

# Reliable Results and Zero Rejection for COVID-19 Test

Customer Education Series 2-2021 CDL

9<sup>th</sup> Dec 2021

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# Content

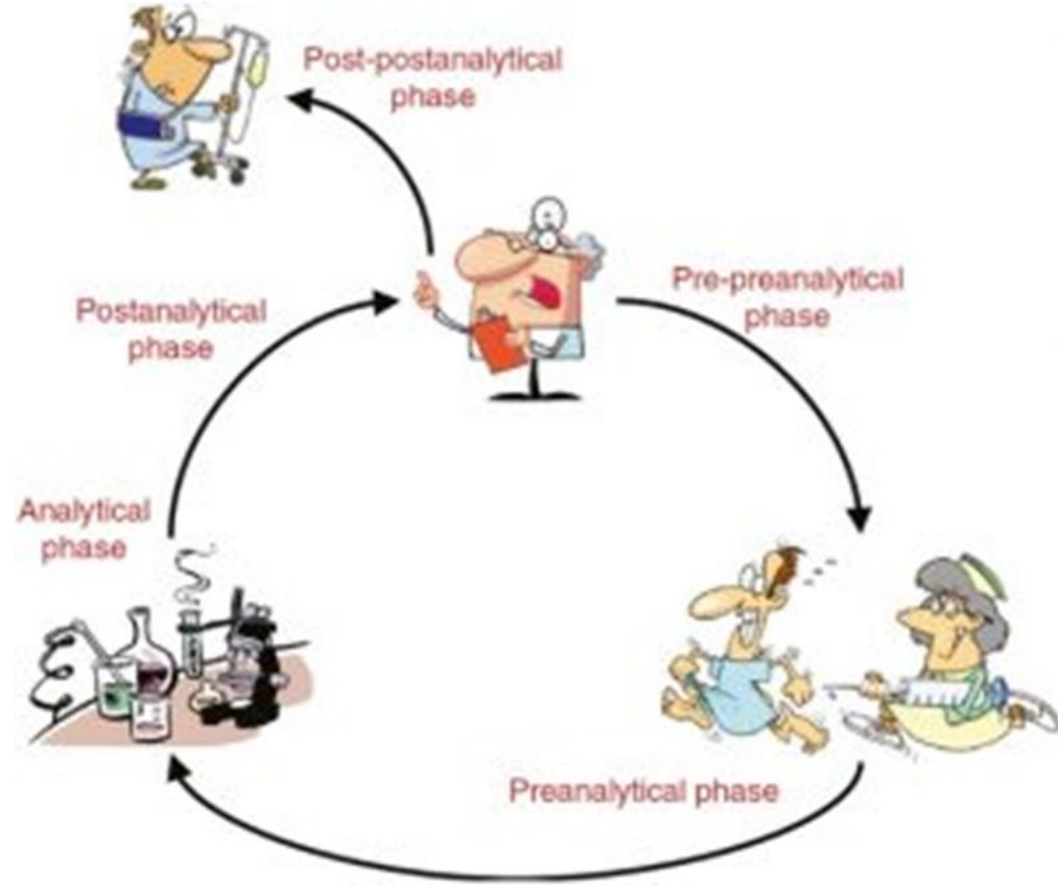
- COVID-19 (SARS-CoV-2) tests in HUiTM
- What is a reliable results?
- What is 'Pre-analytical phase'?
- How to not get rejected request?

