UNIVERSITI TEKNOLOGI MARA

THE CENTRE FOR PATHOLOGY DIAGNOSTICS & RESEARCH LABORATORIES

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CUSTOMER EDUCATION SERIES

SAMPLE REJECTION IN CHEMICAL PATHOLOGY

(CPDRL SG. BULOH & SELAYANG)

18 December 2015

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OUTLINES

- Percentage of rejection criteria in:
  - ❖CPDRL Sg. Buloh
  - ❖CPDRL Selayang
- Issues
- Ways to overcome problems
- Q & A

CPDRL SG. BULOH

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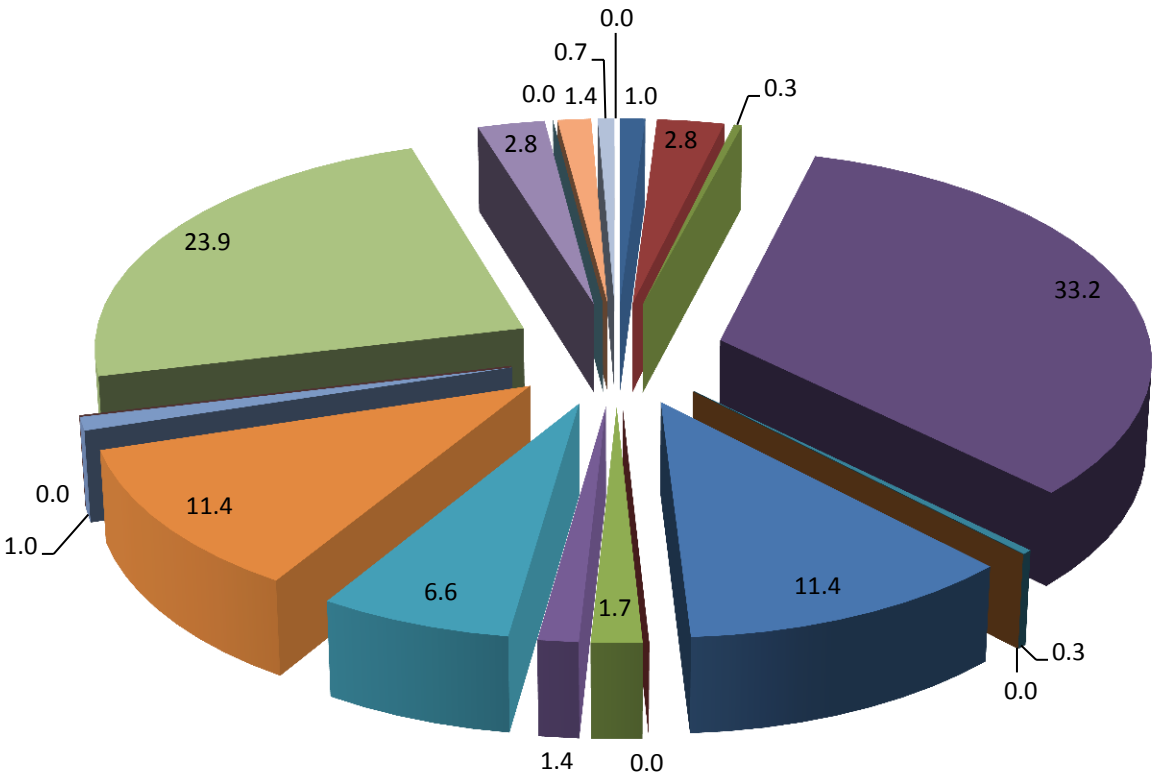
Total specimen received (Jan – June 2015)	**17,814**
Total no. of Rejected cases (Jan - June 2015)	**289**
Percentage of Rejection	**1.6%**
Rejection criteria with the highest no. of cases	**Haemolysis** 96 from total of 289 rejection cases (33.2%)
Requestor with the highest percentage of specimen rejection	**Ward 2** 51 rejected samples from 1220 samples received (4.2%) **Hospital Selayang** 17 rejected samples from 402 samples received (4.2%)
The most rejected specimens	**Plain tube (serum)** 28 plain tubes rejected from 17,814 samples received (0.16%)

PERCENTAGE OF REJECTION CRITERIA IN CPDRL SG. BULOH (CHEMICAL PATHOLOGY ONLY)

