



SPECIMEN REJECTION IN CHEMICAL PATHOLOGY

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17 FEBRUARY 2023

Objectives

- Describe the general overview of processes involved in laboratory testing and relevance of specimen rejection.
- Explain specimen rejection criteria in chemical pathology testing.
- Explain significance of monitoring specimen rejection rate – specimen rejection rate at Chemical Pathology Unit in CDL HASA & CDL PPUiTM Sg Buloh
- Describe ways to minimise risks of selected rejection criteria



What are laboratory test results for?



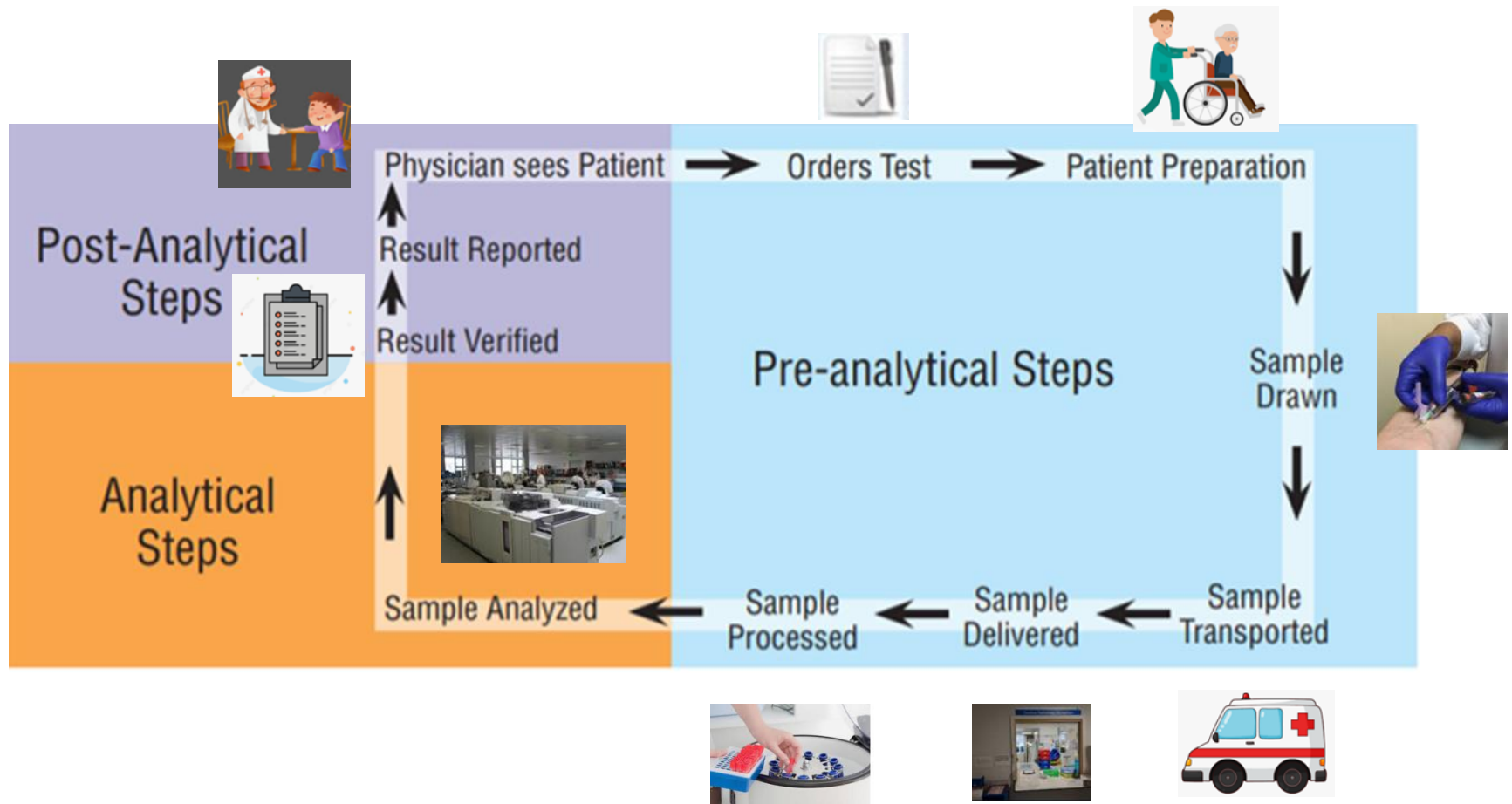
- Screening
- Diagnosis
- Prognosis
- Monitoring response to treatment / patient's progress
- Detection of complications

