COVID-19 Sample Handling Standard Operating Procedure for MAGLUMI 2019 nCoV IgM/IgG

1 Preparation

1.1 Statement

This document is only for reference, customers should make necessary adjustments based on the advices from their national health department.

1.2 Personal Protection

It is vital to ensure the biosafety of the laboratory personnel. Appropriate personal protective equipment should be worn at all time in the laboratory by laboratory personnel handling the specimens from patients suspected or confirmed to be infected with COVID-19. Personal Protective Equipment includes: disposable gloves, medical protective suit, protective goggles or glasses, surgical mask.

Besides, appropriate competence training and practices are also very important, for further information, please refer to the Laboratory Biosafety Guidance Related to Coronavirus disease 2019(COVID-19) by WHO.

1.3 Environment

High risk area and low risk area should be separated to prevent cross-infection.

Areas the samples pass through before inactivation should be classified as high risk areas.

Disinfection Measures should be taken every day in the high risk areas and the equipment. For example, wipe the platforms in the high risk areas and the equipment involved with gauze soaked in 75% alcohols, sterilize the high risk area by exposing the area in germicidal UV light at least once a day.

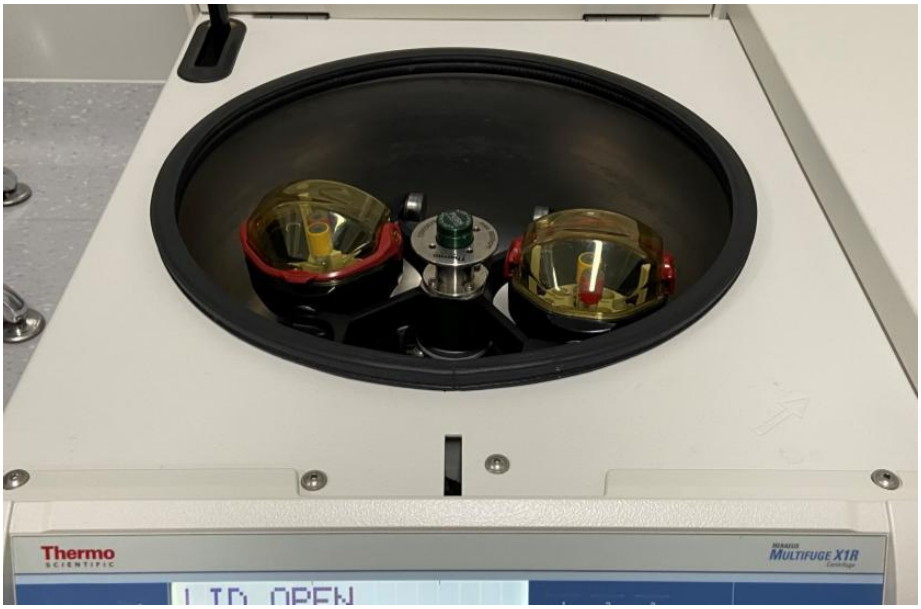
1.4 Material

Picture 1-1 SST Serum Separation Tube with Additive of Separating Gel and Procoagulant

It is recommended to use SST serum separation tube with additive of separating gel and procoagulant, this is to avoid hemolysis or protein precipitation during inactivation.

1.5 Equipment

Picture 1-2 Laboratory Water Bath



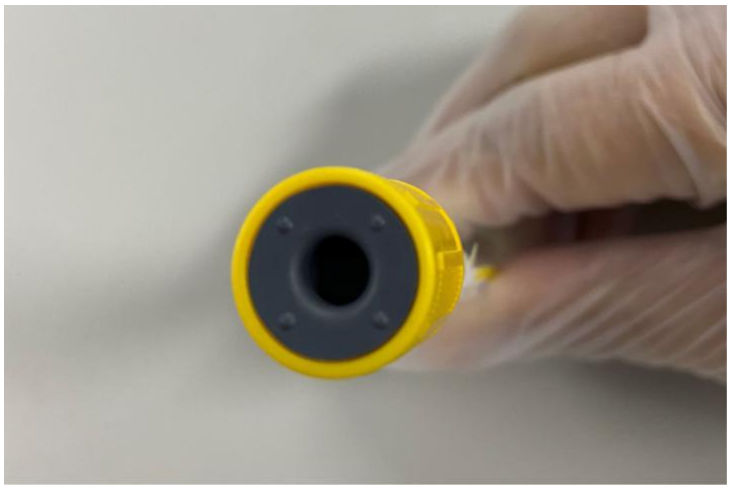
Picture 1-3 Centrifuges

2 Sample Pre-treatment Procedures

2.1 Blood Collection

Use SST Serum Separation Tube with Additive of Separating Gel and procoagulant to collect samples. Be careful when unplugging the blood collecting needle. Avoid blood to drop on the outside of the tube. If there is blood dropping on the outer surface of the tube when unplugging, clean the tube with the alcohol pads.

Do not open the tube cap before finishing inactivation to prevent the operators from being exposed.



Picture 2-1 Sterilize the Tube Cap with Alcohol Pads

2.2 Clot Activation

After collecting samples, set aside the samples to activate sample clotting.

Place the samples in a 37℃ water bath for 30 minutes or in room temperature for 1 hour. Samples from patients that received anticoagulant or thrombolytic therapy may take longer time to form clots.

When a sample finishes clotting, the sample should be slightly layered, and the lower layer should be clotted.

2.3 Centrifuge

After the sample finishes clotting, it should be centrifuged in a speed of 10,000 RCF for 10 minutes.

Before centrifugation, make sure to balance the centrifuge after loading samples. If not, the centrifuge may be damaged.

2.4 Inactivation

After centrifugation, the samples need to be inactivation before further operation. This is to lower the risk of infecting operators or contaminate the equipment and areas in the further operation.

Picture 2-2 Laboratory Water Bath for Sample Inactivation

For inactivation, place the samples in a laboratory water bath of 56℃ for 30 minutes.

2.5 Cooling Down

After inactivation, the samples need to be cooled down before test. This is to prevent the samples from forming aerosol, and sample results from being affected by the high temperature.

Place the samples in the 4℃ refrigerator or in the room temperature till the sample completely cool down.

2.6 Sample Test

Test the samples in MAGLUMI Automatic Chemiluminescence Immunoassay Analyzer. Please operate gently while handling the samples.

If possible, de-cap the sample tubes in a biological safety cabinet.

2.7 Specimens Discard

Recap the sample tubes before discarding the samples that finishes testing. Then discard the specimens in a safe and acceptable manner and in compliance with prevailing regulatory requirements.