

SIEMENS

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| MANUFACTURER ADDRESS: | REGISTRATION ADDRESS: |
| SIEMENS HEALTHCARE DIAGNOSTICS INC. RTE 896 P.O. BOX 6101, BLDG. 100/104 NEWARK, DE 19714 | SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS LTD. GLYN RHONWY LLANBERIS, GWYNEDD LL55 4 EL UNITED KINGDOM |

Certificate of Analysis

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| PRODUCT DESCRIPTION: | IMMULITE 2000 Chemiluminescent Substrate |
| SMN / MATERIAL: | 10385232 / L2SUBM |
| LOT No.: | 1301 |
| EXPIRATION DATE: (YYYY-MM) | 2022 - 03 |
| MANUFACTURING DATE: (YYYY-MM) | 2020 - 09 |
| RELEASED BY: | Robin Walker (QA RELEASE) |

This lot has been tested and approved for release and shipment by the responsible Siemens Healthcare Diagnostics Quality Department. Retains of all samples are held at the manufacturing site until the date of expiration. This certificate has been generated from a validated electronic database and therefore the "RELEASED BY" name entered serves as an electronic signature.

Appearance: Clear, Colorless Liquid
Description: Chemiluminescent substrate
Storage: Store at 2-8°C. Protect from Light

| <u>Characteristic</u> | <u>Specification</u> | <u>Results Observed</u> |
|---------------------------------|--|-------------------------|
| Overall Mean Bias | +/- 5% from the reference substrate | PASS |
| Running Mean Bias | Both calibrators +/-5% and one +/-3% of running mean | PASS |
| Individual Calibrator kCPS Bias | +/- 10% in kCPS for a minimum of 5 calibrator levels vs. the reference substrate | PASS |