JANUARY - JUNE 2015



- Defect label
- Missing label
- Incomplete request form
- Haemolyzed
- Lipaemic
- Icteric
- Clotted
- Expired collection tube
- Wrong collection tube
- Broken/cracked/leaking collection tube
- Insufficient sample
- Sample not received
- Improper transport
- Temp. not maintained
- Double request/ repetitive order
- Wrong label
- Delayed centrifugation
- Test not offered
- Improper specimen collection
- Out of sample stability

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Rejection Criteria	%
Defect label	1.0
Missing label	2.8
Incomplete request form	0.3
Haemolyzed	**33.2**
Lipaemic	0.3
Icteric	0.0
Clotted	11.4
Expired collection tube	0.0
Wrong collection tube	1.7
Broken/ cracked/ leaked tube	1.4
Insufficient sample	6.6
Sample not received	11.4
Improper transport	1.0
Temperatute instability	0.0
Double request/ repetitive order	**23.9**
Wrong label	2.8
Delayed centrifugation	0.0
Test not offered	1.4
Improper specimen collection	0.7
Out of sample stability	0.0

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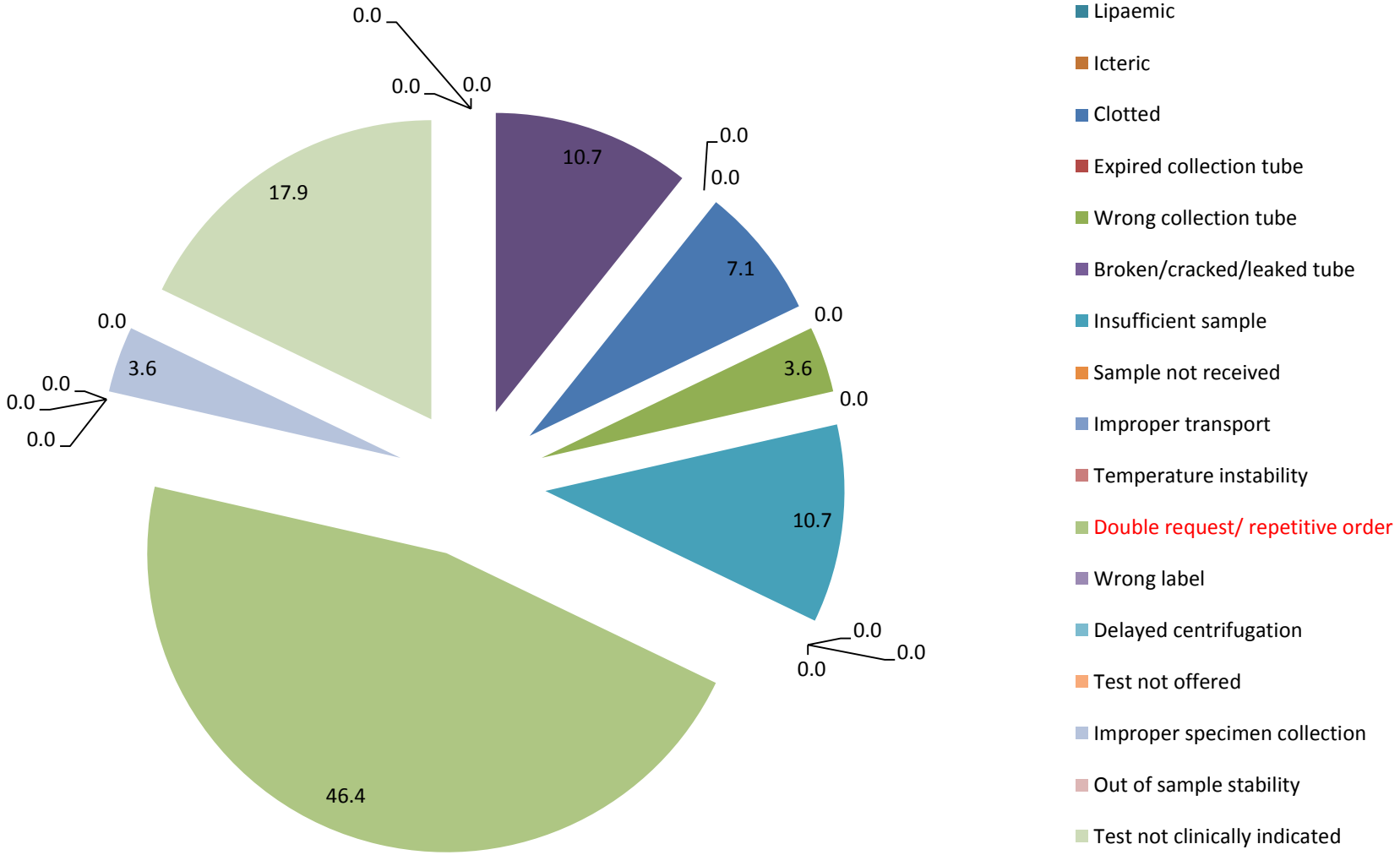
CPDRL SELAYANG

