

Accredited

Foundation for the Accreditation of Cellular Therapy

certifies that

Blood Assurance

Chattanooga, Tennessee

Having Met the FACT-JACIE Standards for Hematopoietic Cellular Therapy is Granted FACT Accreditation for

Peripheral Blood Cellular Therapy Product Collection

From: December 27, 2023

To:

December 27, 2026

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met. This certificate is valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for the violation of the Standards Currently accredited organizations are located at www.foctwebsite.org

Catherine Bollard, MBChB, MD, FRACE

Catherine Bollard, MBChB, MD, FRACP, FRCPA FACT President

Phyllis I. Warkentin, MD

Chair, Accreditation Committee



12/27/2023

Elizabeth Culler, MD **Program Director Blood Assurance** 705 East 4th Street. Chattanooga, TN 37403

Dear Dr. Culler:

The Foundation for the Accreditation of Cellular Therapy (FACT) is pleased to award accreditation under the FACT-JACIE International Standards for Hematopoietic Cellular Therapy, to Blood Assurance in Chattanooga, Tennessee. The accreditation for your organization is effective for three years beginning December 27, 2023. This accreditation applies to all services and facilities that were inspected by FACT, specifically:

Peripheral blood cellular therapy product collection

This letter and the corresponding Response Report are considered confidential. If you choose to share these documents with other parties (i.e., commercial companies providing additional manufacturing), you should develop an agreement with the other party specifying maintenance of confidentiality and intention of use.

Please notify the FACT Accreditation Office if there are significant personnel, facility location, service, or contractual changes in your organization. Any new services provided by your organization within the accreditation cycle, must be implemented in compliance with the FACT Standards and reported to FACT. If you use or change contracted services in your organization, you are responsible for notifying FACT and monitoring the accreditation status of those service providers.

FACT accredited organizations are required to complete an annual report. You will receive an annual report notification 30 days before the report is due. Your organization will be annually invoiced for FACT accreditation fees. Renewal accreditation is required every three years to maintain accredited status.

Accredited organizations are listed on the FACT website at https://accredited.factglobal.org/, FACT encourages your program to publicize its accreditation. A press kit is available to help communicate this accomplishment to patients, providers, insurance carriers, and other community stakeholders. The press kit includes a list of publicity strategies, a sample press release, and an electronic copy of the FACT Seal of Accreditation. If your organization would like

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to obtain the press kit materials, please complete the FACT Seal of Accreditation License Agreement. To complete the process and access the form, please contact Jay Ann Witt at 402-920-7001 or jayann.witt@factglobal.org, note that if this accreditation is used in any advertising, you must specify the areas accredited as described above to accurately represent the activities accredited by FACT. We request that you refrain from linking this accreditation to unsubstantiated medical claims.

We encourage personnel at your organization to become FACT inspectors. Personnel who serve as FACT inspectors enjoy many benefits, including free access to FACT educational sessions, awareness of how other organizations comply with accreditation requirements, and increased exposure to the cellular therapy community. Organizations with inspectors have more impact on the development of standards and accreditation requirements. Information on how to apply to become a FACT inspector can be found at https://www.factglobal.org/inspectors/.

If you have not already, please provide us feedback regarding your FACT on-site inspection experience. This information is reviewed independently of accreditation decisions and helps us continuously improve. Feedback can be provided via the on-site inspection evaluation form available at https://redcap.link/FACTAccreditationEvaluation.

Congratulations on achieving FACT accreditation and your continuing efforts to provide quality care and services. Please contact us at any time if there are questions, comments, or concerns. We will be happy to provide you with any additional information or assistance you need.

Sincerely,

Phylia S. Warkentinimo

Phyllis I. Warkentin, MD
Chief Medical Officer, FACT
Chair, FACT Accreditation Committee

Enclosure(s): FACT Accreditation Certificate

Documentation Due at Annual Report Notification Letter

C: Lee Wouters, RN

Yvette Tanhehco, MD, PhD, MS Catherine Bollard, MD FACT President

Blood Assurance Chattanooga, TN