# Enhanced Safety Considerations


## Specimens and Samples

### Heightened Control Measures for Collecting, Processing, and Testing for Hemostasis and Platelet Function Studies

BIO/DATA CORPORATION
An ISO 13485 Registered Company

www.biodatacorp.com
customer.service@biodatacorp.com

# COVID-19: Abnormal Clotting Common In Severe Disease

"Endothelial damage and subsequent clotting is common in severe and critical COVID-19 Coronavirus. Clots in the small vessels of all organs, not only the lungs but also including the heart, the liver, and the kidney," were described by Bin Cao, MD, of the National Clinical Research Center for Respiratory Diseases in Beijing, who helped develop treatment strategies there from the beginning of the epidemic. The virus can bind to the endothelial cells and may cause damage to the blood vessel especially the microcirculation of the small blood vessels," which leads to platelet aggregation, he said. "You can imagine that it is not a myocardial infarction, it is not a stroke, it is the clots all over the body. Those on antiplatelet drugs should stay on them while checking closely for bleeding"

*- Crystal Phend, Senior Editor, MedPage Today March 24, 2020*

## CLINICAL LABORATORIES ARE BIOSAFETY LEVEL 2 LABORATORIES



- Post Biosafety Signs on All Entrances
- Restrict Access to Laboratory Staff Only
- Secure Locations for Drop Off, Handling and Processing Specimens
- Follow Appropriate Precautions for Specimens
- Use Disinfectants with Known Anti-Viral Activity
- Adhere to Personal Protection Equipment (PPE) Requirements
- Update and Review Personnel Training for Essential Precaution and Containment Practices
- Recommend BSL 2 Personal Protective Equipment (PPE): Gloves, Solid Front Gowns, Scrub Suits, Head Coverings, Goggles or Face Shields, and Fit-Tested Respirators (N95 or Equivalent)

## EPA LIST N: SELECTED DISINFECTANTS AND CONTACT TIMES

| DISINFECTANT | CONTACT TIME | DISINFECTANT | CONTACT TIME |
|---|---|---|---|
| Sodium Hypochlorite | 1 Minute | Clorox® Germicidal Spray | 1 Minute |
| Asepticare | 2 Minutes | Clorox® QS | 2 Minutes |
| Lysol® All Purpose Cleaner | 2 Minutes | Lonza Disinfectant Wipes Plus | 4 Minutes |
| Purell Disinfectant Wipes | 5 Minutes | PureBright Germicidal Bleach | 5 Minutes |
| CPPC Ultra Bleach 2 | 5 Minutes | Maquat (Various) | 10 Minutes |

## SUMMARY OF BSL 2 SAFETY PRACTICES

| BIOSAFETY LEVEL | AGENTS | PRACTICES | SAFETY EQUIPMENT Primary Barriers | FACILITIES Second Barriers |
|---|---|---|---|---|
| 1 | Not Known to Consistency Cause Disease in Healthy Adults | Standard Microbiological Practices | None Required | Laboratory Bench and Sink Required |
| 2 | Agents Associated with Human Disease Routes of Transmission Include Percutaneous Injury, Ingestion, Mucous Membrane Exposure | BSL-1 Practice Plus: Limited Access; Biohazard Warning Signs; Sharps Precautions Biosafety Manual Defining Any Needed Waste Decontamination or Medical Surveillance Policies | Primary Barriers: Class I or II BSCs or Other Physical Containment Devices Used for All Manipulations of Agents that Cause Splashes or Aerosols of Infectious Materials; PPEs: Laboratory Coats; or Gloves; Face Protection As Needed | BSL-1 Plus: Autoclave Available |