Total Specimen received (Jan – June 2015)	**6041**
Total no. of cases (January – June 2015)	**28**
Percentage of Rejection	**0.5%**
Rejection criteria with the highest no. of cases	**Double request/ repetitive order** 13 from total of 28 rejection cases (46.4%)
Requestor with the highest percentage of Specimen rejection (divided by denominator)	**Gastroenterology** Out of 44 specimens, 1 was rejected (2.3%)
The most rejected specimens (divided by denominator)	**Plain tube (serum)** Out of 6,041 specimens, 13 tubes were rejected (0.22%)

PERCENTAGE OF REJECTION CRITERIA IN CPDRL SELAYANG (CHEMICAL PATHOLOGY ONLY)

JANUARY - JUNE 2015



CPDRL SELAYANG (CHEMICAL PATHOLOGY ONLY)

JANUARY - JUNE 2015

Rejection Criteria	%
Defect label	0.0
Missing label	0.0
Incomplete request form	0.0
Haemolyzed	10.7
Lipaemic	0.0
Icteric	0.0
Clotted	7.1
Expired collection tube	0.0
Wrong collection tube	3.6
Broken/cracked/leaked tube	0.0
Insufficient sample	10.7
Sample not received	0.0
Improper transport	0.0
Temperature instability	0.0
Double request/ repetitive order	**46.4**
Wrong label	0.0
Delayed centrifugation	0.0
Test not offered	0.0
Improper specimen collection	3.6
Out of sample stability	0.0
Test not clinically indicated	17.9

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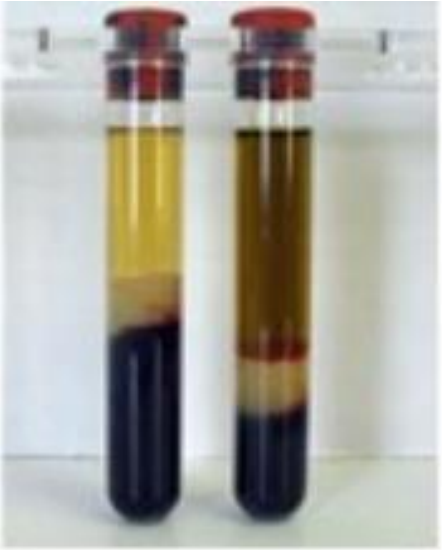

Jaundice

Lipemia

Hemolysis

ISSUE 1

Haemolysis In Chemical Pathology

What Is Haemolysis?

"Damage to the RBC's membrane causing the release of Hb and other internal components into the surrounding plasma".

- A **common** occurrence; may compromise the laboratory's test parameters.

- Two sources:
  - ✓ **In-vivo** hemolysis - due to pathological conditions e.g. such as autoimmune hemolytic anemia or transfusion reaction.

  ➡ **In-vitro** hemolysis - due to improper specimen **collection**, specimen **processing** or specimen **transport**.

How Is Haemolysis Detected?

Hemolyzed serum or plasma will have a pink or reddish hue (easy to visualize).

Haemoglobin added (g/dl)	**0**	**0.05**	**0.1**	**0.25**	**0.5**	**1**
Haemolysis index	**< 2**	**46**	**97**	**227**	**446**	**907**
Sample frequency (%)	*84.4*	*8.5*	*4.6*	*2*	*0.5*	

Why Is Preventing Haemolysis Important?

- ✓ Impact the validity of test results
- ✓ Requires a repeat collection from the patient
- ✓ Delay in diagnosis/treatment
- ✓ Patient discomfort & dissatisfaction
- ✓ Additional expenses

Impact On The Validity Of Test Results (1)

- The amount of hemolysis needed to affect a test is dependent on the test being performed.

