

Vui lòng xem danh mục sản phẩm tại trang 5

9<sup>th</sup>, January, 2024.

## Justification letter for warranty service

To who it may concern

We, Fujirebio, Inc., 1-8-1 Akasaka, Minato-ku, Tokyo 107-0052, Japan as the legal manufacturer hereby confirm that our products listed in Annex are disposal in vitro diagnostics (Single-use) and do not have any Warranty Service.

Products : Refer to Annex



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**Designation: Senior Manager, Regulatory Affairs 1st Section**

**Fujirebio Inc.**



## Annex

| S/N. | Product name (simplified) | Product Official Name                               |
|------|---------------------------|---|
| 1    | Lumipulse G HBsAb-N       | Lumipulse G HBsAb-N Immunoreaction Cartridges       |
|      |                           | Lumipulse G HBsAb-N Calibrators                     |
| 2    | Lumipulse G HBcAb-N       | Lumipulse G HBcAb-N Immunoreaction Cartridges       |
|      |                           | Lumipulse G HBcAb-N Calibrators                     |
| 3    | Lumipulse G HBcrAg        | Lumipulse G HBcrAg Immunoreaction Cartridges set    |
| 4    | Lumipulse G HAVAb         | Lumipulse G HAVAb Immunoreaction Cartridges         |
|      |                           | Lumipulse G HAVAb Calibrators                       |
| 5    | Lumipulse G HAVIgM        | Lumipulse G HAVIgM Immunoreaction Cartridges set    |
| 6    | Lumipulse G HCVAb         | Lumipulse G HCV Ab Immunoreaction Cartridges set    |
| 7    | Lumipulse G HIVAg/Ab      | Lumipulse G HIV Ag/Ab Immunoreaction Cartridges set |
| 8    | Lumipulse G HBcIgM        | Lumipulse G HBcIgM Immunoreaction Cartridges set    |
| 9    | Lumipulse G HBeAg         | Lumipulse G HBeAg Immunoreaction Cartridges set     |
| 10   | Lumipulse G HBsAg-Quant   | Lumipulse G HBsAg-Quant Immunoreaction Cartridges   |
|      |                           | Lumipulse G HBsAg-Quant Calibrators                 |
|      |                           | Lumipulse G HBsAg-Quant Confirmation                |
| 11   | Lumipulse G HBsAg         | Lumipulse G HBsAg Immunoreaction Cartridges         |
|      |                           | Lumipulse G HBsAg Calibrators                       |
| 12   | Lumipulse G HTLV-I/II     | Lumipulse G HTLV-I/II Immunoreaction Cartridges set |
| 13   | Lumipulse G Free PSA      | Lumipulse G Free PSA Immunoreaction Cartridges      |
|      |                           | Lumipulse G Free PSA Calibrators                    |
| 14   | Lumipulse G PSA-N         | Lumipulse G PSA-N Immunoreaction Cartridges         |
|      |                           | Lumipulse G PSA-N Calibrators                       |
| 15   | Lumipulse G TP-N          | Lumipulse G TP-N Immunoreaction Cartridges set      |
| 16   | Lumipulse G TPOAb         | Lumipulse G TPOAb Immunoreaction Cartridges set     |
| 17   | Lumipulse G CEA-N         | Lumipulse G CEA-N Immunoreaction Cartridges         |
|      |                           | Lumipulse G CEA-N Calibrators                       |

| S/N. | Product name (simplified)        | Product Official Name                                      |
|------|----------------------------------|--|
| 18   | Lumipulse G AFP-N                | Lumipulse G AFP-N Immunoreaction Cartridges                |
|      |                                  | Lumipulse G AFP-N Calibrators                              |
| 19   | Lumipulse G Testosterone         | Lumipulse G Testosterone Immunoreaction Cartridges         |
|      |                                  | Lumipulse G Testosterone Calibrators                       |
|      |                                  | Lumipulse G Specimen Diluent 3                             |
| 20   | Lumipulse G FT <sub>4</sub> -N   | Lumipulse G FT <sub>4</sub> -N Immunoreaction Cartridges   |
|      |                                  | Lumipulse G FT <sub>4</sub> -N Calibrators                 |
| 21   | Lumipulse G T <sub>3</sub>       | Lumipulse G T <sub>3</sub> Immunoreaction Cartridges       |
|      |                                  | Lumipulse G T <sub>3</sub> Calibrators                     |
|      |                                  | Lumipulse G Specimen Diluent 4                             |
| 22   | Lumipulse G CA19-9-N             | Lumipulse G CA19-9-N Immunoreaction Cartridges             |
|      |                                  | Lumipulse G CA19-9-N Calibrators                           |
| 23   | Lumipulse G Prolactin            | Lumipulse G Prolactin Immunoreaction Cartridges            |
|      |                                  | Lumipulse G Prolactin Calibrators                          |
| 24   | Lumipulse G KL-6                 | Lumipulse G KL-6 Immunoreaction Cartridges                 |
|      |                                  | Lumipulse G KL-6 Calibrators                               |
| 25   | Lumipulse G FT <sub>3</sub> -III | Lumipulse G FT <sub>3</sub> -III Immunoreaction Cartridges |
|      |                                  | Lumipulse G FT <sub>3</sub> -III Calibrators               |
| 26   | Lumipulse G C-Peptide            | Lumipulse G C-Peptide Immunoreaction Cartridges            |
|      |                                  | Lumipulse G C-Peptide Calibrators                          |
| 27   | Lumipulse G TgAb                 | Lumipulse G TgAb Immunoreaction Cartridges set             |
| 28   | Lumipulse G T <sub>4</sub>       | Lumipulse G T <sub>4</sub> Immunoreaction Cartridges       |
|      |                                  | Lumipulse G T <sub>4</sub> Calibrators                     |
|      |                                  | Lumipulse G Specimen Diluent 4                             |
| 29   | Lumipulse G PIVKA II-N           | Lumipulse G PIVKA II-N Immunoreaction Cartridges           |
|      |                                  | Lumipulse G PIVKA II-N Calibrators set                     |
| 30   | Lumipulse G TSH-III              | Lumipulse G TSH-III Immunoreaction Cartridges              |
|      |                                  | Lumipulse G TSH-III Calibrators                            |