## REVIEW / UPDATE 6 CORE PROCESS

1. Appropriate Use and Disposal of PPE at Each Workstation
2. Proper Collection, Transportation, Acceptance, Retention and Disposal of Specimens
3. Centrifuge Specimens in a Rotor with Safety Cups or in Un-Opened Primary Specimen Collection Tubes
4. Keep Test Specimens, Samples and Aliquots Capped at All Times
5. Decontaminate Work Area and Instrumentation, Centrifuges, and Pipettes Periodically
    a. Know the Required Contact Time for Disinfectant Solution in Use
    b. Wash or Sanitize Hands Thoroughly After De-Gloving
6. Follow UN3373 (Category B) Regulations for Packaging and Shipping of Samples to Reference Laboratories or the Procedure Provided by the Reference Laboratory

# Specimen Collection and Sample Preparation

## SPECIMEN COLLECTION:

1. Put On PPE as Required by Laboratory or Hospital Policy Prior to Entering the Patient Room
2. Take Only the Supplies Necessary to Collect and Secure the Test Specimen (s)
    a. Use Evacuated Specimen Collection Tubes
    b. Label the Tubes and Biohazard Transport Bag Prior to Entering the Patient Room
        i. Verify Patient Identification at the Bedside
3. Prepare the Venipuncture Site in Accordance with Laboratory Policy
4. Collect the Required Number of Tubes Using a Winged Needle Collection Kit
5. Place the Specimen Tubes in the Labeled Biohazard Specimen Transport Bag
6. Dispose of the Winged Needle Set, Tourniquet, and Other Used Items in the Proper Biohazard Waste Containers in the Patient Room
7. Exit the Patient Room with the Bagged Specimen Tubes
8. Remove PPE in Accordance with Hospital Instructions

9. Wash or Sanitize Hands Thoroughly
10. Re-Glove and Place the Bagged Specimen Collection Tubes Into a Second Labeled Biohazard Specimen Transport Bag, then De-Glove
11. Transport the Specimen to the Laboratory Processing Area

*NOTE: It is Especially Important to Assess the Specimens for Acceptability. Hemolyzed, Lipemic or Icteric Specimens Must be Rejected and Properly Disposed of as Infectious Waste.*

## SAMPLE PREPARATION:

1. Put On the PPE Required by Laboratory Policy / BSL 2 Guidelines
2. If the Workstation, Centrifuge or Analyzer Appear Contaminated or Have Been Used Previously, Decontaminate the Area and Instrumentation with an Approved Disinfectant
    a. Make Sure to Observe the Required Contact Time for Effective Decontamination

3. Confirm Patient Identification by Checking the Test Request
4. Place the Closed Specimen Collection Tubes in a Centrifuge Rotor with Biosafety Cups or Use a Centrifuge in a Biosafety Hood or Enclosure
5. Follow Laboratory Procedure for the Preparation of Platelet Rich Plasma

6. To Harvest the Platelet Rich Plasma, Carefully Open One Specimen Collection Tube at a Time
    a. Cover the Cap with a 2 x 2 Gauze Pad to Contain Any Aerosolization while Removing the Cap
7. Transfer PRP to a Labeled Plastic Sample Tube Using an Electronic Pipette Preset to a Low Dispense Rate
8. Carefully Re-Cap the Specimen Collection Tube
9. Tightly Cap the Labeled Plastic Sample Tube
10. Repeat with Each Specimen Collection Tube
11. Dispose of All Pipette Tips as Biohazardous Waste

## PREPARE PLATELET POOR PLASMA (PPP) OR PLATELET FREE PLASMA (PFP) AFTER HARVESTING PLATELET RICH PLASMA (PRP):

1. Return the Closed Specimen Collection Tubes to the Centrifuge (as above) and Follow the Laboratory Procedure for the Preparation of Platelet Poor or Platelet Free Plasma
2. To Harvest the Platelet Poor or Platelet Free Plasma, Carefully Open One Specimen Collection Tube at a Time
    a. Cover the Cap with a 2 x 2 Gauze Pad to Contain Any Aerosolization while Removing the Cap

3. Transfer PPP or PFP to a Labeled Plastic Sample Tube Using an Electronic Pipette Preset to a Low Dispense Rate and then Re-Cap the Specimen Collection Tube
4. Tightly Cap the Labeled Plastic Sample Tube
5. Repeat with Each Specimen Collection Tube