Chemical Pathology Tests & Associated Specimens



- General chemistry:
 - blood (serum / plasma) e.g., RP, LFT
 - urine e.g. urine FEME, electrolytes
 - body fluids e.g., csf, peritoneal fluid
- Tumour markers – serum
- Hormones – serum / plasma / urine
- Therapeutic drug monitoring (serum) e.g., vancomycin, phenobarbitone
- Special proteins (serum / whole blood) e.g., CRP, HbA1c

Total Testing Process



Specimen Rejection Criteria



- Objectives:
 - Ensure accurate test results – patient safety
 - Cost effective & appropriate patient care
- Requirement of MS ISO 15189
- Specimens that do not meet criteria are rejected



APPENDIX 11.4

SPECIMEN REJECTION FORM

Patient Name : _____

Registration No. : _____

Lab ID : _____

Requester (Clinic/Ward) : _____

Date & Time of Reception: _____

Test Request : _____

Reason for Rejection : _____

Defective label
Missing label
Wrong label
Incomplete Request form
Hemolyzed sample
Lipæmic 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
Repetitive test order/double request
Test is not clinically indicated
Out of sample stability
Test is not offered
Improper Specimen Collection
Others (specify: _____)



APPENDIX 11.4

ADDITIONAL SAMPLE REJECTION CRITERIA FOR CHEMICAL PATHOLOGY SAMPLES

1. HbA1c request is less than 8 weeks from previous testing.
2. Insufficient amount of urine
 - a. urine drug of abuse and urine toxicology - less than ¾ universal urine container
 - b. urine 24-hour cortisol and catecholamine – less than 750ml
3. Renin test is requested without aldosterone.
4. Renin and aldosterone sample are collected at different sampling time.
5. Free PSA is rejected when total PSA result is not within 2.5 – 10 ng/ml.

Specimen Rejection: Implication For Patient Care



- Inconvenience & discomfort of repeated specimen collection.
- Possible delays in critical value notification, ability to make diagnoses, decision on managing current therapy.
- Abandonment of tests

Specimen Rejection Rate

SERVICE STANDARD 15: PATHOLOGY SERVICES

There is tracking and trending of specific performance indicators which include but not limited to at least two (2) of the following indicators:

No	INDICATOR	TARGET	Reporting Frequency
1.	Timeliness of urgent requests		Monthly
2.	Rejection Rate of specimens	<1%	
3.	Notification of critical results.		Monthly



