



Certificate of Analysis

Abbott Ireland Diagnostics Division,
Lisnamuck,
Longford,
Co. Longford,
Ireland

Product Name: Albumin BCG2 SCP / revision 4U300030/004
List number: 04U3030
Lot number: 39287UD00
Reagent Lot Number: 39287UD00
Expiry Date: 2023-06-21

| Component name | List Number | Lot Number | Production date | Expiry date |
|----------------|-------------|------------|-----------------|-------------|
| AlbBCG2 R1 | 04U30R | 39286UD00 | 2022-03-21 | 2023-06-21 |

Acceptance Table: Grand Mean Concentration (g/dL)

| Description | Lower Limit | Upper Limit | Value | Result |
|---------------|-------------|-------------|-------|------------|
| REF Control 1 | 3.98 | 4.52 | 4.26 | Acceptable |
| REF Control 2 | 2.51 | 2.97 | 2.75 | Acceptable |
| REF GC1 Lv5 | 6.65 | 7.79 | 7.28 | Acceptable |

This product has been manufactured, including packaging and quality control in full compliance with ISO 13485, IVD Directive 98/79/EC and GMP guidelines as applicable.

Note: The specifications in this certificate reflect the internal Abbott release specifications. When performing the assay in a laboratory the specifications listed in the package insert apply.

Quality:

Caroline Hayes C. Hayes
Printed name and signature

Date:

05 April 2022