- **Slight hemolysis** has little effect on most tests; however, it will cause **increased levels** for specific tests like **K, PO4, AST** and **LDH.**
  - **Samples with slight hemolysis are analyzed and the results will be reported with a comment indicating the degree of hemolysis & the effect on the test result.**

- If the specimen is **grossly hemolyzed**, a **recollected (fresh) specimen** will be requested if clinically indicated.

Table 1 Laboratory parameters affected by haemolysis and/or blood cell lysis in the specimen.

Parameter	Bias	Cause
Adrenocorticotropic hormone	Negative	Proteolysis
Activated partial thromboplastin time	Negative	Release of thromboplastic substances
Antithrombin	Negative	Analytical interference
Aspartate aminotransferase	Positive	Cellular release
Alanine aminotransferase	Positive	Cellular release
Albumin	Negative	Dilution
Alkaline phosphatase	Negative	Analytical interference
Bilirubin (neonatal)	Variable	Analytical interference
Bilirubin (total)	Negative	Analytical interference
Calcitonine	Positive	Proteolysis
Chloride	Negative	Dilution
Cortisol	Negative	Analytical interference
Creatine kinase	Positive	Analytical interference
Creatinine	Positive	Analytical interference
D-dimer	Positive	Release of thromboplastic substances
Fibrinogen	Negative	Release of thromboplastic substances
Folate	Positive	Cellular release
γ-Glutamyltransferase	Negative	Analytical interference
Gastrin	Negative	Proteolysis
Glucagon	Negative	Proteolysis
Glucose	Negative	Dilution
Haptoglobin	Negative	Analytical interference
Homocysteine	Negative	Analytical interference
Insulin	Negative	Proteolysis
Iron	Positive	Analytical interference
Lactate dehydrogenase	Positive	Cellular release
Lipase	Positive	Analytical interference
Magnesium	Positive	Cellular release
Parathormon	Negative	Proteolysis
Phosphorus	Positive	Cellular release
Potassium	Positive	Cellular release
Prostate specific antigen	Positive	Analytical interference
Prothrombin time	Positive	Release of thromboplastic substances
Sodium	Negative	Dilution
Urea	Positive	Cellular release
Testosterone	Negative	Analytical interference
Troponin I	Positive	Analytical interference
Troponin T	Negative	Analytical interference
Vitamin B12	Negative	Analytical interference

↑ AST

↑ LDH

↑ PO4

↑ K

Impact On The Validity Of Test Results (2)

Reporting of Elevated K+

Based on IFCC recommendation, measured value **incompatible with human life** is when **K+ > 9.0 mmol/L.**

- If a sample is found to be haemolysed with K+ > 9.0
  - **Report K+ > 9.0 mmol/L** with a comment indicating the degree of hemolysis (H index).

- If a sample is NOT haemolysed but K+ > 9.0
  - **Report K+ > 9.0 mmol/L** with a comment of possible causes of elevated K+ (e.g. cross contamination, delay in sample processing > 2hrs).

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What Are The Causes of Haemolysis?

Preanalytical Specimen Workflow

Patient

- Patient ID
- In Vivo Haemolysis due to patient factors
  - Metabolic Disorders (eg. Liver disease)
  - Chemical Agents (eg. Medication)
  - Physical Agents (eg. Mechanical heart valves)
  - Infectious Agents (eg. Bacteria)

Phlebotomy

- Catheter, IV Collection
- Capillary Collection
- Needle Gauge
- Position of Arm
- Location of Venipuncture
- Antiseptic Used for Phlebotomy
- Tourniquet Time
- Traumatic Draw
- Fist Clenching
- Tube Type Collected
- Tube Under Filled
- Order of Draw
- Vigorous Mixing
- No Mixing
- Syringe Transfer

Specimen Transport

- Origin of Specimen Maternity, Emergency & Intensive Care
- Origin of Specimen In-patient
- Origin of Specimen Physician Office Lab
- Origin of Specimen Out-patient
- Tubes Transported Vertical or Horizontal
- Transport by Pneumatic Tube
- Courier Transport
- Transport Duration
- Pre-Centrifugation and Transport Temperature

Processing

- Verify Tube with Request
- Generate Laboratory Barcode
- Time between Collection and Centrifugation
- Type of Centrifuge
- Centrifuge Calibrated
- Centrifuge Temperature Extremes
- Speed of Centrifuge
- Duration of Centrifugation
- Poor Separator Barrier Integrity
- Cells on Stopper
- Automated Decapping
- Specimen Re-Centrifugation
- Aliquot Labeling
- Specimen Aliquoted

Analysis

- Long Time after Centrifugation
- Serum vs. Plasma vs. Whole Blood
- Tube mixed prior to analysis
- Re-run Specimen (Same Day)
- Verify Instrument Cal & Controls
- Identify Instrument Used for Testing
- Identify Tech Performing Testing
- Verify Report Value

Specimen Storage

- Re-Centrifugation Add-On
- Post-Analysis Storage Temperature
- Duration of Storage

Red- Steps that may cause haemolysis

Black- Steps not likely the cause of haemolysis

How To Prevent Haemolysis?

