

# Certificate of Analysis

## Product Information

| Catalog ID | Product Name                      | Size                        | Unit Volume | Vessel                |
|------------|-----------------------------------|-----------------------------|-------------|-----------------------|
| PB001CLP   | Cryopreserved HemaPrime™ leukopak | 2-2.5 x 10 <sup>9</sup> TNC | 70 mL       | CS250 Bag from OriGen |

| Lot Number | Cryopreservation Date | Pre-Cryopreservation WBC    |
|------------|-----------------------|-----------------------------|
| 00000000   | 2019-12-18            | 2480 x 10 <sup>6</sup> /bag |

### Description

Leukopak from peripheral blood was collected from a healthy, IRB-approved volunteer donor. This mononuclear cell-rich leukapheresis product is extracted using continuous flow centrifugal technology directly into the collection bag containing ACD-A anticoagulant. The leukapheresis material was stained to identify various subpopulations by flow cytometry and then quickly cryopreserved on site in CryoStor® CS10 freeze media (Catalog #: 210102) using a controlled rate cryopreservation procedure.

### Source Material

Fresh leukopak (PB001F-1)

### Handling Instructions

Upon receipt, either prepare cells for long-term storage in liquid nitrogen vapor phase or thaw for use. Storage in liquid phase nitrogen is NOT recommended. Long-term storage of cells at -80°C is NOT recommended. Once thawed, samples must be used immediately.

## Donor Information

| Source ID | Age | Gender | Height | Weight  | BMI   | Ethnicity        | ABO/Rh |
|-----------|-----|--------|--------|---------|-------|------------------|--------|
| D000000   | 56  | Male   | 5'11"  | 241 lbs | 33.61 | Mexican/American | A-POS  |

| HLA -A | HLA-B |
|--------|-------|
| 24     | 39    |
| 26     | 44    |

Displayed HLA results are from donor's previous screening. HemaCare can further test donor for an additional fee.

## Testing Information

Donors are tested prior to each collection according to current FDA requirements for allogeneic blood donation, with the exception of Zika. The following screening tests have been performed:

- Syphilis
- Red Blood Cell Antibody Screen
- CMV Antibody (Anti-CMV IgG and IgM) – *result upon request*
- Hepatitis B Core Antibody (Anti-HBc EIA)
- Hepatitis B Surface Antigen (HBsAg EIA)
- Hepatitis C Virus Antibody (Anti-HCV EIA)
- Human Immunodeficiency Virus Antibody (HIV 1/2 plus O)
- Human T-Lymphotropic Virus Antibody (HTLV-I/II)
- HIV-1/HCV/HBV Nucleic Acid Testing
- West Nile Virus Nucleic Acid Testing
- Trypanosoma cruzi Antibody (Chagas Disease)

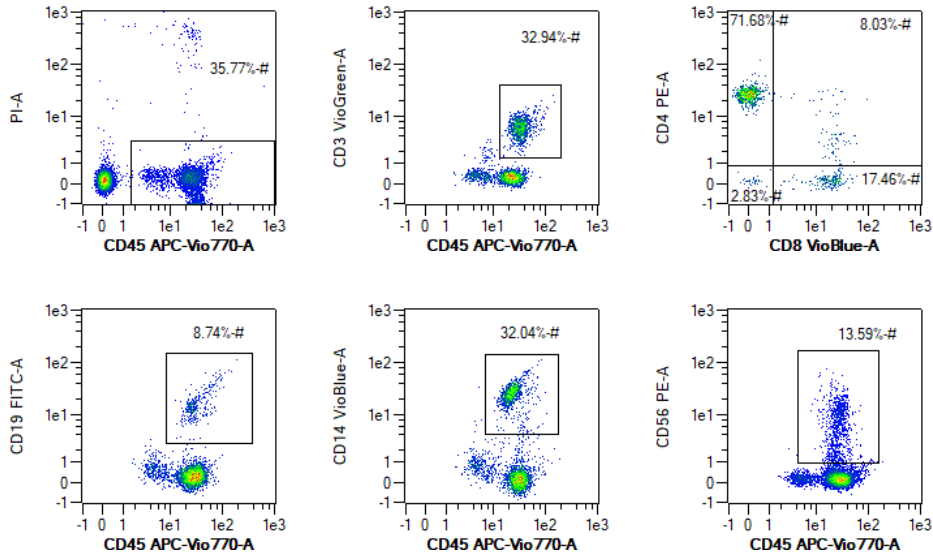
Testing panel results: Acceptable

### HemaCare Corporation

8500 Balboa Boulevard, Suite 130 • Northridge, CA 91325  
 (877) 944-4362 | techsupport@hemacare.com | www.hemacare.com

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## Flow Cytometry Analysis



| Viability | CD45 vs PI | CD45 vs CD3 | CD45 vs CD19 | CD45 vs CD14 | CD45 vs CD56 |
|-----------|------------|-------------|--------------|--------------|--------------|
| 99.57 %   | 35.77 %    | 32.94 %     | 8.74 %       | 32.04 %      | 13.59 %      |

**Biosafety** This material should be handled following biosafety level 2 biohazard procedures. Universal precautions should be utilized when working with this material.

Released By John Smith

Date 2021-01-15