CUSTOMER EDUCATION SERIES 2021



PRE-ANALYTICAL ERRORS IN CHEMICAL PATHOLOGY LAB

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9th December 2021

The Department of Clinical Diagnostic Laboratories (CDL)

- Its operation began in October 2010 (previously known as Centre for Diagnostic Pathology and Research Laboratories (CPDRL).
- The main laboratory is located at Level 1, Block A, Hospital UiTM, Puncak Alam and two other locations are in Sg. Buloh and Selayang campuses.
- CDL provides diagnostic, research and consultancy services in the following disciplines:
 - Chemical Pathology
 - Hematology & Transfusion Medicine
 - Anatomic Pathology
 - Medical Microbiology & Parasitology
- CDL has been certified with MS ISO 15189 accreditation by the Dept of Standards Malaysia since 2014.



OUTLINES

- Total Testing Process & Pre-analytical Errors
- Specimen Rejection Criteria
- Chemical Pathology Specimen Rejection Rate
- Issues in Chemical Pathology testing
- Quizzes
- Q&A

INTRODUCTION

- A patient's diagnosis & treatment are often based on laboratory test results - this is why accurate results are critical
- Incorrect test results could lead to misdiagnosis which could have potentially fatal consequences
- Proper specimen collection and handling is a critical part of obtaining a valid laboratory result.



TOTAL TESTING PROCESS (TTP)

TTP is the total process from the ordering of a test to the interpretation of a test result.

ERRORS WITHIN THE TOTAL TESTING PROCESS



SPECIMEN REJECTION CRITERIA IN CHEMICAL PATHOLOGY

Defective/ Missing/ Wrong label	Improper specimen collection (e.g. wrong order of draw, blood collection from infusion route)
Incomplete request form	Repetitive test requests (e.g.HbA1c request is <8 weeks from previous testing)
No specimen received (only request form received)	Improper transportation method/ temperature not maintained
Haemolysed/ Clotted sample	Out of sample stability/ delayed sample arrival
Lipaemic/ Icteric sample	Test not offered
Insufficient specimen	Test is not clinically indicated
Wrong/ Expired/ Broken/ Leaking collection containers	(e.g. Free PSA is rejected when total PSA result is not within 2.5–10 ng/ml)

HURTM-CLD-CDL-F-012-05



OTHER DESIGNATION.	DEJECTION	FORM
SPECIMEN	REJECTION	LOW!

Regist		
Lab II	P(1)	-
Reque	ester (Clinic/Ward) :	
Date &	& Time of Reception : 117404 C 18644400	
Fest R	Request :HbAh (
Reason	n for Rejection :	
	Defective label	
	Missing label	
	Wrong label	
	Incomplete Request form	
	Hemolyzed sample	
	Lipaemic sample	
	Icteric sample	
	Clotted sample	
	Expired collection containers	
	Wrong collection containers	
	Broken or cracked collection containers	
	Insufficient specimen	
	No specimen received (only request form received)	
	Improper transportation method (specify:)
	Temperature not maintained	
	Delayed specimen received	
1	Repetitive test order/double request 8/11/2021	
	Test is not clinically indicated	
	Out of sample stability	
	Test is not offered	
	Improper Specimen Collection	
	Others (specify:)	

SPECIMEN REJECTION FORM	
Patient Name :	
Registration No.	
Lab ID :	
Requester (Clinic/Ward) :	
Date & Time of Reception : $\frac{2/ 2/2\ell}{2\ell} \otimes 6 - 6 \otimes a^m$	
Test Request :	
Reason for Rejection :	
Defective label]
Missing label	1
Wrong label	
Incomplete Request form	
Hemolyzed sample # : 130	
Lipaemic sample	
Icterio sample	
Clotted sample	
Expired collection containers	
Wrong collection containers	
Broken or cracked collection containers	
Insufficient specimen	
No specimen received (only request form received)	
Improper transportation method (specify:)	
Temperature not maintained	_
Delayed specimen received	_
Repetitive test order/double request	
Test is not clinically indicated	
Out of sample stability	_
Test is not offered	_
Improper Specimen Collection	_
Others (specify:)	
Informed by :	
Received by	
Date & Time informed : 6-39 , 2/12/21	

Requesters will be notified as soon as possible should the test request be unacceptable for any of the above reasons.