When **collecting** specimens:

- ✓ Do not leave tourniquet on for longer than one minute
- ✓ Allow alcohol to dry completely before puncturing the skin
- ✓ Use a properly sized needle; 20-22 gauge needles work best for routine collections
- ✓ Do not remove the needle from the vein with the vacuum tube still engaged

When **processing** specimens:

- ✓ Make sure sample is not exposed to extreme heat or cold
- ✓ Allow blood to clot completely prior to centrifugation
- ✓ Avoid vigorous mixing or shaking of tubes
- ✓ Do not centrifuge specimens at higher speed or for longer than necessary

When **transporting/shipping** specimens:

- ✓ Make sure sample is not exposed to extreme heat or cold
- ✓ Do not ship whole blood containers on dry ice (unless it's an SST or PST that has been centrifuged prior to shipment)
- ✓ Do not subject the specimen to significant jostling or jarring.

Sample NOT Haemolysed ... but Gives Misleading Results

Example:

K+ > 9.0 mmol/L (? Haemolysis)

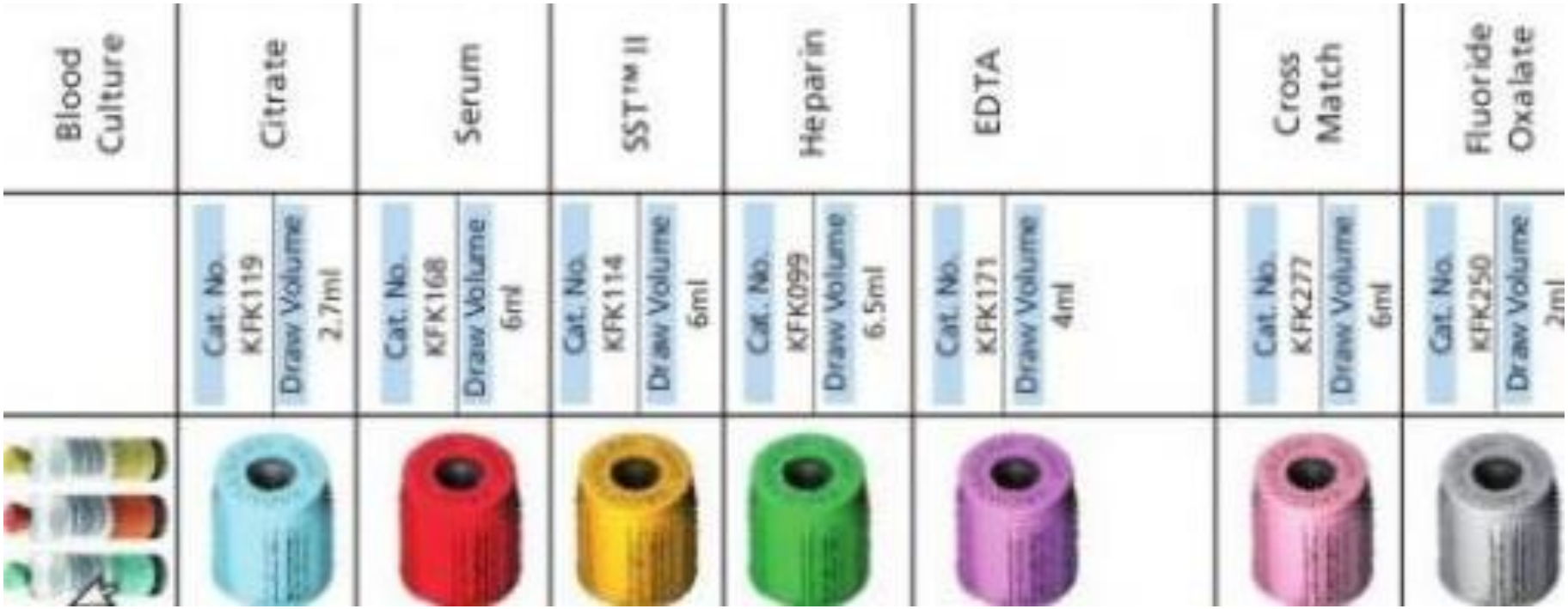
Low ALP, Ca2+ & Mg2+

Suspect contamination with K_2EDTA tube (purple top) or Fluoride/ Oxalate tube (grey top) ***chelates Ca2+ & Mg2+**

