

NITTOBO MEDICAL CO.,LTD

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Date 2022/03/21

CERTIFICATE OF ANALYSIS

Abbott Commodity# : 06E5703
Product : Prealbumin Calibrator
Product Code : ABT45333 Abbott List No. : 06E5703
LOT# : A417C22A Package Insert commodity# : G96047R01
Expiry : 2023.02.07 Total Lot Quantity Manufactured(kits) : 370
Date of Manufacture : 2022.02.07 Component

| Name | LOT# | Expiry |
|-------|----------|------------|
| Cal-1 | A417C22A | 2023.02.07 |
| Cal-2 | A417C22A | 2023.02.07 |
| Cal-3 | A417C22A | 2023.02.07 |
| Cal-4 | A417C22A | 2023.02.07 |
| Cal-5 | A417C22A | 2023.02.07 |

| TESTS | SPECIFICATIONS | RESULTS | DISPOSITION |
|--|--|---|----------------------|
| 01 Appearance | Colorless, or Pale yellow, and clear liquid and no solid substances. | Corresponds | Pass |
| 02 Volume | 1 : 0.97 - 1.03 mL 2 : 0.97 - 1.03 mL 3 : 0.97 - 1.03 mL 4 : 0.97 - 1.03 mL 5 : 0.97 - 1.03 mL | 1.01 mL 1.01 mL 1.01 mL 1.00 mL 1.01 mL | Pass(all) |
| 03 Calibrator Concentration (on Hitachi7180) | 1 : 4.0 - 6.0 mg/dL 2 : 13.5 - 16.5 mg/dL 3 : 27.0 - 33.0 mg/dL 4 : 40.5 - 49.5 mg/dL 5 : 54.0 - 66.0 mg/dL | 5.0 mg/dL 15.0 mg/dL 30.0 mg/dL 45.0 mg/dL 60.0 mg/dL | Pass(all) |
| 04 Calibrator Traceability | Traceable to ERM-DA470k/IFCC. | Complies | Pass |
| 05 Value assignment | Performed on Hitachi 7180 | Complies | Pass |
| 06 Lot to Lot Variability | Primary calibrator lot within 5% of its assigned value. | Complies | Pass |
| 07 Infectious disease inspection | Components sourced from human blood have been tested and found to be nonreactive for HbsAg, anti-HCV, and anti-HIV-1/HIV-2 (by FDA approved tests) | Complies | Pass(all) |
| | <ul style="list-style-type: none"> Open Vial Stability : 30days at 2 to 8 degrees C. Closed Vial Shelf-Life : 12months at 2 to 8 degrees C from date of manufacture. | | |
| 08 Barcode printing information | Calibrator Lot Number Calibrator Level ID Calibrator Serial Number (SN) | Complies Complies Complies | Pass Pass Pass |

The listed product meets the requirements of MS.MASTER342.

This is to certify that the listed product was manufactured in accordance with Quality System Regulations, and passed all of our Final Release Specifications and Abbott Acceptance Requirements.

Signature



Date

