROSET System Information Highlighted
(Supplemental and format changes are not highlighted)

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Practice Tip #7 : Use a Word Template for All Your Other Methods

TITLE OF LABORATORY PROCEDURE

1. **PURPOSE AND/OR SCOPE** : Brief description the clinical context in which the investigation is required and to whom it should be applied.

Example : This test must be performed on serum samples from antenatal clinic patients who are in their second trimester of pregnancy.

2. **DETAILS THAT MUST BE RECORDED BY CPU ON SPECIMEN RECEIPT** eg time of collection, time and date of last dose etc.
3. **PATIENT PREPARATION** eg. Fasting, 1 hour post dose etc.
4. **SPECIMEN REQUIREMENTS** eg 1 SST Gel tube and 1 Blue top
5. **SPECIMEN REJECTION CRITERIA** eg haemolysed, not kept refrigerated, tube not filled to the line etc.
6. **PRINCIPLE OF THE ANALYTICAL METHOD** eg. colorimetric end point
7. **REAGENTS, STANDARDS, CALIBRATORS AND QUALITY CONTROL MATERIALS**

7. REAGENTS, STANDARDS, CALIBRATORS AND QUALITY CONTROL MATERIALS
8. EQUIPMENT REQUIRED eg. CellDyn 4000
9. CALIBRATION PROCEDURE
10. SPECIMEN PREPARATION AND PROCESSING
11. STEPWISE DESCRIPTION OF THE PROCEDURE
12. ASSESSMENT OF QUALITY CONTROL RESULTS
13. CRITERIA FOR THE ASSESSMENT OF PATIENT RESULTS
 - NORMAL
 - ABNORMAL
 - ABNORMAL NOTIFY MEDICO
14. REPORTING THE RESULTS
15. TROUBLE SHOOTING
16. REFERENCES TO RELEVANT TEXBOOKS AND JOURNAL ARTICLES

