

Certificate of Analysis

Assay Buffer

Tris BSA – 100 mL

Stock Solution – 0.5 M Tris pH 7.3 (20°C), 2.0 M NaCl, 10% Bovine Serum Albumin (BSA)

Art No: TB035-100
 Lot No: TTM2008-100
 Expiry Date: 2018 09
 Storage: 2-8°C

Dilute 1 + 9 with water prior to use to obtain buffer working solution.

NB: The vials are slightly over dispensed. Always measure up the desired volume prior to 10-fold dilution with water.

Analysis	Specification	Result
pH (after dilution 1 + 9 with water)	7.3 ± 0.06 at 20°C (Temp. coefficient = -0.028 per °C)	7.32 at 20°C
Ionic strength (after dilution 1 + 9 with water)	20.0 ± 1 mS/cm at 20°C (Temp. coefficient = +2.1% per °C)	20.8 mS/cm at 20°C
Test of Function Chromogenic FVIII method	Approved	Approved

The above Lot# of Tris BSA has been approved for release after analyses according to established protocols with results demonstrating fulfillment of product specifications.

All data concerning materials used, production data and release testing are documented and traceable under the individual Lot# which is stated on each vial.

Approval of included lot# of BSA consists of the following:

Documents

Rossix requests documents which demonstrate the source of bovine plasma used for manufacturing of BSA to originate from countries shown to be free from TSEs affecting animals, including BSE and scrapie.


Test for absence of protease activity

Bulking agent in a chromogenic FVIII method

- Function of fresh solutions
- Function of solutions stored for 5 h

Bulking agent in a chromogenic FVII method

- Function of fresh solutions
- Function of solutions stored for 5 h



Pia Bryngelhed
 Quality Control Rossix AB

Rossix AB
 Taljegardsgatan 3B
 SE-431 53 Molndal
 Sweden

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Date

Phone: +46 31 706 8965
 Fax: +46 31 706 8966
info@rossix.com
www.rossix.com