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#### **Preparation of Positive and Negative Gel DAT QC Samples**

#### Document Type: Procedure

Status (Scheduled) PolicyStat ID (13116288)

# **I. PURPOSE AND OBJECTIVE:**

The purpose of this document is to provide the information necessary to prepare positive and negative gel DAT QC samples. Quality control (QC) must be performed each day of use prior to performing Blood Bank testing on patient and donor samples. The positive and negative gel DAT QC samples prepared in this document are used to perform the necessary QC for the manual gel DAT test and the gel DAT tests performed on the ORTHO VISION™ analyzer.

### **II. DEFINITIONS/ACRONYMS:**

- A. **DAT:** Direct Antiglobulin Test.
- B. **RBC:** Red Blood Cell.
- C. QC Samples: Also known as controls.
- D. **"Fresh":** As it pertains to this document for QC sample preparation, "fresh" refers to any RBC unit that has at least 1 month until it expires.

### **III. INSTRUCTIONS:**

- A. Fresh RBC donor units from the general Blood Bank inventory that have at least 1 month until expiration are used to create the positive and negative controls.
- B. The gel DAT QC samples should be prepared at the beginning of each month if possible to provide the longest expiration date.
- C. The expiration date of the QC sample is the **shorter** of the expiration date out of the donor unit, buffered saline, and Ortho BioClone<sup>®</sup> Anti-D Reagent.

- D. Prepared QC samples must be properly labeled with a *Positive Gel DAT Control Sticker* or *Negative Gel DAT Control Sticker* (depending on the control prepared) as well as the donor unit number, tech initials, and date prepared.
- E. Documentation of every QC sample prepared must take place on the *Log of Positive and Negative Gel DAT QC Samples* or in the Blood Bank computer system.
- F. When QC samples are not in use, they will be capped and stored at 1°C 6°C.
- G. If the negative control fails QC then it is likely due to the donor unit already having a positive DAT. Order and perform a DAT on the unit in the Blood Bank computer system and document an internal variance. Select a new donor unit and create a new negative gel DAT QC sample.

## **IV. REAGENTS / EQUIPMENT / SUPPLIES:**

- A. Ortho BioClone<sup>®</sup> Anti-D Reagent
- B. RBC segments of Rh(D) positive donor units from the Blood Bank inventory
- C. 12 x 75 mm plastic test tubes
- D. Test tube caps
- E. Segment splitters or scissors
- F. Plastic disposable pipettes
- G. Buffered saline

### V. PROCEDURE:

- A. Positive Gel DAT Control Preparation:
  - 1. Select a "fresh" Rh(D) positive RBC unit from the general Blood Bank inventory that has at least 1 month until it expires.
  - 2. Label a 12 x 75 plastic test tube with a Positive Gel DAT Control Sticker .
  - 3. Using a segment splitter or scissors, add 5 segments from the Rh(D) positive RBC unit into the 12 x 75 plastic test tube labeled with the *Positive Gel DAT Control Sticker*
  - 4. Add 5 drops of buffered saline to the 12 x 75 plastic test tube with a plastic disposable pipette.
  - 5. Add 5 drops of the Ortho BioClone<sup>®</sup> Anti-D reagent to the 12 x 75 plastic test tube.
  - 6. Cap the plastic test tube and gently mix by inverting multiple times.
  - 7. Preparation of the control is complete and ready for use.

#### B. Negative Gel DAT Control Preparation:

- 1. Select a "fresh" Rh(D) positive RBC unit from the general Blood Bank inventory that has at least 1 month until it expires.
- 2. Label a 12 x 75 plastic test tube with a Negative Gel DAT Control Sticker.
- 3. Using a segment splitter or scissors, add 5 segments from the Rh(D) positive RBC unit into the 12 x 75 plastic test tube labeled with the *Negative Gel DAT Control*

Sticker.

- 4. Add 10 drops of buffered saline to the 12 x 75 plastic test tube with a plastic disposable pipette.
  - a. Do not add Anti-D to the negative control.
- 5. Cap the plastic test tube and gently mix by inverting multiple times.
- 6. Preparation of the control is complete and ready for use.

### **VI. REFERENCES:**

- A. AABB, Standards for Blood Banks and Transfusion Services, current edition.
- B. College of American Pathologists, *Transfusion Medicine Checklist*, current edition.

#### Attachments

Log of Positive and Negative Gel DAT QC Samples (02/11/2021) Negative Gel DAT Control Sticker (02/11/2021) Positive Gel DAT Control Sticker (02/11/2021) Approval Signatures				
Step Description	Approver	Date		
	Kristina Davis: Staff Physician	5/4/2023		
	Ann Marie Blenc: System Med Dir, Hematopath	3/17/2023		
	Vaishali Pansare: Chief, Pathology	3/6/2023		
	Ryan Johnson: OUWB Clinical Faculty	3/2/2023		
	Muhammad Arshad: Physician	3/1/2023		
	Jeremy Powers: Chief, Pathology	3/1/2023		
	John Pui: Chief, Pathology	3/1/2023		
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	3/1/2023		

Policy and Forms Steering Committe (if needed)

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Kelly Sartor: Supv, Laboratory	2/14/2023