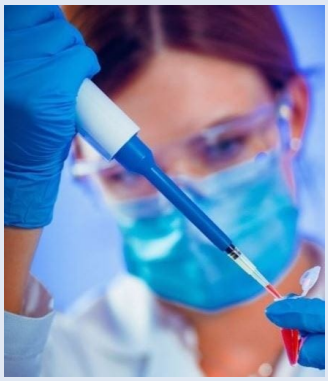
*NOTE: For Coagulation Tests, Follow the Platelet Poor or Platelet Free Plasma Instructions .*

# Performing Light Transmission Aggregometry (LTA) Testing

## SPECIAL CONSIDERATIONS

1. Discuss the Use of a Known Donor Once per Week, Month, or Reagent Lot with the Laboratory's Medical Director Approval Instead of on Each Day of Testing
2. For Ristocetin CoFactor Activity Assays, Prepare One Standard Curve per Test Kit or Reagent Lot Rather than Preparing a New Standard Curve for Each Day of Testing if Approved by the Laboratory's Medical or Technical Director
3. Dispose of Reagents and Controls as Biohazardous Waste at the End of Each Day of Testing
    a. Do Not Return the Un-Used Portions of the Reagents, Reference or Control Plasmas to the Laboratory Refrigerator
4. After the PAP-8E Reports Print in the Laboratory Workspace, Use the “Clip” Feature to Easily Email the Results to the Medical Director for Review
    a. Avoid Taking the Analyzer Printout Out of the Laboratory

## TEST PROCEDURE



1. Put On Required PPE
2. Decontaminate Workspace and Aggregometer if Necessary
3. Take Reagents and Control Plasmas Out of the Refrigerator
    a. Refrigerator Handles Should Be Decontaminated On a Routine Basis

3. Reconstitute Reagents According to the Manufacturer's Instructions, Tightly Re-Capping Each Vial After the Diluent is Added

4. Set Up the Test Cuvettes for Blanking and Test Samples, Properly Labeling Each
5. Add a Plastic Coated Stir Bar to Each Test Cuvette
6. Transfer the Required Volumes of PRP and PPP to the Appropriate Cuvettes Using an Electronic Pipette
    a. Set the Electronic Pipette Dispense Rate to 3 or Lower
7. Dispose of the Pipette Tips in a Biohazard Waste Container
8. Follow the Aggregometer Manufacturer's Instructions for Use to Perform the Tests

a. Set the Electronic Pipette to a Dispense Rate of 3

b. Discharge the Reagent Into the Center of the Test Cuvette

c. Dispose of the Pipette Tips in a Biohazard Waste Container

9. Re-Cap Each Reagent After Aspirating the Required Volume
10. Once the Tests are Complete, Dispose of the Blank and Test Cuvettes in an Appropriate Biohazardous Waste Container
11. Pipette Tips, Cuvettes and Stir Bars are Clearly Marked with as "Do Not Re-Use" Symbol:

    Do Not Rinse and Re-Use Cuvettes or Stir Bars

12. Properly Dispose of Remaining Specimens, Test Samples, Reagents and Other Materials Used in the Testing Process
13. Decontaminate the Work Area and Aggregometer Using an EPA Approved Disinfectant
    a. Ensure the Disinfectant's Required Contact Time is Observed
14. Remove and Dispose of PPE in Accordance with Laboratory Policy

*NOTE: Glasses and Contact Lenses are Not PPE*

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Bio/Data Corporation Supports the Physicians, Scientists, Medical Technologists, and Technicians in Laboratories Around the World Who Work to Develop Groundbreaking Products that Lead to a Better Understanding of Hemostasis, Thrombosis and Platelet Function.

BIO/DATA CORPORATION

**An ISO 13485 Registered Company**

**Website: www.biodatacorp.com / Email: customer.service@biodatacorp.com**

**155 Gibraltar Road, Horsham, PA 19044 USA**

**Telephone: +1 215-441-4000 Worldwide / 1-800-257-3282 USA**



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