



Our STN: BL 125802/18

SUPPLEMENT APPROVAL
February 17, 2026

Roche Diagnostics
Attention: Kelly Brennan
9115 Hague Road
Indianapolis, IN 46250

Dear Kelly Brennan:

We have approved your request received October 22, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Elecsys HBsAg II 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