

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: TTM0349-100
 Expiry Date: 2019 06
 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) | 7.29 at 20°C |
| Conductivity (after dilution 1 + 9 with water) | 20.0 ± 1 mS/cm at 20°C (Temp. coefficient = +2.1% per °C) | 19.9 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.

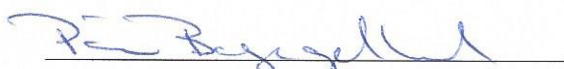
Approval of included lot# of BSA consists of the following:

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 chromogenic methods for test of function and stability of coagulation factors.



Pia Bryngelhed
 Quality Control Rossix AB

Rossix AB
 Taljegardsgatan 3B
 SE-431 53 Molndal
 Sweden

January 7, 2016

Date

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