# SARS-CoV-2 tests

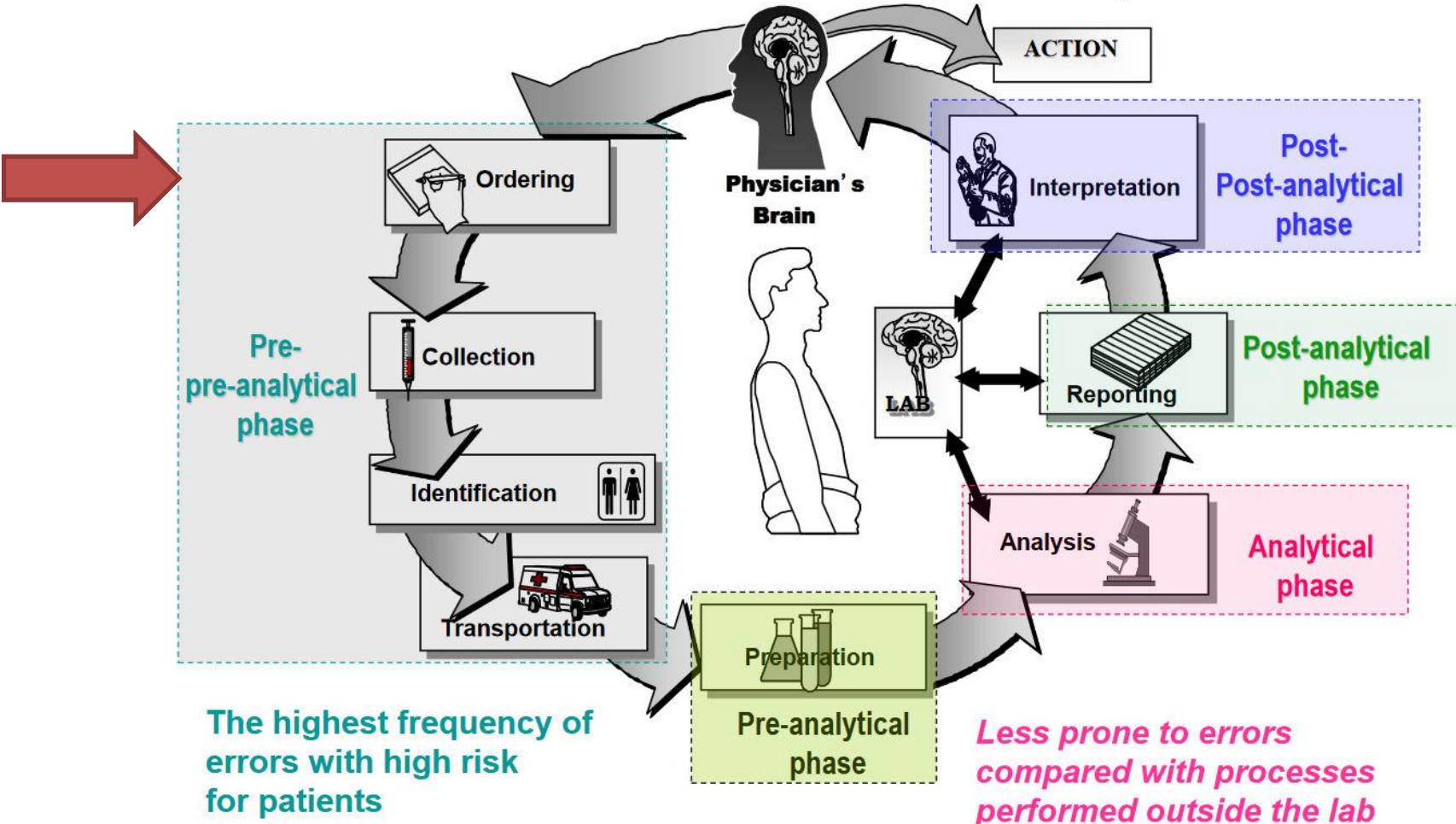
	Molecular test (RT-PCR)		Antigen test (RTK-Ag)	Antibody test (IgM / IgG)
	Laboratory test	Rapid test		
Availability in HUiTM	Temporarily no	Puncak Alam	Sungai Buloh Puncak Alam	No
Detect	Current infection	Current infection	Acute infection	Past infection
Detect 'dead' virus	Yes	Yes	No	No
Sensitivity	High	High	Moderate	N/A
Specificity	High	High	High	N/A