→ Need to know **'Order of Draw'.**

Order of Draw

To avoid CROSS CONTAMINATION of additives between blood tubes



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ISSUE 2

Double request (or repetitive order)

Why We Need to Prevent Double Request/ Repetitive Order ?

Patient discomfort & dissatisfaction

Most Common Analytes with Repetitive Order

1. HBA1c

- Used for monitoring diabetic control
- Sample is **rejected** if previous request is **less than 8 weeks interval.**

2. TSH

- Used for monitoring treatment for thyroid disease
- Sample is **rejected** if previous request is **less than 6 weeks interval.**

3. Fasting Serum Lipid (FSL)

- Sample is NOT processed during Non-Office hours (but not rejected)

How To Prevent Repetitive Orders?

- **Minimum Retesting Intervals (MRI)**
  - ✓ The minimum time before a test should be repeated (based on the properties of the test and the clinical situation in which it is used).
  - ✓ Determined by consensus recommendations.

- **Turn Around Time (TAT) for urgent, routine and specialised tests.**

Example

The Association for
Clinical Biochemistry &
Laboratory Medicine

The Royal College of Pathologists
Pathology: the science behind the cure

National Minimum Re-testing Interval Project:

A final report detailing consensus recommendations for

minimum re-testing intervals for use in Clinical Biochemistry

Prepared for the Clinical Practice Group of the

Association for Clinical Biochemistry and Laboratory Medicine and

supported by the Royal College of Pathologists.

Report Author: Dr Tim Lang – Project Lead

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ENDOCRINE RELATED Cont.....

REF	Clinical situation	Recommendation	Source
E5	Hypothyroidism - monitoring treatment	The minimum period to achieve stable concentrations after a change of dose of thyroxine is 2 months and TFTs should not normally be assessed before this period has elapsed Patients stabilised on long-term thyroxine therapy should have serum TSH checked annually An annual fT4 should be performed in all patients with secondary hypothyroidism stabilised on thyroxine therapy	Association for Clinical Biochemistry and Laboratory Medicine, British Thyroid Association and British Thyroid Foundation (2006) UK guidelines for the use of thyroid function tests. Association for Clinical Biochemistry, British Thyroid Association, British Thyroid Foundation, July 2006.
E6	Monitoring Adult sub-clinical hyperthyroidism	If a serum TSH below ref range but >0.1 mU/L is found, then the measurement should be repeated 1-2 months later along with T4 and T3 after excluding non-thyroidal illness and drug interferences. This is contradicted later in the guidelines when the authors state that a 3-6 month repeat interval is appropriate unless the patient is elderly or has underlying vascular disease If treatment not undertaken then serum TSH should be measured in the long term every 6-12 months, with follow up with fT4 and fT3 and fT3 if serum TSH result is low	Association for Clinical Biochemistry, British Thyroid Association and British Thyroid Foundation (2006) UK guidelines for the use of thyroid function tests. Association for Clinical Biochemistry, British Thyroid Association, British Thyroid Foundation July 2006
E7	Monitoring adult sub-clinical hypothyroidism.	Patients with subclinical hypothyroidism should have the pattern confirmed within 3-6 months to exclude transient causes of elevated TSH Subjects with subclinical hypothyroidism who are ATPOab positive should have TSH and fT4 checked annually Subjects with subclinical hypothyroidism who are ATPOab neg should have TSH and fT4 checked every 3 years	Association for Clinical Biochemistry, British Thyroid Association and British Thyroid Foundation (2006) UK guidelines for the use of thyroid function tests. Association for Clinical Biochemistry, British Thyroid Association, British Thyroid Foundation July 2006

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TAT for URGENT TESTS

URGENT/ Clinical STAT service	Turn-Around Time (TAT)
• Troponin & CKMB • Others – Renal profile, LFT, amylase, glucose etc	**1 hr**
• ABG	**45 mins**