*

UNIVERSITI UNIVERSITI TEKNOLOGI MARA

CHEMICAL PATHOLOGY SPECIMEN REJECTION (JULY – DEC 2020)

Rejection Rate (SG BULOH)	547 out	t of 28,059 specimens (1.95%) Target MSQH: <1%
Top 3 Reasons for	No. 1	No. 2	No. 3
Rejection (with %	Double/repetitive order	Haemolysis	Clotted
	37.1%	24.1%	19.2%

Rejection Rate (SELAYANG)	47 ou	t of 15,562 specimens (0.3%)	Target MSQH: <1%
Top 3 Reasons for	No. 1	No. 2	No. 3
Rejection (with %	Double/repetitive order	No sample received	Clotted
	46.8%	14.9%	12.8%

CHEMICAL PATHOLOGY SPECIMEN REJECTION (JAN – JUNE 2021)

Rejection Rate (SG BULOH)	512 οι	ut of 28,396 specimens (1.8	3%) Target MSQH: <1%
Top 3 Reasons for	No. 1	No. 2	No. 3
Rejection (with %	Double/repetitive order	Haemolysis	Clotted
	42.6%	30.5%	8.8%

Rejection Rate (SELAYANG)	32 ou	t of 15,643 specimens (0).2%) Target MSQH: <1%
Top 3 Reasons for	No. 1	No. 2	No. 3
Rejection (with %	Double/repetitive order	Clotted	Insufficient sample
	32.3%	25.8%	16.1%

DOUBLE/ REPETITIVE ORDER

WHY WE NEED TO PREVENT DOUBLE REQUEST/ REPETITIVE ORDER ?





- INCREASE UNNECESSARY PHLEBOTOMY
- DECREASED PATIENT SATISFACTION
- INCREASED HEALTHCARE COSTS

COMMON TESTS WITH REPETITIVE ORDER

1. Haemoglobin A1c (HbA1c)

- Blood test that is used to help diagnose and monitor people with diabetes
- Sample is NOT processed during Non-Office hours (but not rejected)
- However, sample will be rejected if previous request is less than 8 weeks interval

2. Fasting Serum Lipid (FSL)

- Blood test that measures the amount of cholesterol & fats in the body as well as predicts the risk of developing cardiovascular disease
- Sample is NOT processed during Non-Office hours (but not rejected)



CLINICAL DIAGNOSTIC LABORATORIES DEPARTMENT LEVEL 1, PUSAT PAKAR PERUBATAN UITM (PPUITM) UNIVERSITI TEKNOLOGI MARA CAWANGAN SELANGOR, SUNGAI BULOH CAMPUS Jalan Hospital, 47000 Sungai Buloh, Selangor Darul Ehsan.

Tel: 03-6126 5215 Faks: 03-6126 5212







Analyte	Results	Unit	Flag Reference	Methodology	
BLOOD					
BLOOD					
HbA1c(%)	REJECTED	%	<= 5.7	HPLC (Ion Exchange)	
HbA1c(mmol/mol)	REJECTED	mmol/mol	<= 39	HPLC (Ion Exchange)	
REJECTED: HbA1c was rejected due	to repetitive order (previous request	is less than 8 weeks intervi	al). Please refer to request	
on date (08/11/2021) of previous reau	est. Informed to	on 07/12/2	021. at 10:39am.		

Verified by

Validated by Reported Date : 07-12-2021 10:52

Note: Test indicated with (*) are not Skim Akreditasi Makmal Malaysia (SAMM) accredited

HOW TO PREVENT REPETITIVE ORDERS?

- Follow recommendations of 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.
- Know the lab Turn Around Time (TAT) for urgent, routine and specialised tests





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

© ACB 2013

LAB TURN AROUND TIME (TAT)

Defined as the time interval between sample arrival at the lab to the release of validated result

Type of request	TAT
Blood gases	45 minutes
hs Troponin T Urgent requests	1 hour
Inpatient but non-urgent requests	4 hours
Outpatient requests	5 working days
Special tests (run in batches) e.g. HbA1c, endocrine tests	5 working days
Outsourced tests	Depends on referral lab

- Blood gases
- hs Troponin T
- Renal Profile
- Liver Function Test
- Bone Profile
- Glucose
- Calcium
- Magnesium
- Phosphate
- Bilirubin
- Creatine Kinase

- Amylase
- AST
- CRP
- Urine FEME (dipstick only)
- Urine Pregnancy Test
- Body Fluids Biochemistry

LIST OF 24 HR (ONCALL) TESTS

FSL & HbA1c are not part of 24hr/ oncall tests

Specimens received out-of-office hrs will be kept an analyzed on the next working day.