# Reliable test result

comes from reliable test  
request during pre-  
analytical phase



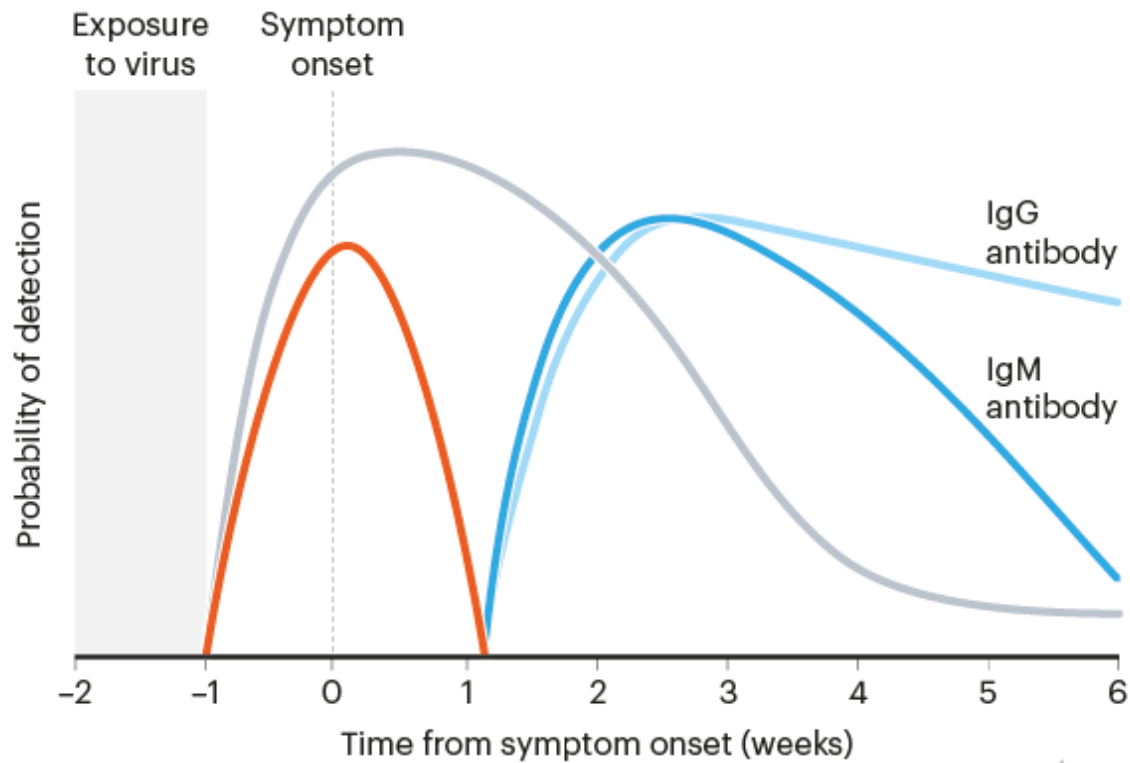
# What is the Pre-analytical phase?