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TAT for ROUTINE TESTS

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Tests which are offered during:	Turn-Around Time (TAT)
Office Hour • Renal profile, LFT, AST, glucose, FSL, calcium, magnesium, phosphate, LDH, CK, amylase , CRP, ABG • Body fluids biochemistry - urine FEME, UACR/ UPCR, UPT, CSF biochemistry etc	**In-patient: 4 hrs** **Outpatient: 5 working days**
Non-office Hour • **Renal profile, LFT, ABG, glucose, calcium, magnesium, phosphate, amylase, CK, CKMB, Trop T** • **Urine dipstick only (+ UPT), CSF biochemistry**	**In-patient: 4 hrs**

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TAT for SPECIALISED TESTS

Tests that are run in batches:	Turn-Around Time (TAT)
HbA1c ➢ Every other day **Thyroid function tests (TFT)** ➢ Every Wednesdays **Other endocrine (hormone) tests** ➢ Every Thursdays	**5 working days**

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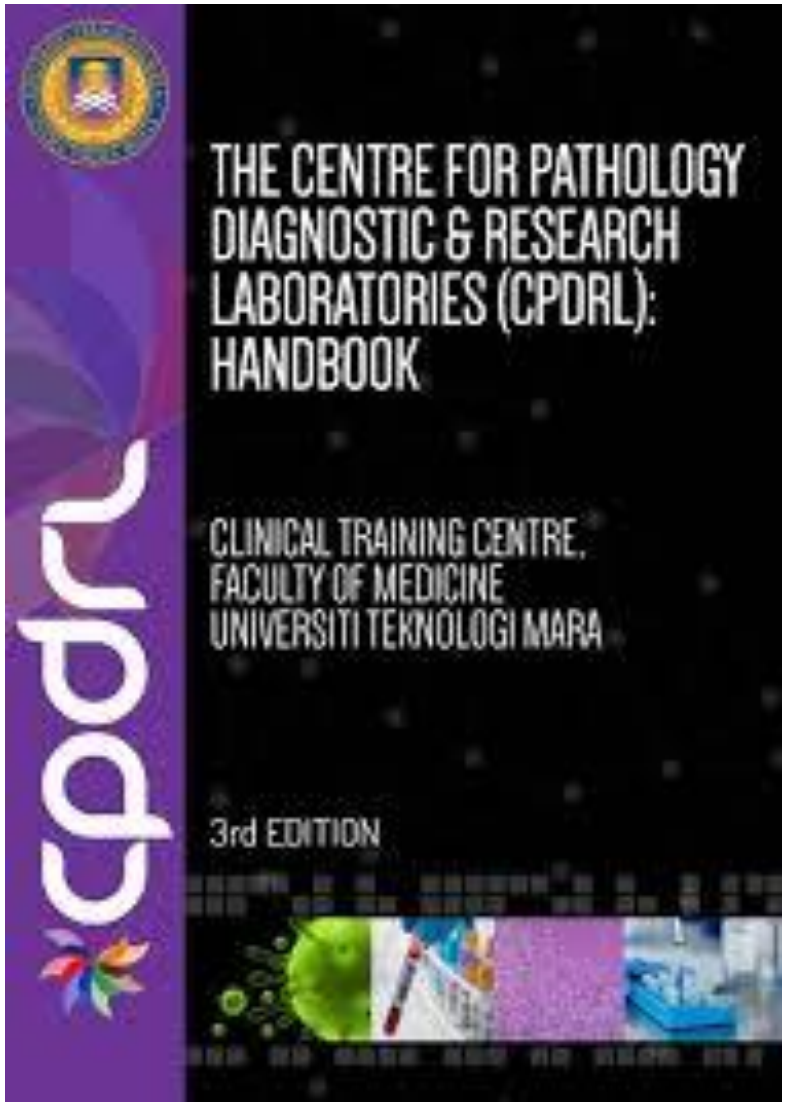

Q & A

http://cpdrl.weebly.com/handbook.html

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Announcement

CPDRL Sg. Buloh

REMINDER!

Please fill in the Log Book for Results Collection (Chemical pathology & Haematology) by ward/ clinic staff.

