



Our STN: BL 125799/12

SUPPLEMENT APPROVAL
October 23, 2025

Roche Diagnostics
Attention: Reanna Toney
9115 Hague Road
Indianapolis, IN 46250

Dear Reanna Toney:

We have approved your request received June 27, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Elecsys Chagas for an addition to the Intended Use of this device for testing serum specimens to screen cadaveric (non-heart-beating) donors.

We will include the information contained in the above-referenced supplement in your BLA file.

Sincerely,

Hira L. Nakhasi, PhD
Director
Division of Emerging and
Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research