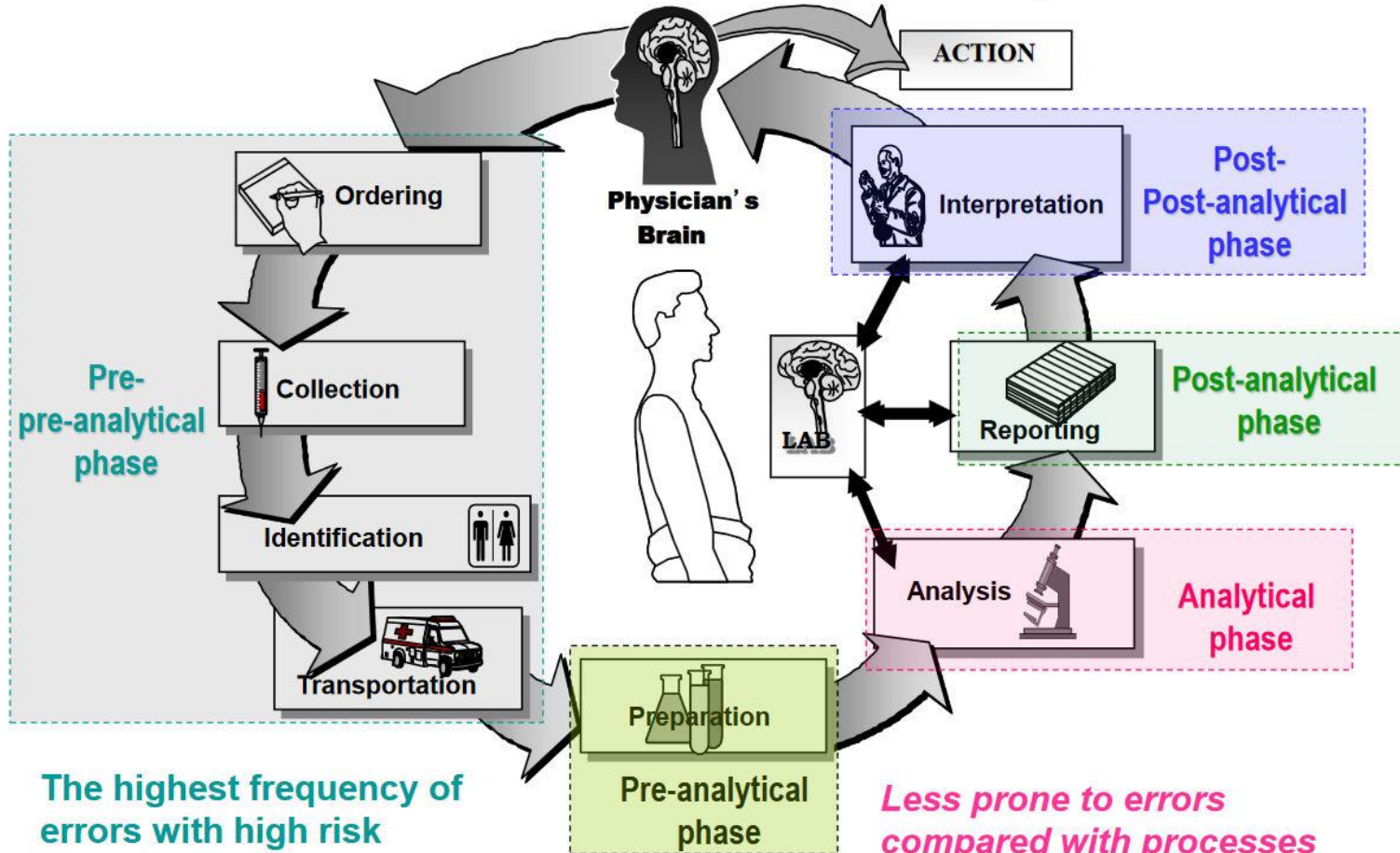
# Ordering / Requesting

- Correct patient
- Correct time for diagnostic test
  - RT-PCR & RTK-Ag: At least 3 days post-exposure
  - RTK-Ag test: within 1 week before & after symptom onset
- Correct time for screening test
  - RTK-Ag: after 1 month of acute infection
  - RT-PCR: after 3 months of acute infection
- Correct test

- **PCR-based tests** can detect small amounts of viral genetic material, so a test can be positive long after a person stops being infectious.
- **Rapid antigen tests** detect the presence of viral proteins and can return positive results when a person is most infectious.
- **Antibody tests** detect the body's immune response to the virus and are not effective at the earliest phase of infection.



