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**Catalog Number**
HABS001-GMP-100 mL

**Volume**
100 mL

# GMP Human AB Serum

## Product Description

GMP Human AB Serum is collected from a maximum of sixteen (16) healthy male donors of the AB serotype at FDA-licensed facilities in the United States. This material is defibrinated from source plasma AB using therapeutic grade recombinant human Thrombin. All donor units are tested for viral markers and found to be non-reactive or negative per 21 CFR 610.40 guidelines. GMP Human AB Serum is 0.1 µm sterile filtered, manufactured Xeno-free, and does not contain non-human animal-derived components.

## Storage & Handling

When preparing GMP Human AB Serum for use, it should be allowed to thaw gradually, either at room temperature until no visible ice crystals are observed or at 2-8 °C conditions overnight to minimize thermodynamic stress. GMP Human AB Serum appearance is a straw-like or amber color. It could be slightly cloudy and may contain precipitates due to freezing and/or thawing; this occurrence does not impact cell culture performance. Solution may partition, gently mix product by swirling (minimize foaming) after thawing. It is strongly recommended to use the entire 100 mL bottle upon thawing. Otherwise, it is recommended to minimize the number of freeze/thaws cycles the product undergoes by aliquoting the serum into single use volumes and storing for a specific application.

| Product | Format | Storage | Stability |
|---|---|---|---|
| **GMP Human AB Serum** | 100 mL, Bottle | Upon receipt, store frozen at ≤-10 °C. | See use by Date on the Certificate of Analysis |

## Precautions

- The human plasma used to manufacture this product has been tested and shown to be negative or non-reactive for infectious agents per 21 CFR 610.40 as described on the Certificate on Analysis. Human blood products should always be treated in accordance with universal handling precautions.
- When handling bio-hazardous materials, safe laboratory procedures should always be followed, and PPE should be worn.

## Limitations

- For pre-clinical or ex vivo clinical use only.
- This reagent should not be used past the Use by Date on the Certificate of Analysis.
- Results may vary due to donor-to-donor variations among primary cell populations.

## Other Materials Used

- Recombinant Human IL-7 GMP Protein, CF, R&D Systems®, BT-007-GMP
- Recombinant Human IL-15 GMP Protein, CF, R&D Systems, BT-015-GMP
- Recombinant Human IL-2 GMP Protein, CF, (alternatively), R&D Systems, BT-002-GMP
- Human CD3 GMP Antibody, R&D Systems, MAB11411-GMP
- Human CD28 GMP Antibody, R&D Systems, MAB11412-GMP
- GMP Human T Cell Media, R&D Systems, CCM038-GMP-1L
- G-Rex® Bioreactors, Wilson Wolf™

## Procedure for ex vivo Culture of Human T Cells

The protocol describes the expansion of human T cells using complete GMP Human T Cell Media.

**Note:** The activation and cytokine/growth factor combinations used with this media should be optimized by application or experimental protocol.

## Reagent Preparation

**Complete GMP Human T Cell Media:** Aliquot media and add 10 ng/mL of rhIL-7 GMP Protein and 10 ng/mL of rhIL-15 GMP Protein or 10 ng/mL of rhIL-2 GMP protein. Supplement with 5% GMP Human AB Serum. Complete media is stable for 5 weeks at 2-8 °C. Store protected from light.

## Recommended Protocol (G-Rex® 6M well plate)

1. Isolate T cells or thaw isolated T cells using desired protocol.
2. Plate T cells at 0.5 x $10^6$ cells/$cm^2$ in 1 mL/$cm^2$ of complete GMP Human T cell Media in G-Rex bioreactor.

   a. **Example:** 5 x $10^6$ cells in 10 mL media in each well of a G-Rex 6M Well Plate.
3. Activate cells with CD3/CD28 activation reagent of choice using manufacturer's specifications.
4. **Optional:** Perform gene editing by either TcBuster™ Transposition or Lentivirus Transduction.

   a. **TcBuster Transposition:** 42-48 hours after activation, introduce CAR/TCR construct via electroporation with platform of choice using TcBuster-M transposase and transposon (see TcBuster electroporation protocols for detailed information about platform specific recommendations).

   b. **Lentivirus Transduction:** Recommended to omit 5% GMP Human AB Serum prior to and during transduction. 24 hours after activation, carefully mix the cell culture to break up the complexes and count the cell numbers. Apply lentivirus (recommend MOI of 5), and transduction enhancer if desired, to cells and gently mix.
5. Approximately 24 hours after transduction, 48 hours after TcBuster transposition, or 48 hours without gene editing, bring volume of G-Rex bioreactor to 10 mL/$cm^2$ with fresh complete media.
6. Expand cells in 37 °C incubator without manipulation.
7. Recommend harvest timing 7-9 days of culture or when cell confluency exceeds 30 x $10^6$ cells/$cm^2$.
8. Additional T cell activation and expansion protocols using GMP Human T Cell Media can be found below:
   - T Cell CD3 Immobilized, CD28 Soluble
   - T Cell Bead-Conjugated
   - PBMCs Soluble and Bead-Conjugated

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