



**Our STN: BL 125778/20**

**SUPPLEMENT APPROVAL  
March 31, 2026**

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

Dear Reanna Toney:

We have approved your request received December 5, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Elecsys HIV Duo 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