6TH EDITION HOSPITAL ACCREDITATION STANDARDS

PERFORMANCE INDICATOR

SPECIMEN REJECTION IN CHEM PATH UNIT PUNCAK ALAM



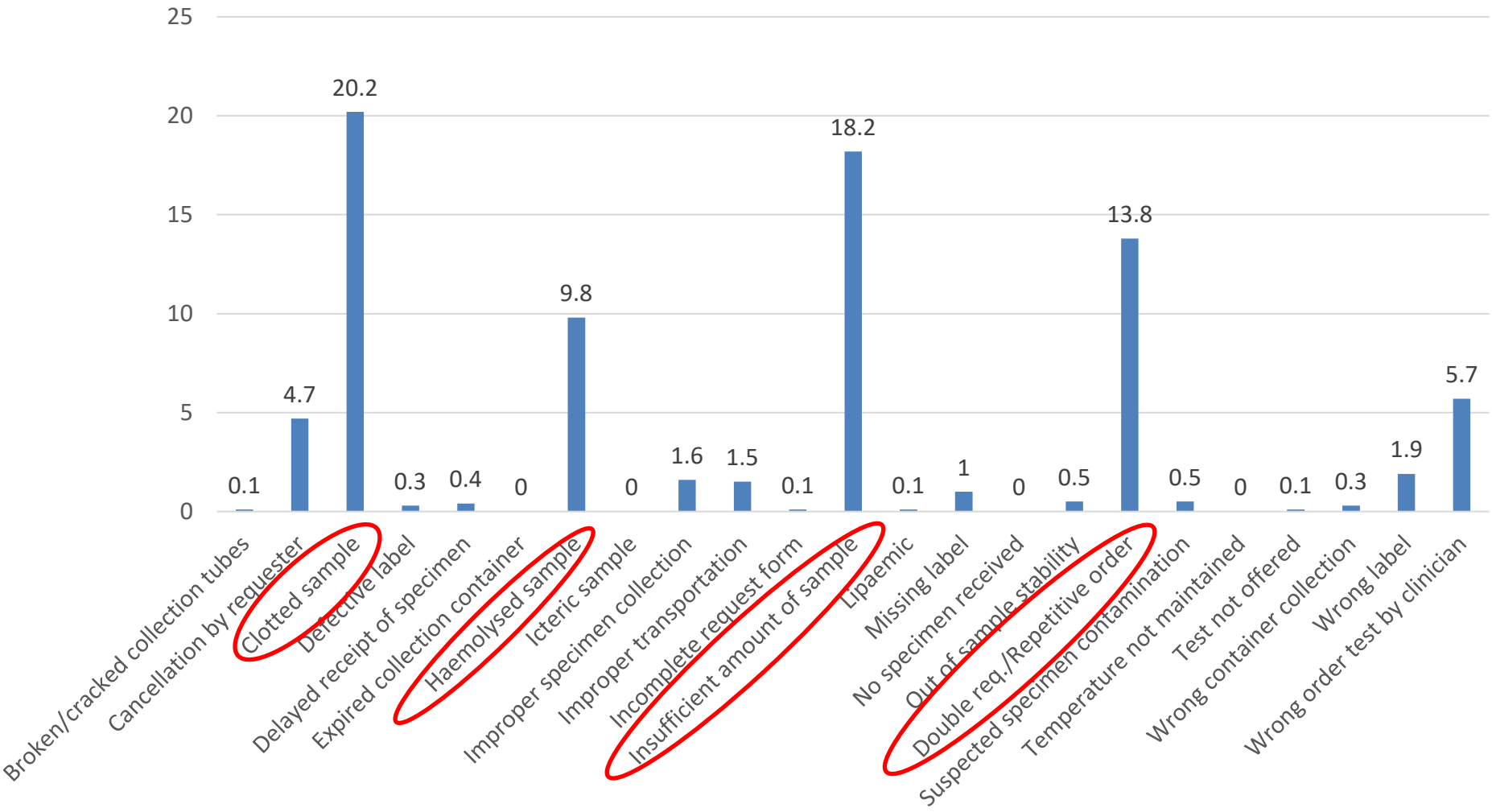
Duration	Jan – June 2022	July – Dec 2022
Rejection details		
Total specimens received	23,326	38,505
Total no. of rejected specimens	351	731
Percentage of rejection	1.5%	1.9%
Rejection criteria with the highest no. of cases	Clotted specimens	Clotted specimens
	20.2%	20.2%
The most rejected type of specimens (divided by denominator [total no of tubes received])	Serum (Plain tube)	Serum (Plain tube)
	out of 23,326 specimens received, 167 plain tubes were rejected (0.72%)	out of 38,505 specimens received, 363 plain tubes were rejected (0.94%)