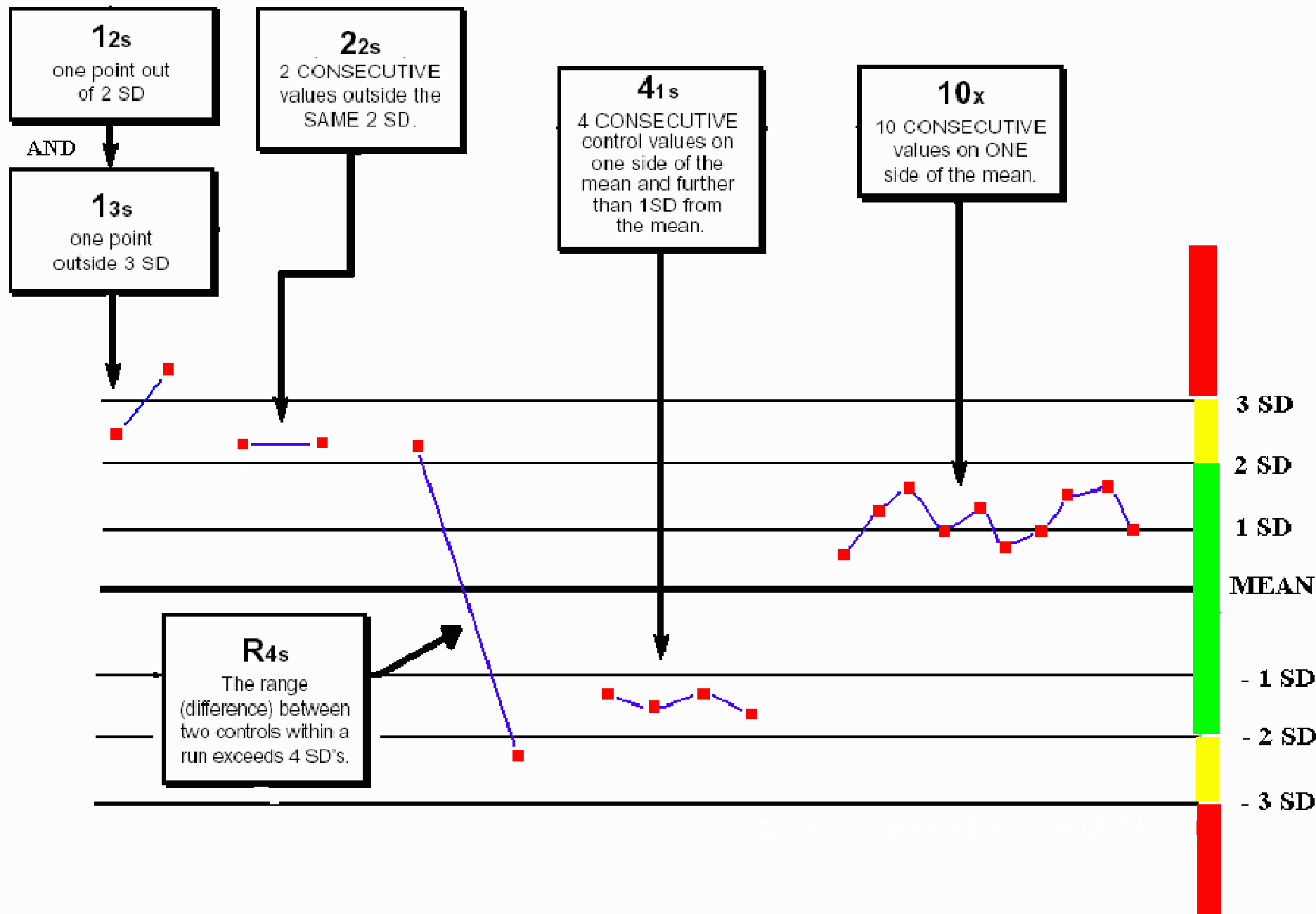
Components of a TOTAL QUALITY SYSTEM

ANALYTICAL

Components of a TOTAL QUALITY SYSTEM : ANALYTICAL

- Use Statistical Quality Control within all Quantitative Procedures
- Use Quality Control Materials that are Independent of the Instrument Manufacturer
- Participate in External Quality Assurance Programmes
- Keep meticulous records of QC data, your assessments of those data, and all corrective actions made as a result of those assessments

THE WESTGARD RULES IN PRACTICE



Albumin Low Control

Target Mean = 25.4
 Target SD = 1.1
 Target CV% = 4.3

Aug-07

DEVIATION	Date	1	2	3	4	5	6	6	8	9	10	
+ 3 SD	28.7						28.2					
+ 2 SD	27.6	27.2		26.9					26.6	26.8	27.1	
+ 1 SD	26.5		26.4		25.7							
0 SD	25.4					25.4						
- 1 SD	24.3							25.2		24.9		
- 2 SD	23.2											
- 3 SD	22.1											
INITIALS		TH	FG	TH	UR	TH	UR	UR	TH	JK	RB	JK
COMMENT		OK	OK	OK	OK	OK	BAD	OK	OK	OK	OK	OK
	ACTION						<i>Recalibrated and then repeated</i>					

WHAT MAKES FOR A GOOD CHECKLIST :

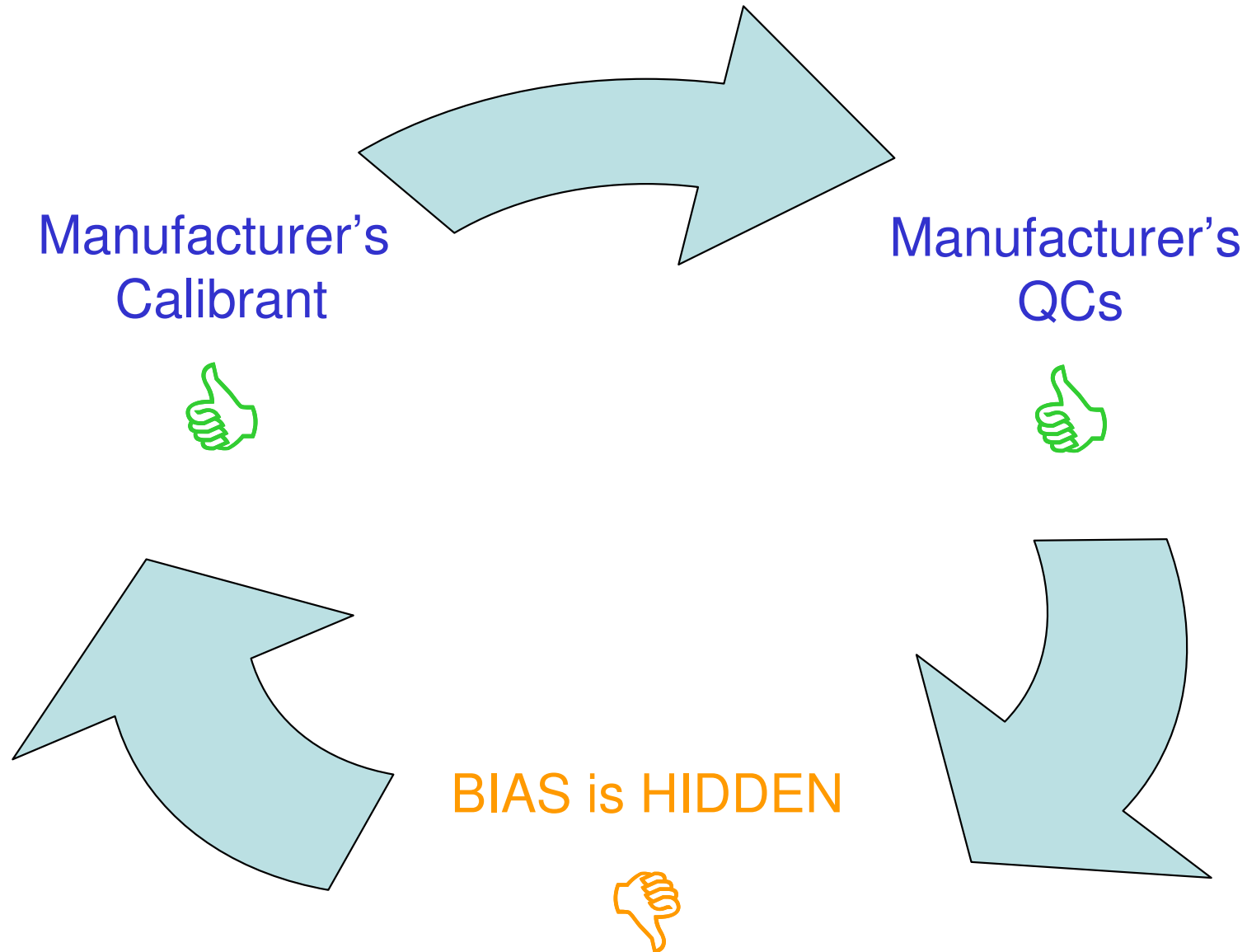
“Checklist responses should portray the desired status or the value of the item being considered (not just “checked” or “set”).