# What is the Pre-analytical phase?



The highest frequency of errors with high risk for patients

Less prone to errors compared with processes performed outside the lab



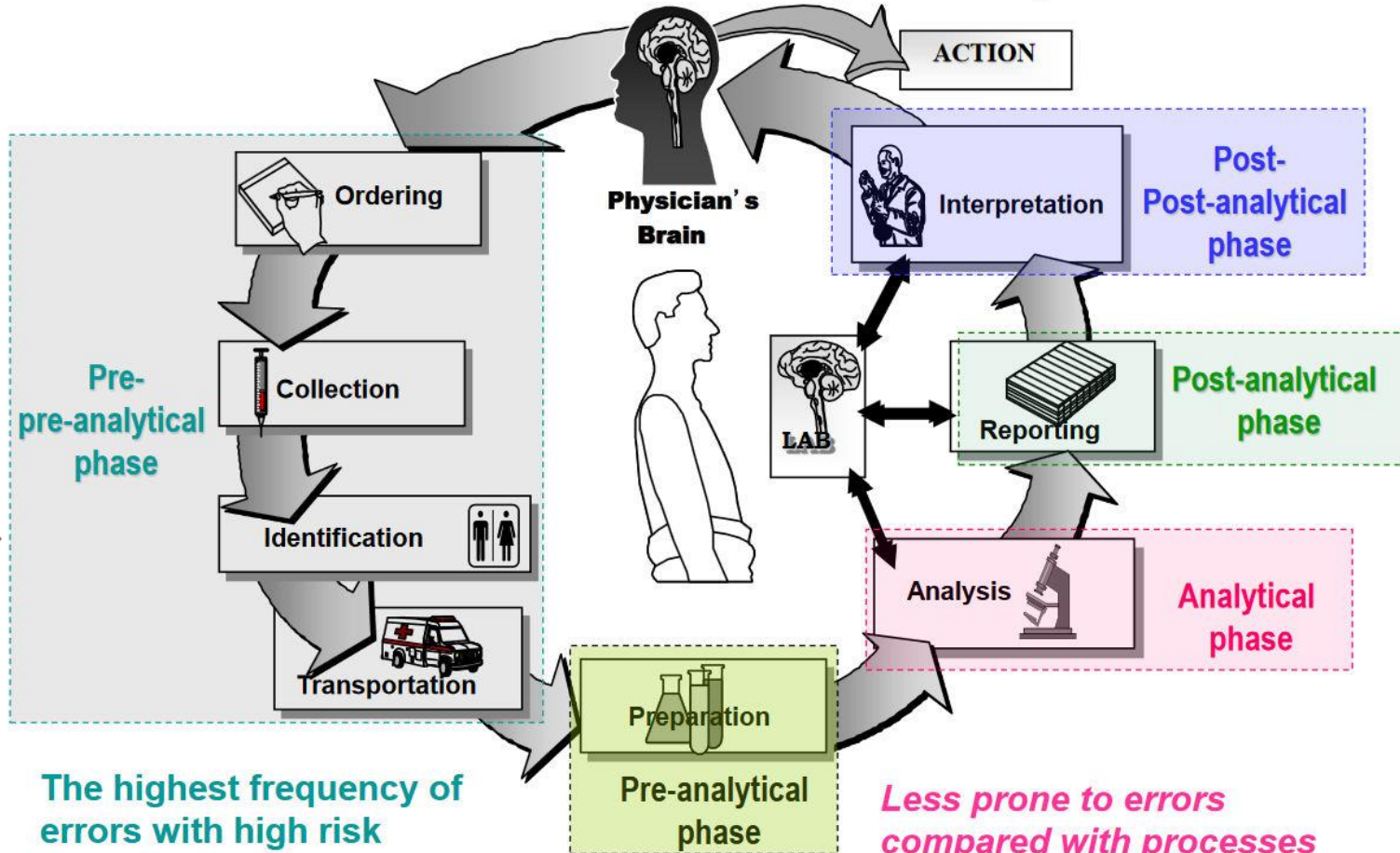
# Collection

- Correct method
  - Heavily blood-stained, ? false positivity
- Correct volume
  - Insufficient quantity, ? false negativity
- Correct specimen container
  - VTM preserve viability of RNA during transportation and storage
- Correct time
  - Convenient sampling vs ordered sampling