TARGET: < 1.0%

SPECIMEN REJECTION IN CHEM PATH UNIT PUNCAK ALAM



PERCENTAGE OF REJECTION CRITERIA IN CHEMICAL PATHOLOGY UNIT, HASA PUNCAK ALAM FOR JULY - DECEMBER 2022



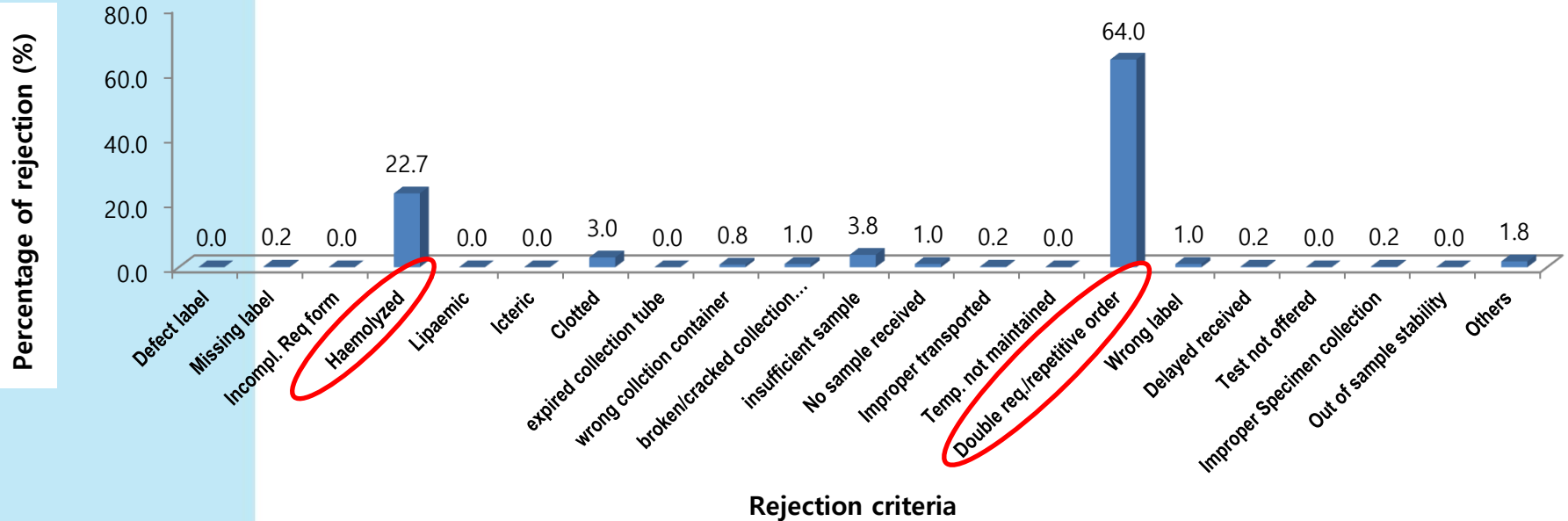
SPECIMEN REJECTION IN CHEM PATH UNIT SG BULOH



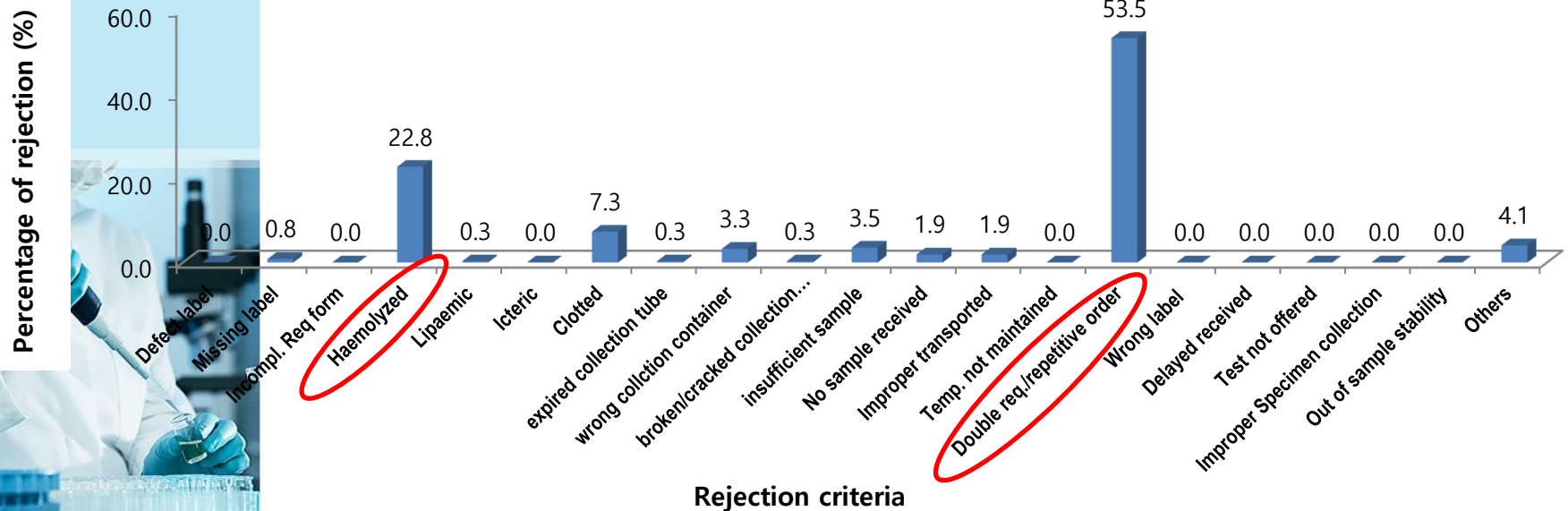
Duration	Jan – June 2022	July – Dec 2022
Rejection details		
Total specimens received	33,953	36,224
Total no. rejected specimens	497	368
Percentage of rejection	1.46%	1.02%
Rejection criteria with the highest no. of cases	Double request/repetitive order 318 from total of 497 rejection cases (64.0%)	Double request/repetitive order 193 from total of 368 rejection or 53.5%
	Highest percentage of requester with this rejection criteria : SBC Phlebotomy Unit (118 rejections)	Highest percentage of requester with this rejection criteria : SBC Phlebotomy Unit (130 rejections)
The most rejected specimen	Whole Blood (EDTA tube) Out of 497 specimens received, 301 (60.6%) specimens were rejected.	Whole Blood (EDTA tube) Out of 368 specimens rejected, 204 (55.4%) specimens were rejected