Many checklists examined employed the ambiguous responses “set,” “check,” “completed,” etc. to indicate that an item is accomplished. *We believe that whenever possible, the response should always portray the actual status or the value of the item (switches, levers, lights, fuel quantities, etc.).*

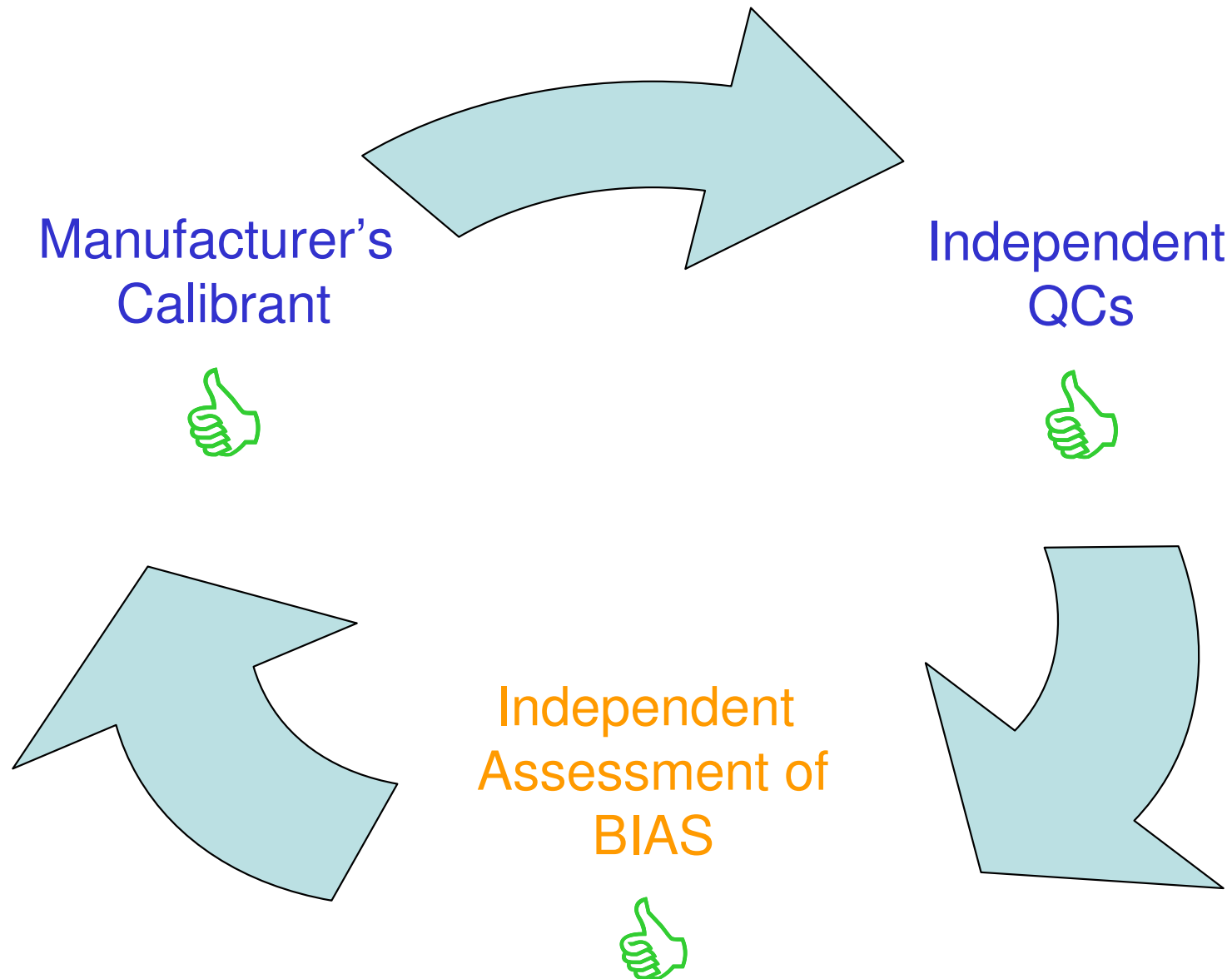
In the Lab a Tick and a Squiggle is open to misinterpretation ... instead for say a daily 37°C waterbath temperature check staff should write