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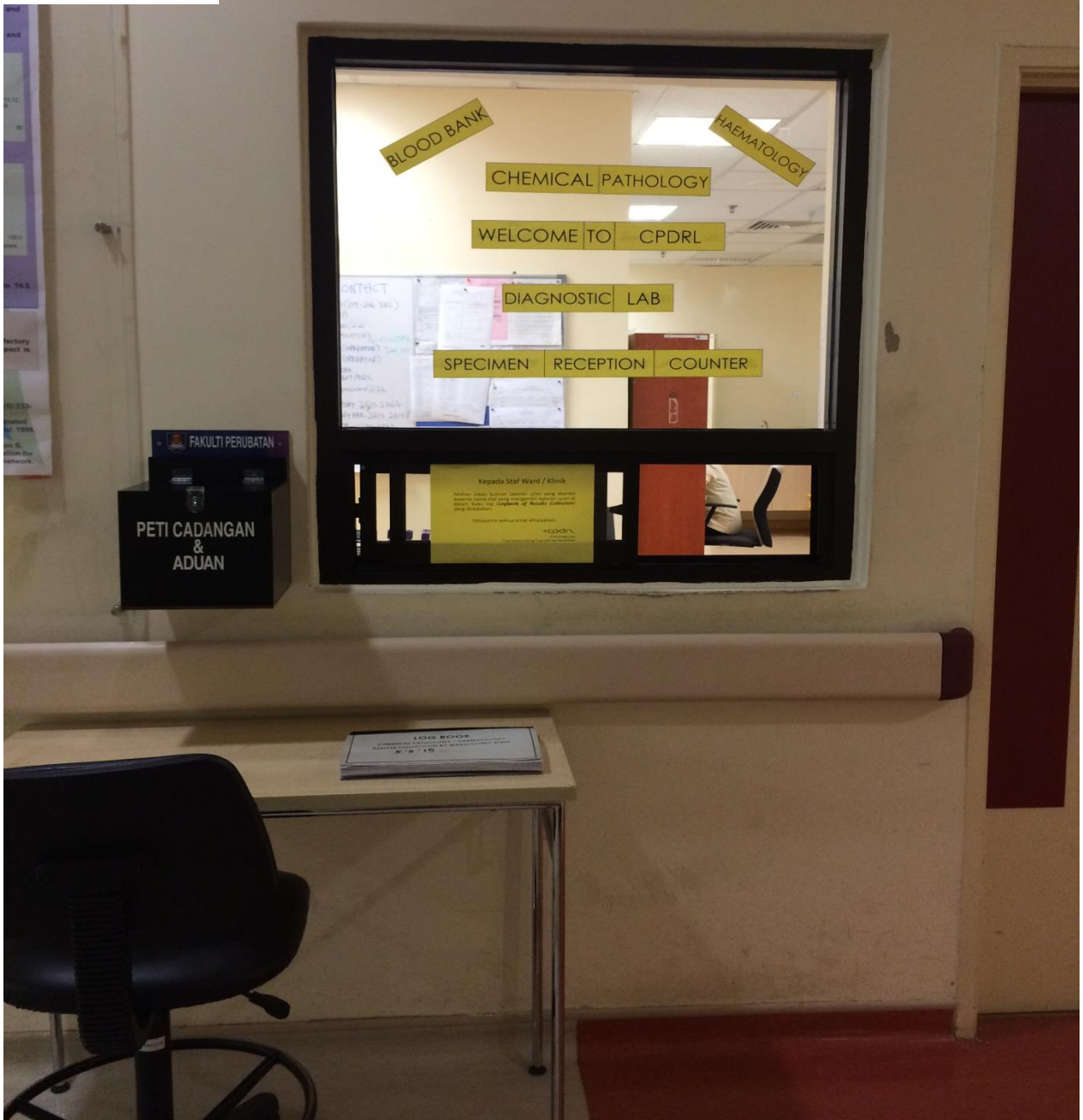

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Please feel free to contact the individual unit representatives:

Pn. Rafezah Razali, Pn. Che Wan Juliana

- Chemical Pathology : Cik Sarina Ali (03 - 61265209 / 5215)
- Haematology & Transfusion Medicine **Pn. Rosnani/ Pn. Mariana** 03 -61265209 / 5215)
- Anatomic Pathology : En. Muhammad Fa'iz Hussin (03-61265053)
- Medical Microbiology : Pn. Norzilawati Mohd Isa (03-61265139)
- Selayang Campus CPDRL: Pn. Che Wan Juliana (03 - 61264813/4814)

Pn. Rafezah Razali, Cik Sarina Ali