Australian Government
Department of Health
Therapeutic Goods Administration

Mr Emmanuel Casasola
Quality Assurance Director
QualTex Laboratories
6211 IH 10 West
San Antonio
TEXAS 78201 USA

Our Reference: 2014/046234

Dear Mr Casasola

Subject: Issue of GMP certificate MI-2017-CE-08896-1

Please find enclosed the GMP certificate for your manufacturing premises.

The certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The inspection frequency is not a reflection of the expiry date shown on the certificate but is consistent with the re-inspection frequency applicable to Australian manufacturers of the same class of products.

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

Yours sincerely,

Signed and authorised by

Stephen Hart
Senior Inspector
Manufacturing Quality Branch

19 November 2018

Contact: gmp@tga.gov.au, phone +61 2 6221 6881 or fax +61 2 6232 8426

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of ingredients and/or components for blood derived medicinal products

Certificate Number:

MI-2017-CE-08896-1

Issued to:

QualTex Laboratories

Manufacturing Site Address:

6211 IH 10 West
San Antonia Texas 78201
United States of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer of ingredients and/or components for blood derived medicinal products has been inspected following section 25(1)(g) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing ingredients and/or components manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10 to 13 April 2018, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products (2013).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 13 April 2020

ISSUE DATE: 19 November 2018

This Certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of ingredients and/or components for blood derived medicinal products

Certificate Number:

MI-2017-CE-08896-1

MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of ingredients and/or components for therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Manufacturing Step
Testing Laboratory - Blood Tissue Cellular	NAT Testing for HIV and HCV NAT Testing for HBV, HAV and B19 HIV I/II Screening HBsAg Screening

The following limitations are applicable to these manufacturing operations:

The certificate does not authorise testing conducted by third party testing laboratories such as the NAT testing using the Abbott HIV Ag/Ab Combo kit.

INGREDIENTS AND/OR COMPONENTS MANUFACTURED

Testing is restricted to plasma pools for further manufacture.

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