36.5°C, OK, TFH

- Use Quality Control Materials that are Independent of the Instrument Manufacturer



When Quality Control Materials are Independent of the Instrument Manufacturer



ASSAYED QC MATERIAL ARE A HELP BUT NOT THE COMPLETE ANSWER TO YOUR PROBLEMS

Where is your analyzer ?

Where is your Target
Mean & SD ?

CALCIUM

Abbott Aeroset/Architect (Arsenazo III)

Arsenazo III (6)

Atomic Absorption

Bayer ADVIA 1650 (O-Cresolphthalein Complexone)

Beckman Coulter Synchron CX Systems-Cartridge (Arsenazo

Beckman Coulter Synchron CX Systems-Modular (Arsenazo I

Beckman Coulter Synchron CX Systems (ISE Indirect)(CALC)

Beckman Coulter Synchron LX20 (ISE Indirect)(CALC)

DADE BEHRING Dimension (O-Cresolphthalein Complexone)

Flame Photometry

ISE Indirect (6)

O-Cresolphthalein Complexone (6)

Olympus AU400 / AU600 / AU640 / AU2700 (Arsenazo III)

Ortho VITROS (Arsenazo III)

Roche Cobas INTEGRA (O-Cresolphthalein Complexone)

Roche Hitachi (Europe/Asia) (O-Cresolphthalein Complexone)

Roche Hitachi (US) (O-Cresolphthalein Complexone)

1.42	1.28 - 1.56	2.72	2.44 - 2.99
1.45	1.30 - 1.59	2.82	2.53 - 3.10
1.48	1.33 - 1.63	2.80	2.24 - 3.36
1.44	1.29 - 1.58	2.95	2.36 - 3.54
1.43	1.29 - 1.58	2.69	2.15 - 3.23
§		§	
1.33	1.19 - 1.46	2.56	2.31 - 2.82
1.41	1.27 - 1.55	2.75	2.48 - 3.03
1.50	1.35 - 1.65	2.90	2.61 - 3.19
1.46	1.32 - 1.61	2.71	2.44 - 2.98
1.37	1.23 - 1.50	2.66	2.39 - 2.92
1.47	1.33 - 1.62	2.97	2.67 - 3.26
1.39	1.25 - 1.53	2.84	2.55 - 3.12
1.55	1.39 - 1.70	3.03	2.72 - 3.33
1.53	1.38 - 1.69	3.13	2.82 - 3.44
§		§	
1.43	1.28 - 1.57	2.89	2.60 - 3.17

Practice Tip #8 : How to Set Better Target Means

A good source of “assayed” QCs are the surplus material from External Quality Assurance Programmes

Run these in parallel with Independent Assayed QC Material to get a ‘better’ estimate of the target mean for these Independent Assayed QCs when run on your instrumentation.

Do 30 batches before you assign Your Target Mean and SD

- Participate in External Quality Assurance Programmes
- Keep meticulous records of QC data, your assessments of those data, and all corrective actions made as a result of those assessments

**THE LABORATORY ACCREDITOR'S
RULE OF THUMB - If it isn't written
down then it is not being done !**

Written Policies

Written Procedures

Written Records ... QC RECORDS !!!

..... Training Records !!!