## Viral Transport Media (VTM)



# What is the Pre-analytical phase?



The highest frequency of errors with high risk for patients

Less prone to errors compared with processes performed outside the lab

# Identification

- Correct label
- Sufficient info on label
- Accompanying request for specimen

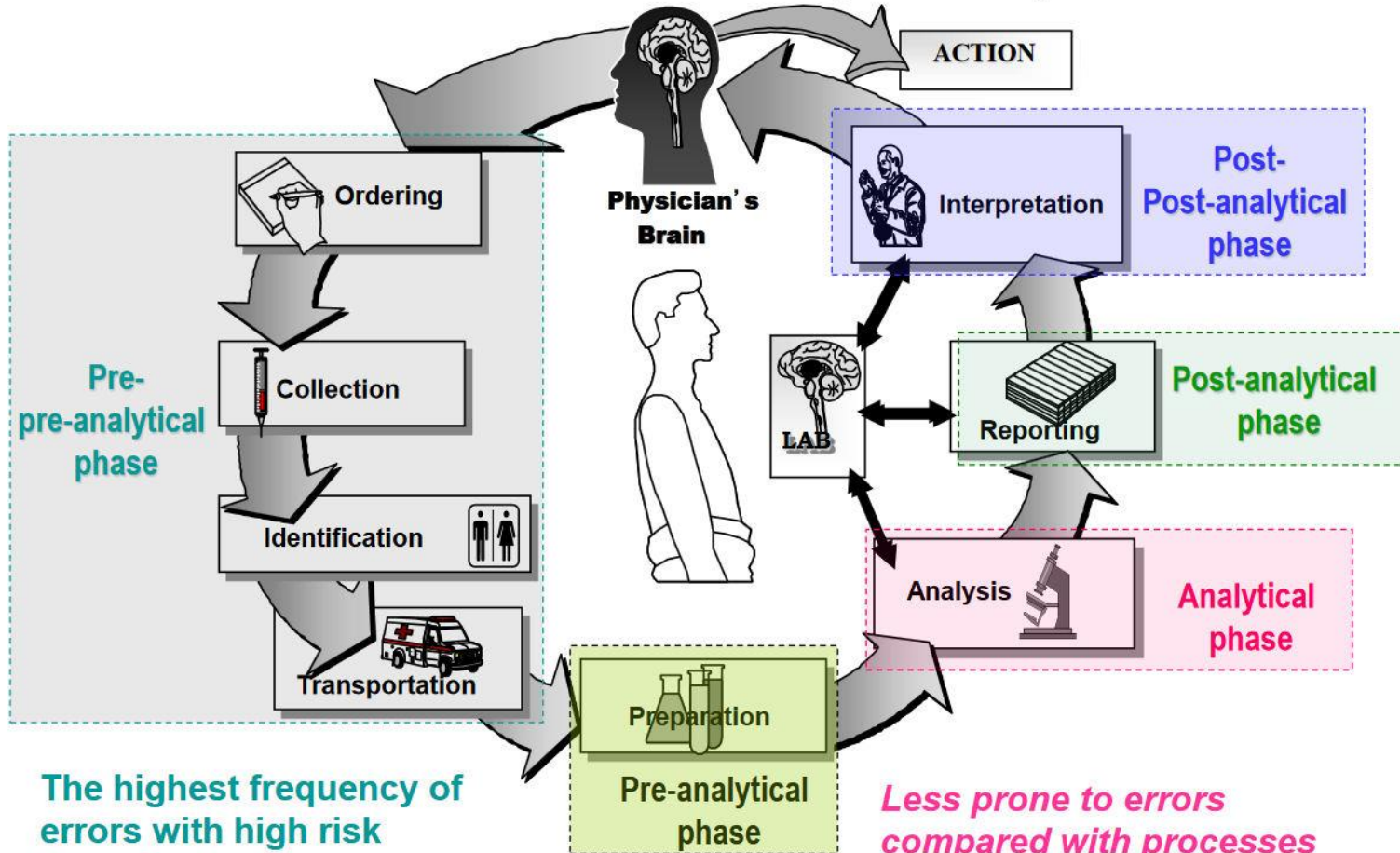
## Unlabelled specimen



## Adequately labelled specimen



# What is the Pre-analytical phase?



The highest frequency of errors with high risk for patients

Less prone to errors compared with processes performed outside the lab

# Transportation

## - Correct temperature

- Sample must be kept between 2-8°C



# Transportation - time duration

- RTK-Ag test must be performed within 4 hours of specimen collection





# Rejected Medical Microbiology test request including COVID-19 (Jan-Oct 2021)

Reason	Number
Test not indicated	97
Wrong test	94
Cancelled by requester	27
Duplicate request (others)	36
Duplicate request (serology)	24
No specimen	14
Heavily blood-stained	10

# Garis Panduan Pengurusan COVID-19 di Malaysia

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## ANNEX 4







- Annex 4a : Senarai Makmal Yang Menjalankan Ujian RT-PCR Bagi COVID-19 - 02/12/2021 **更新**
- Annex 4b : Senarai Pegawai Untuk Dihubungi Untuk Penghantaran Sampel Di Luar Waktu Pejabat, Hujung Minggu Dan Cuti Umum - 22/03/2020
- Annex 4c : Guideline On COVID-19 Testing Using Antigen Rapid Test Kit (RTK-Ag) Version 6 - 28/06/2021
- Annex 4d : Carta Alir Permohonan Bagi Makmal COVID19 - 14/08/2020