Tests that are run in batches:

- Thyroid function tests (TFT)
- Iron profile, Folate & vit B12
 > Every Wednesdays
- Other endocrine (hormone) tests: LH, FSH, E2, PROG, TESTO, PRL, CORTISOL
 > Every Thursdays

Turn-Around Time (TAT)

5 working days

HAEMOLYSIS

HAEMOLYSIS

What is haemolysis?

 Hemolysis is the breakdown of RBC and the release of intracellular contents into surrounding fluid (e.g. blood plasma)

How do you know when a blood specimen has been hemolyzed?

 Hemolysis cannot be detected until after the tubes have been spun.

How many types of haemolysis?

- **In-vivo (in the patient):** Due to medical conditions e.g. such as autoimmune hemolytic anemia or transfusion reaction.
- In-vitro (in the collection tube): Due to improper specimen collection, specimen processing or specimen transport.

HAEMOLYSIS

The first tube is not hemolyzed.

This sample is acceptable.



Tube number 2 is slightly hemolyzed, and may or may not be acceptable depending on the test.

Tubes 3 and 4 are grossly hemolyzed and will need to be recollected.

FACTORS AFFECTING HAEMOLYSIS IN PREANALYTICAL PROCESS





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Tel: 03-6126 5215 Faks: 03-6126 5212



Name		MRN	:
Order No		DOB	:
Order Date	: 02-12-2021	Gender	:
Location		Order From	:
Requester		NIRC	:
Collection Date	: 02-12-2021 06:07	Received Date	: 02-12-2021 06:12

Analyte	Results	Unit	Flag	Reference	Methodology
EDIM					
	74.0				
Total Protein	74.6	g/L		64.0 - 83.0	Biuret/endpoint (with blank)
Albumin	28.7	g/L	L	35.0 - 52.0	BCG-Citrate Buffer
Alanine Transaminase (ALT)	10.6	U/L		< 33.0	IFCC (w/out pyridox. phos)
Sample is haemolyzed (haemolytic Ind Suggest to repeat blood test with a ne	dex: 130). Haemolysis w sample if clinically i	may interfere v ndicated.	vith seru	im ALT and Direct Bilirubi	n measurement.
Alkaline Phosphatase	90.0	U/L		35.0 - 105.0	AMP Buffer rate (IFCC)
GGT	18.0	U/L		< 40.0	Other g-Glut-3-carboxy-nitro
Total Bilirubin	4.8	umol/L		<= 21.0	Diazonium salt
Direct Bilirubin	<1.5	umol/L		<= 5.0	Diazo method
Direct Bilirubin C-Reactive Protein	<1.5 37.6	umol/L mg/L	н	<= 5.0 < 5.0	Diazo method Particle enhanced turbidimetri

REJECT. Hemolysed sample. Informed SN Zulaiha at 6.39am on 02/12/2021 by MLT Lela

Comment for Order: Sample is haemolyzed (haemolytic Index: 130). Haemolysis may interfere with serum ALT and Direct Bilirubin measurement. Suggest to repeat blood test with a new sample if clinically indicated.

Verified by : Validated by :

Reported Date : 02-12-2021 06:42

Note: Test indicated with (*) are not Skim Akreditasi Makmal Malaysia (SAMM) accredited

WHY IS HEMOLYSIS AN ISSUE?

Impact the validity of test results

- Certain lab tests can be affected and the reported results will be inaccurate.
- Falsely decreases values such as Na, ALP, GGT, glucose, albumin
- Falsely elevates values such as K, ALT, AST, creatinine, CK, LDH, PO4, Mg

✓ Requires a repeat collection from the patient

- ✓ Delay in diagnosis/ treatment
- Patient discomfort & dissatisfaction
- ✓ Additional healthcare expenses

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.



ORDER OF DRAW

ORDER OF DRAW

- Specimens must be collected in the appropriate collection container, correctly labeled and transported promptly to the laboratory.
- 'Order of draw' is the <u>tube sequence</u> that a phlebotomist needs to follow while collecting blood.
- A correct Order of Draw ensures a good quality sample to be used for diagnostic purposes to provide accurate results.

Order of Draw: The Correct Tube Sequence



WHY IS THE ORDER OF DRAW IMPORTANT?

 If the order of draw is not followed, then the additives in one tube can be transferred to another, causing cross-contamination and inaccurate results.

 Inaccurate results may lead to misdiagnosis which may prevent patients from receiving the correct treatment.