Components of a TOTAL QUALITY SYSTEM : POST ANALYTICAL

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- Audit and then Change
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- Audit and then Change
- Keep **all levels** Laboratory Staff Informed of the quality of the Service they are delivering

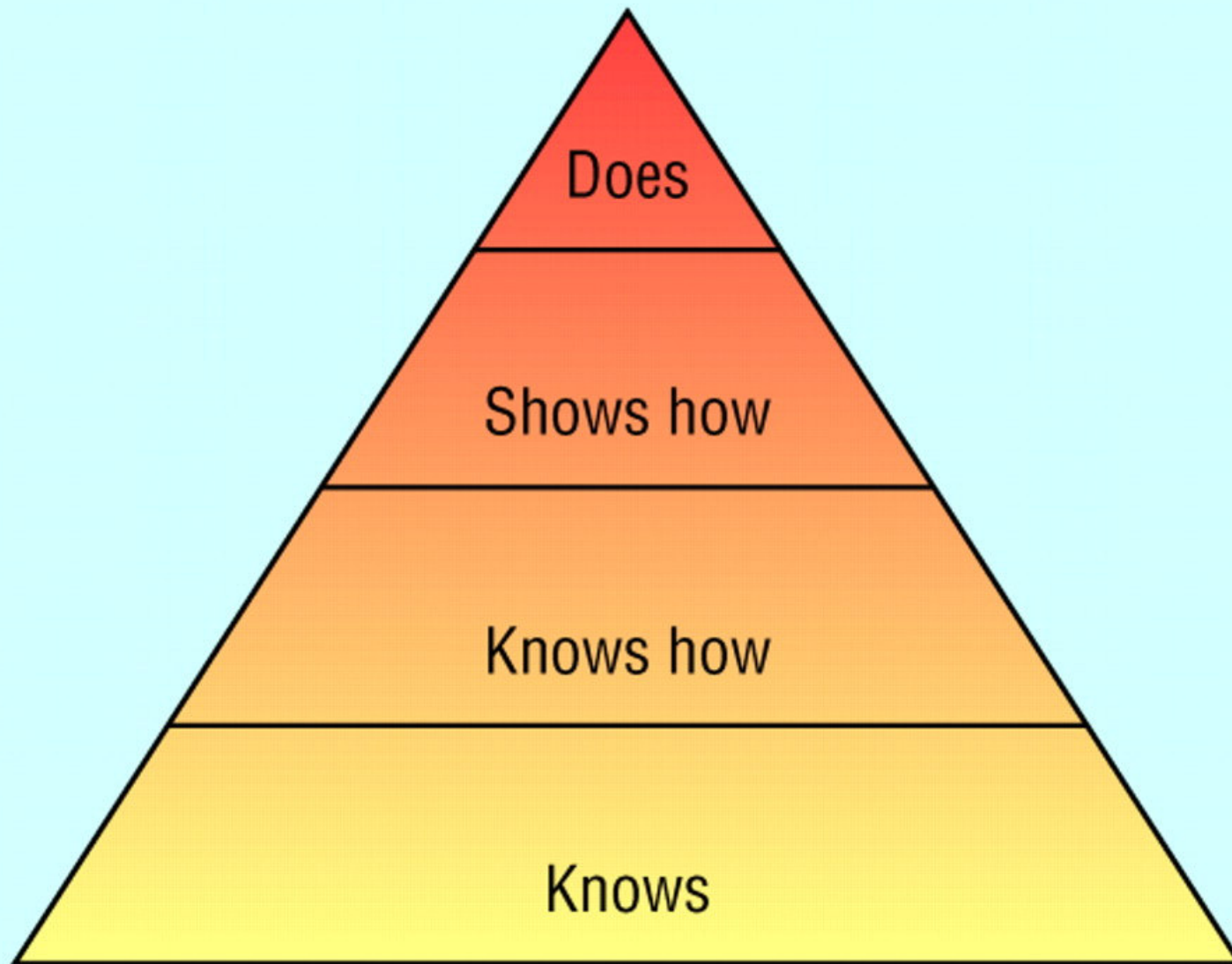
INCIDENTS – or getting it wrong !

Incidents happen because

- ❖ It is a genuine mistake
- ❖ Or
- ❖ The person has not been trained properly.