TARGET: < 1.0%

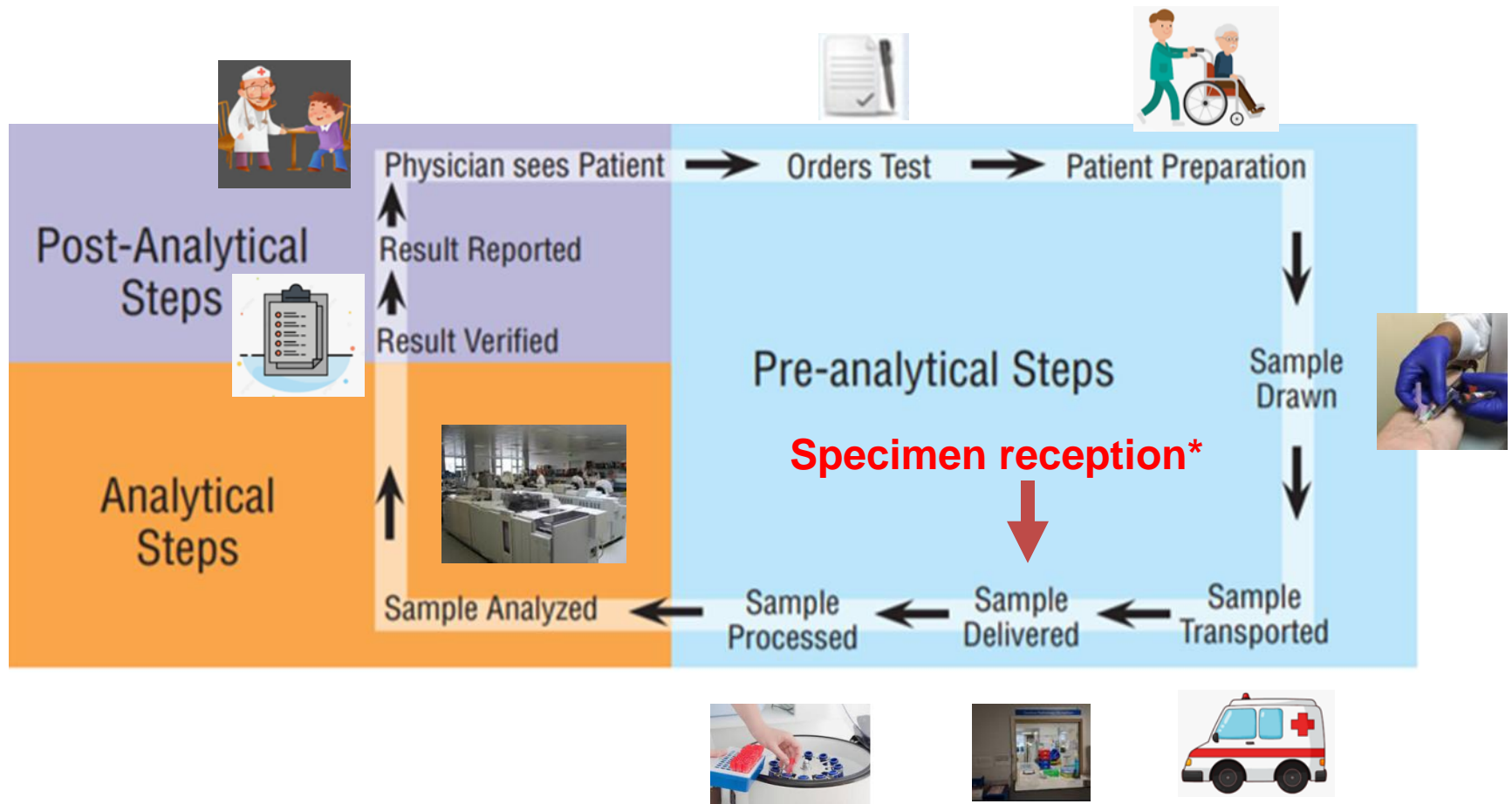
PERCENTAGE OF REJECTION CRITERIA IN CHEMICAL PATHOLOGY, CDL SG. BULOH (JANUARY - JUNE 2022)