GUIDELINES WHICH RECOMMEND 'ORDER OF DRAW'

Clinical and Laboratory Standards Institute (CLSI) Guideline: GP41 Collection of Diagnostic Venous Blood Specimens, 7th Edition, April 2017





Cornes M et al. Order of blood draw: Opinion paper by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE). Clin Chem Lab Med 2017;55:27–31





Can you spot the error?

Tests ordered:

- FBC (EDTA tube)

- Renal & Bone profile, Magnesium (SST gel tube) Patient's blood results:

K+ > 36.4 mmol/L (from analyser)

Others results: \downarrow ALP, \downarrow Ca2+, \downarrow Mg2+

Sample NOT HAEMOLYSED ... but Gives Erroneous Results!

The erroneous results are due to **contamination** with additives present in the **purple top tube** as **K-EDTA** additives bind with ALP, Ca2+ & Mg2+ giving low results \rightarrow importance of 'Order of Draw'.



IMPORTANT REMINDERS

- Separate request form is required for different Units (do not print on both sides of paper).
- Segregate samples into different biohazard bags according to the different Units.
- For dynamic function tests, inform CDL at least 1 day before performing the test and sending samples.
- Do check with the lab staff first before ordering add-on tests via UniMEDS.
 A new request form should be sent to the lab for the add-on tests.

Add-on tests can be requested for samples that has been sent to the lab, provided:

- Adequate sample volume remains after the initial tests have been completed
- ✓ Stability of the analyte(s) requested are still acceptable.

TOP 10 TIPS FOR REDUCING SAMPLE COLLECTION ERRORS

1. Before a sample is collected, ALWAYS check for the **CORRECT** patient's identity.

6. ALWAYS label the sample at the patient's side to prevent patient and specimen mix ups.

2. Ensure the **CORRECT** bottle is selected for the test(s) requested.

3. AVOID haemolysis during phlebotomy.

- 7. All samples MUST be labelled **CORRECTLY** with the appropriate Request Forms.
- 8. ALWAYS verify the accuracy of specimen labelling before you/ patient leaves the treatment area.

4. Use the **CORRECT** Order Of Draw to avoid sample contamination.

9. Use **CORRECT** urine containers with the **CORRECT** preservative for urine analysis.

5. Ensure sample tubes are **CORRECTLY** filled (esp. for tubes containing anticoagulant and for clotting studies).

10. If in doubt, **CONTACT the laboratory** or refer to the laboratory handbook.





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2.Anatomic Path 03-61265000 ext 5	ology Unit 5053 / 5244						
3.Haematology 8 03-61265000 ext 5	Transfusion Medicine (5215 / 5209	Unit					
4.Medical Microb 03-61265000 ext 5	biology & Parasitology U 5247 / 5246	Init					
Medical Specialis	st Centre UiTM Selayang	J:					
1.Selayang Camp 03-61264813	us Lab						

https://hospital.uitm.edu.my/images/departments/clinical/pathology/download/2021-CDL-Handbook-v11Oct.pdf





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DIGITAL MOBILE APPS



For further information:



First Edition, September 2021

Causes of in-vitro haemolysis include:

i.	small needle gauge
ii.	forcing blood into tube using syringe
	vigorous mixing of blood tubes
iv.	tubes transported horizontally

ANSW	ER	
Α.	i and ii	
В.	i and iii	
C.	i, ii and iii	
D.	All the above	

Causes of in-vitro haemolysis include:

i.	small needle gauge
ii.	forcing blood into tube using syringe
111.	vigorous mixing of blood tubes
iv.	tubes transported horizontally

ANSWI	ER
Α.	i and ii
B.	i and iii
С	i, ii and iii CORRECT!
D.	All the above

Fill in the blanks:

1.	Blood sample for HbA1c test is rejected if previous request is less than weeks interval.
2.	TAT for urgent Troponin test is hour.
3.	TAT for outpatient test request is working days.
4.	Hemolysis is detected (before/ after) the blood tubes have been spun.

Fill in the blanks:

1.	Blood sample for HbA1c test is rejected if previous request is less than _8_ weeks interval.
2.	TAT for urgent Troponin test is1_ hour.
3.	TAT for outpatient test request is _5_ working days.
4.	Hemolysis is detected <u>after</u> (before/ after) the blood tubes have been spun.



ANY QUESTIONS?

The online 'Laboratory Customer Survey' or 'Kaji Selidik Pelanggan Makmal' is available for further feedback on laboratory services.

Kindly click the links below to fill in the survey:

https://forms.gle/NWf8XSvugf56rs7n8 (English version)

https://forms.gle/vNEhurJJPAGeew8G7 (Bahasa Melayu version)