



Our STN: BL 125803/16

SUPPLEMENT APPROVAL
March 6, 2026

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

Dear Reanna Toney:

We have approved your request received November 12, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Elecsys Anti-HCV II for use on the cobas pro serology solution equipped with a **cobas e** 801 analytical unit for an addition to the Intended Use of this device for testing serum specimens to screen cadaveric donors when specimens are obtained after the donor's heart has stopped beating.

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