PERCENTAGE OF REJECTION CRITERIA IN CHEMICAL PATHOLOGY, CDL SG. BULOH (JULY - DECEMBER 2022)



Total Testing Process



* Specimen rejection criteria applied

Clotted Blood Samples

- Causes:
 - Blood slow to fill the tube
 - Prolonged use of a tourniquet
 - Samples incompletely mixed
 - Syringe collect and slow transfer of sample
- Erroneous test results



<https://lab.waikatodhb.health.nz/assets/Guides/Haemolysed-or-Clotted-Samples-1.pdf>

Tangye SH. Questionable blood draws. *Laboratory Medicine*, Volume 40, Issue 9, September 2009, Page 565,
<https://doi.org/10.1309/LMNEW3EELDD4GN3Q>












Clotted Blood Samples

- Preventive measures to minimise risk of clotted blood samples:



- use Vacutainer system with an adapter/tube holder and straight needle or butterfly needle
- apply recommended number of inversion times
 - adequate mixing of sample & anticoagulant



Tube type by Order of draw		Additive (helps or prevent clotting)	Mixing – Inversion (1) →  (Secures good mixing with additive)	Let Clot For (Clot traps away from serum or plasma)	Centrifuge Before (separates serum or plasma from cells)
Top	Top				
Blue		Citrate	4 times	N/A	N/A
Dark Blue		Clot activator	8 times	60 minutes	2 hours after clotting
Red		Clot activator	8 times	60 minutes	2 hours after clotting
Gold		Clot activator with gel	5 times	30 minutes	2 hours after clotting
Green		Lithium (Li) Heparin with gel / Sodium (Na) Heparin	8 times	N/A	N/A
Lavender		K2EDTA	8 times	N/A	N/A
Pink		K2EDTA	8 times	N/A	N/A
Dark blue		K2EDTA	8 times	N/A	N/A
White		EDTA with gel	8 times	N/A	N/A
Grey		Sodium Fluoride Potassium oxalate	8 times	N/A	N/A



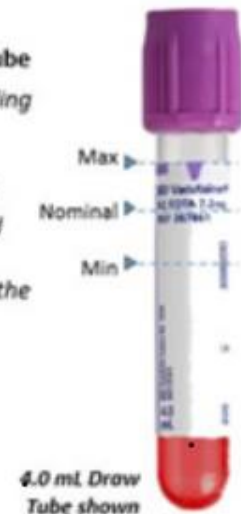
Insufficient sample volumes

Current Tube	BD Vacutainer® Tube	Volume	Instructions
		1.8ml 2.7ml	Check that the blood is level with or above the <i>Minimum Fill Indicator Line</i> Mix gently by inversion 3-4 times
	Sodium Citrate		
		5ml 8.5ml	Mix gently by inversion 6 times
	Serum Gel SSTII		
		8.0mL 5.5ml	Mix gently by inversion 8 – 10 times
	Lithium Heparin Gel PSTII Barricor		
		10.0ml	Mix gently by inversion 8 – 10 times
	Lithium Heparin No Gel		
		2.0ml 4.0ml 10.0 ml	Mix gently by inversion 8 – 10 times
	EDTA		
		8.5ml	Mix gently by inversion 8 – 10 times
	EDTA + GEL		
		6.0ml	Mix gently by inversion 8 – 10 times
	Crossmatch EDTA		
		2.0ml 4.0ml	Mix gently by inversion 8 – 10 times
	Sodium Fluoride Na ₂ EDTA		



BD Vacutainer™ EDTA Collection Tube
Ensure proper draw volume by holding tube up to this guide.

Sufficient volume check achieved if blood drawn falls within the dashed minimum and maximum fill lines illustrated on the tubes pictured to the right.