The important thing is to take the 'No Blame Approach' and go in and fix the problem(s)

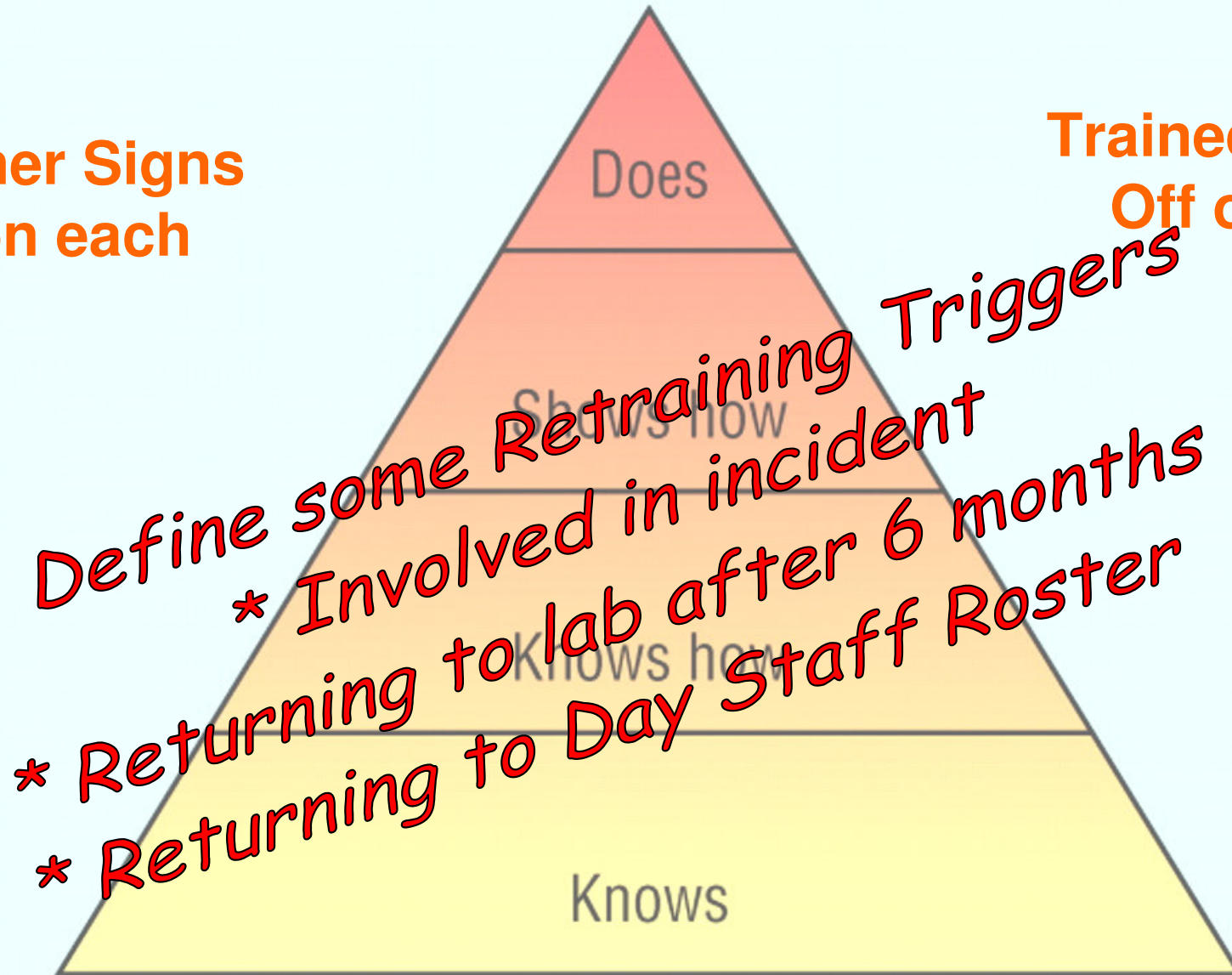
MILLER's PYRAMID OF COMPETENCY ASSESSMENT