- Annex 4e : Standard Operating procedure (SOP) RT-PCR Testing Laboratory - 14/08/2020
- Annex 4f : Application Form For SARS-CoV-2 RT-PCR Testing Laboratory Laboratory- 14/08/2020
- Annex 4g : Garis Panduan Pengurusan Penggunaan Kit Ujian Kendiri COVID-19 - 23/07/2021
- Annex 4h : Guide For COVID-19 Rapid Molecular Testing
- Annex 4i : Guideline On The Use Of Deep Throat Saliva To Test For COVID-19 By RT-qPCR - 19/05/2021

## ANNEX 5

- Annex 5a : Laboratory Biosafety Guidelines for Handling and Processing Specimens
- Annex 5b : Specimen collection, packaging, transportation and storage - 23/11/2020
- Annex 5c : Laboratory Diagnosis of SARS-CoV-2 in Suspected Case of COVID-19 Admitted to the Hospital - 23/11/2020
- Annex 5d : Clinical Sampling for OPS/NPS at Health Centre and Field Setting - 24/03/2020
- Annex 5e : Protocol On COVID-19 Rapid Molecular Testing For The Health Facilities, Ministry of Health Malaysia, Version 1.0 - 30/10/2020

# Other Medical Microbiology unit related matter

## PATIENT DETAILS

**Report No.** : IR/2021/050  
**MRN** :   
**Identification Card No.** :   
**Name** :   
**Age** :   
**Gender** :   
**Race** :   
**Patient Type** : Inpatient  
**Patient Status** : Alive  
**Date and Time of Incident** : 02-12-2021 08:30:00  
**Location of Incident** : CICU  
**Diagnosis** : IHD 3 vessel disease

## INFORMATION FROM REPORTER OF THE INCIDENT

**Name of Department** : Cardiovascular & Thoracic Service Centre  
**Type of Incident** : Actual  
**Category of Incident** : Infective screening not run by Lab