Double requests / Repetitive orders

Table 1 Recommended minimum time intervals for the repetition of some medical laboratory tests.

		References
HbA _{1c}	3 months in patients with diabetes mellitus undergoing insulin therapy, 6 months in patients with diabetes mellitus without insulin therapy, no specifications for use in the diagnosis of diabetes mellitus outside of pregnancy.	
Note:	Amended intervals in patients receiving transfusions or in the case of hemolysis [8, 11].	
Ferritin	2 months	[38]
Vitamin B12	2 months in case of suspected vitamin B ₁₂ deficiency Parenteral substitution requires repeat testing only at very long intervals. For enteral substitution, normalization of vitamin B ₁₂ is regularly achieved in the serum; analysis may be useful for compliance monitoring.	[38]
ANA	4 weeks, only if clinical picture changes and in connection with previous negative findings; serial measurements for standard activity determination are not recommended	[39–41]
ENA	4 weeks, only with conspicuous ANA	[40, 41]
dsDNA	6–12 weeks with active, 6–12 weeks with inactive Lupus erythematosus. This requires a conspicuous ANA.	[40, 41]
Note regarding requirements of autoimmune serology: the request is indicated only for corresponding clinical suspicion. Follow-ups are not generally advisable. The time intervals indicated refer to patients for whom a negative finding has been obtained and for whom, due to a change in the clinical picture, further clarification is needed.		
RF	4 weeks, except for Sjögren's syndrome	[40, 42]
AMA	4 weeks	[40]
ASMA	4 weeks	[40]
Parietal cell AB	4 weeks	[40]
IgG, IgA, IgM	4 weeks, to determine the CSF/serum ratio, if necessary more frequently	[40]
AFP	12 weeks	[40]
CEA	12 weeks	[40]
CA15.3	12 weeks	[40]
PSA	12 weeks	[40]
Note: To estimate the residual tissue after tumor removal, a repeated determination of tumor markers (such as β -HCG and AFP in connection with testicular carcinoma) is recommended at weekly intervals [7, 43].		
Urine albumin/g creatinine	2x, in discrepant cases, 3x analysis on 2 and/or 3 non-consecutive days necessary (to exclude renal involvement with diabetes mellitus)	[44]
Creatinine	1 day (after application of X-ray contrast media) – 6 months as checkup for diabetic patients	[44–46]
Infectious serology (depending on the immune status of the patient and/or the presumptive stage of the disease) ^a		
	Patients	Seronegative
HBS-Ag	180 days	7 days
Note: In case of isolated positive result of HBS-Ag ELISA, after 30 days test for HBV-DNA, as well as in case of suspected escape mutants [47].		
Hbs-Ab, Hbc-Ab, Hbc-IgM Ab, Hbe-Ag, HBe-Ab	180 days	25 days [48–50]
HCV-Ab	180 days	25 days [51]
HCV-RNA	60 days	7 days [51]
HIV-Ab	–	28 days [31]

^aA follow-up regarding a continuing clinical problem – especially in the early phase of infection – may be necessary at intervals of several days, with an individual assessment especially of IgM/IgA antibodies.

Orth M, Aufenanger J, Hoffman G, Hoffman W, Klosson R, Lictinghagen R, et al. Recommendations for the frequency of ordering laboratory testing. *J Lab Med* 2014; aop. DOI 10.1515/labmed-2014-0045



Haemolysis

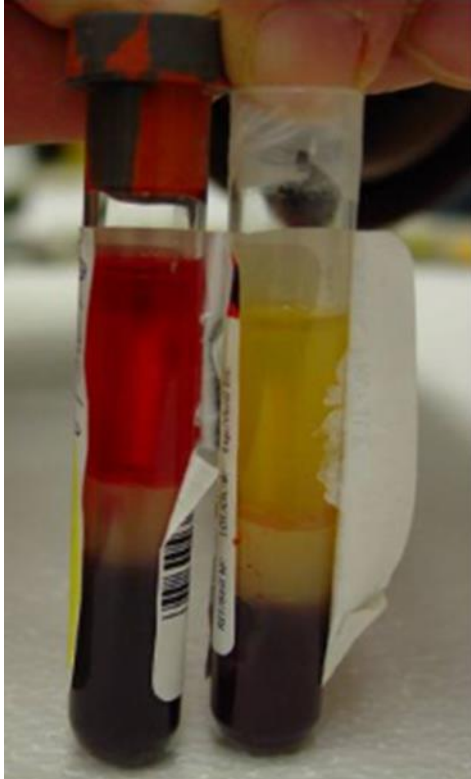


Table 1. Some of the reported causes of haemolysis.^{14–20}

Collection into syringe with excessive suction applied to plunger or aspiration against resistance