Practice Tip #9 : TRAINING RECORDS

Trainer Signs
Off on each
level

Trainee Signs
Off on each
level



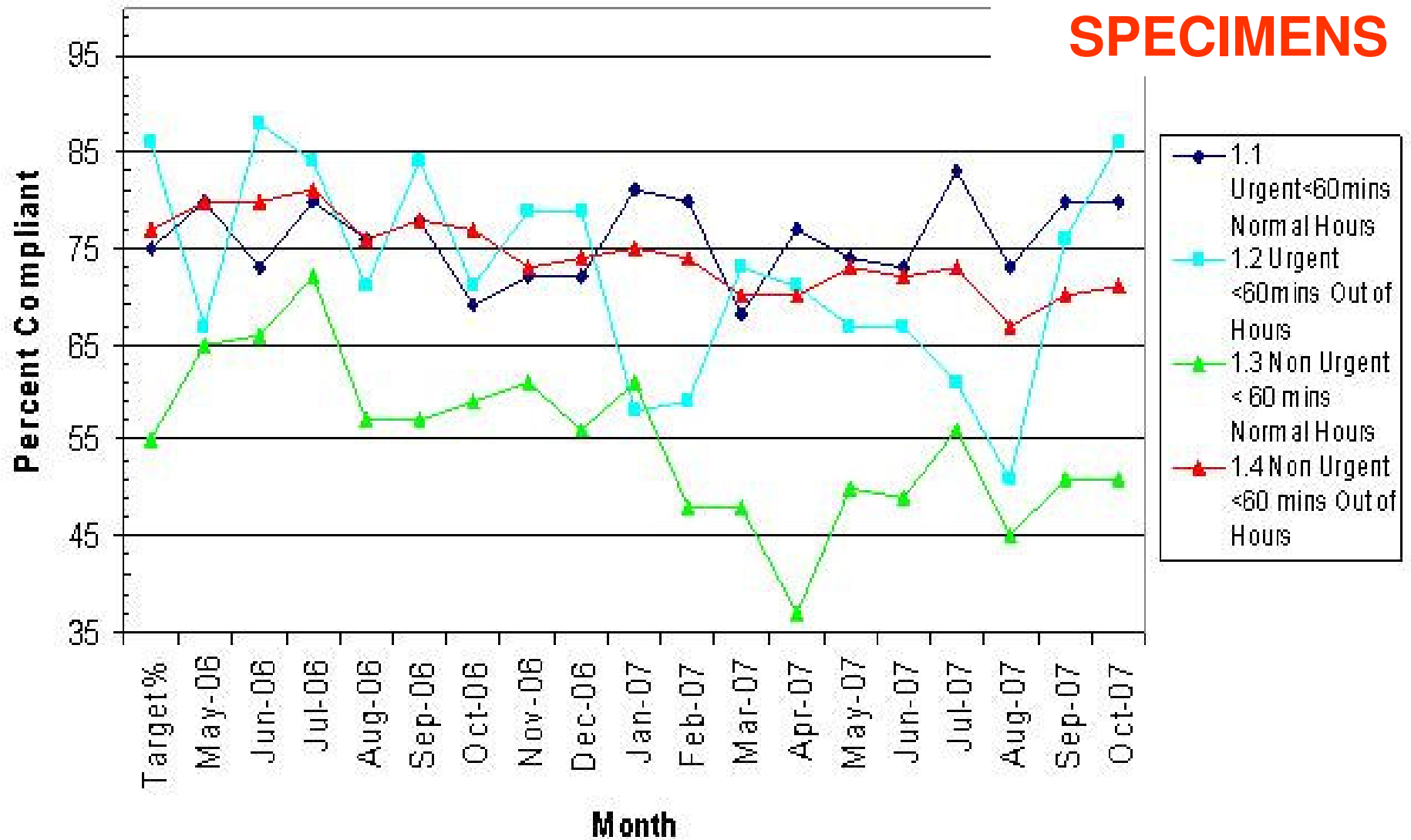
KEY PERFORMANCE INDICATORS

- Transit Time of samples between the Phlebotomist and the Lab's Specimen Reception area.
- Transit Time of samples through your Specimen Reception and Data Entry areas
- Transit Time of samples through your specimen centrifugation area
- Transit Time of samples on your analyzers
- Transit Time of results data from Interim Status to Authorised and Reported status
- Number of Internally generated Incident Reports
- Number of Externally generated Incident Reports – customer complaints
- Time taken to produce Final Reports on Urgent Specimens
- Rankings with your Peer Laboratories in External Quality Assurance Programmes