Collection through an intravenous cannula, especially if:

The cannula is partially obstructed

Blood froths due to a loose connection in the collection assembly

Syringe transfer into sample tube, particularly if force is used
'Traumatic' collection

Site of collection other than antecubital fossa

Use of smaller gauge needles

Errors in handling, including:

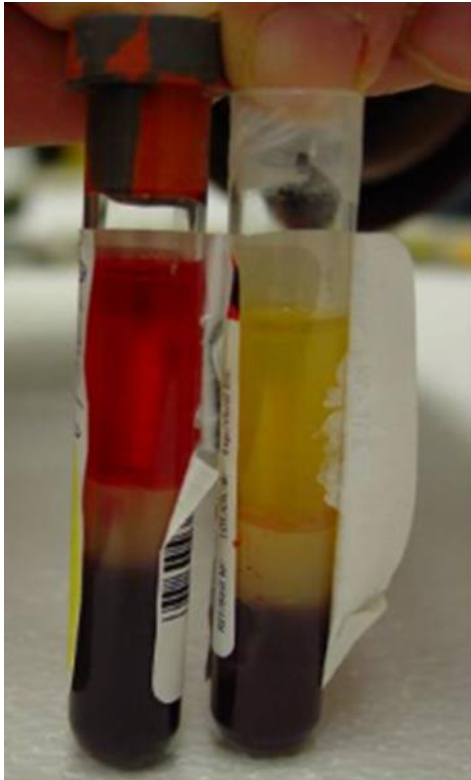
Freezing the sample

Vigorously shaking the sample tube

Extracorporeal circulation

In-vivo haemolysis

Haemolysis



HOW DOES HAEMOLYSIS IMPACT LABORATORY TESTING?

- LYSIS OF RBCS RELEASES INTRACELLULAR CONSTITUENTS (E.G., AST, LDH & POTASSIUM) → FALSELY ELEVATED LEVELS
- HAEMOLYSIS RELEASES PROTEASES FROM RBCS THAT CAN DEGRADE PROTEINS, E.G., INSULIN AND CARDIAC TROPONIN → FALSELY LOWER LEVELS
- EXCESS HAEMOGLOBIN & OTHER CONSTITUENTS IN THE PLASMA/SERUM CAN INTERFERE WITH SPECTROPHOTOMETRIC MEASUREMENTS

Haemolysis



The risk of haemolysis can be minimised by:

- Avoid pulling or pushing on the plunger when collecting blood using a syringe – allow blood to flow into evacuated tube
- Use Vacutainer system with an adapter/tube holder and straight needle or a butterfly needle – prevent “pushing” blood into tubes as both systems allow the blood to flow from the vein into the tubes.
- Avoid collecting from sites other than antecubital area
- Avoid excessive shaking of the tube - samples should be inverted gently 8 - 10 times to mix with anticoagulants.
- Needle size – avoid using small needles (> 21 gauge)
- Avoid extended tourniquet time (more than 2 mins)
- Allow the antiseptic used for collection to dry before collecting blood
- Avoid patient fist pumping can cause haemolysis.



<https://lab.waikatodhb.health.nz/assets/Guides/Haemolysed-or-Clotted-Samples-1.pdf>

Tangye SH. Questionable blood draws. *Laboratory Medicine*, Volume 40, Issue 9, September 2009, Page 565, <https://doi.org/10.1309/LMNEW3EELDD4GN3Q>



Quiz time!



The following are criteria for specimen rejection

EXCEPT:

- A. Clotted specimen
- B. Missing label
- C. Insufficient sample
- D. HbaA1c test request 10 weeks from previous testing

A scientist in a white lab coat and blue gloves is working in a laboratory. The scientist is holding a pipette and a small vial. In the background, there are various pieces of laboratory glassware, including a round-bottom flask containing a yellow liquid, a beaker, and a graduated cylinder. The scene is lit with a cool, blue light, creating a professional and scientific atmosphere.

Thank you