ACHS KPI : TATs Serum Potassiums

ACHS Key Performance Indicators 2006 - 7
TATs for Serum Potassiums

KPI : URGENT SPECIMENS

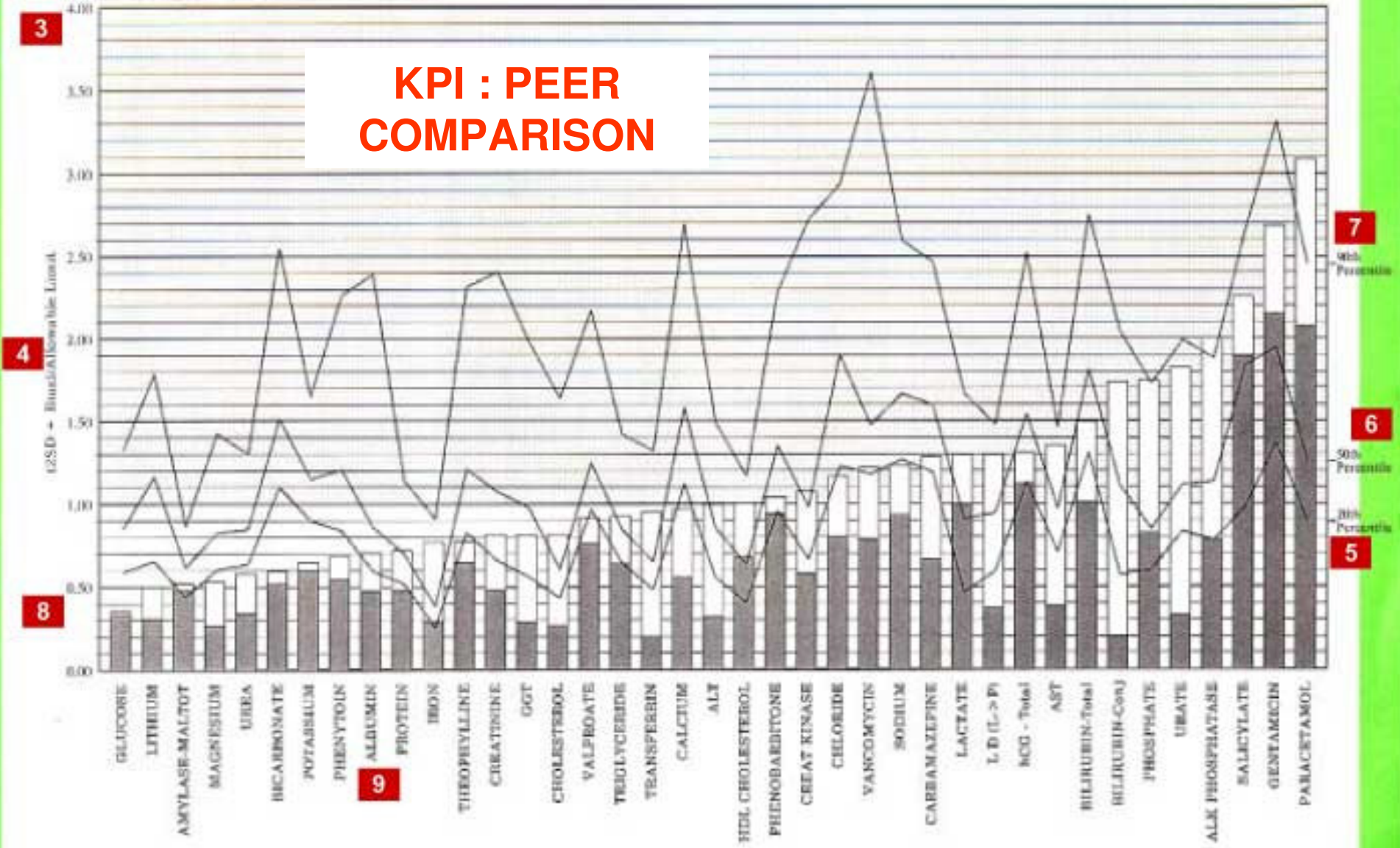


1 PERFORMANCE SUMMARY FOR LABORATORY NUMBER

2 (2SD + Bias)/Allowable Limit Assessment - Compared to 20th, 50th & 90th Percentile Rankings

■ 2SD fraction □ Bias fraction of Total Error

**KPI : PEER
 COMPARISON**



Practice Tip #10 : COMMUNICATE

- Regular **SHORT** meetings at all levels of staff
- Always have an **AGENDA**
- Always produce **BRIEF** minutes
- Always produce **ACTION LISTS** with **NAMES** and delivery **DATES**
- Use '**COMMUNICATIONS DIARIES**' in Shiftwork Areas

Communications Diary Example

NOVEMBER 2007

13 Tuesday
Week 46 · 317-048

7.00 KS Toil. ~~Book~~.

7.30 Gina off at BAS (ok SSC).

8.00 BS ill 9.30 am ~~Ab.~~

9.00 JC caterers leave ~~*~~

9.30 John ON-CALL TIL FRIDAY AM.

10.00 TERRI to cover weekend. + FRIDAY AM.

10.30

11.00

11.30

12.00

12.30

1.00

CLC Blood Gas machine is dead. A new computer will be coming tomorrow (Greg will install) ? time.

1.30

All gases will have to be done in ICU overnight.

2.00

ICU have been informed & happy to do them.

2.30

Your Objectives Have Been Reached ?? !!!

- Results with Known Accuracy and Precision**
- On the Right Patient**
- Have been**
 - ❖ Delivered to the Right Doctor**
 - ❖ On Time**
 - ❖ And you have Complete Audit Trail of every critical step of that Patient Pathology Request Episode through your Department should any queries arise in the future.**

Thank You Any Questions