| S/N. | Product name (simplified)   | Product Official Name                                 |
|------|-----------------------------|---|
| 31   | Lumipulse G Insulin-N       | Lumipulse G Insulin-N Immunoreaction Cartridges       |
|      |                             | Lumipulse G Insulin-N Calibrators                     |
| 32   | Lumipulse G CYFRA           | Lumipulse G CYFRA Immunoreaction Cartridges           |
|      |                             | Lumipulse G CYFRA Calibrators set                     |
| 33   | Lumipulse G CA125II         | Lumipulse G CA125II Immunoreaction Cartridges         |
|      |                             | Lumipulse G CA125II Calibrators                       |
| 34   | Lumipulse G $\beta$ HCG     | Lumipulse G $\beta$ HCG Immunoreaction Cartridges     |
|      |                             | Lumipulse G $\beta$ HCG Calibrators                   |
| 35   | Lumipulse G CA15-3          | Lumipulse G CA15-3 Immunoreaction Cartridges          |
|      |                             | Lumipulse G CA15-3 Calibrators                        |
| 36   | Lumipulse G IgE             | Lumipulse G IgE Immunoreaction Cartridges             |
|      |                             | Lumipulse G IgE Calibrators                           |
| 37   | Lumipulse G ProGRP          | Lumipulse G ProGRP Immunoreaction Cartridges          |
|      |                             | Lumipulse G ProGRP Calibrators set                    |
|      |                             | Lumipulse G Specimen Diluent 5                        |
| 38   | Lumipulse G FSH-N           | Lumipulse G FSH-N Immunoreaction Cartridges           |
|      |                             | Lumipulse G FSH-N Calibrators                         |
| 39   | Lumipulse G Progesterone-N  | Lumipulse G Progesterone-N Immunoreaction Cartridges  |
|      |                             | Lumipulse G Progesterone-N Calibrators                |
|      |                             | Lumipulse G Specimen Diluent 6                        |
| 40   | Lumipulse G Ferritin-N      | Lumipulse G Ferritin-N Immunoreaction Cartridges      |
|      |                             | Lumipulse G Ferritin-N Calibrators                    |
| 41   | Lumipulse G LH              | Lumipulse G LH Immunoreaction Cartridges              |
|      |                             | Lumipulse G LH Calibrators                            |
| 42   | Lumipulse G B•R•A•H•M•S PCT | Lumipulse G B•R•A•H•M•S PCT Immunoreaction Cartridges |
|      |                             | Lumipulse G B•R•A•H•M•S PCT Calibrators set           |

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|------|---------------------------------|---|
| 43   | Lumipulse G BNP                 | Lumipulse G BNP Immunoreaction Cartridges                 |
|      |                                 | Lumipulse G BNP Calibrators set                           |
| 44   | Lumipulse G 25-OH Vitamin D     | Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges     |
|      |                                 | Lumipulse G 25-OH Vitamin D Calibrators                   |
| 45   | Lumipulse G E <sub>2</sub> -III | Lumipulse G E <sub>2</sub> -III Immunoreaction Cartridges |
|      |                                 | Lumipulse G E <sub>2</sub> -III Calibrators               |
|      |                                 | Lumipulse G Specimen Diluent 2                            |
| 46   | Lumipulse G whole PTH           | Lumipulse G whole PTH Immunoreaction Cartridges           |
|      |                                 | Lumipulse G whole PTH Calibrators                         |
| 47   | Lumipulse G Myoglobin           | Lumipulse G Myoglobin Immunoreaction Cartridges           |
|      |                                 | Lumipulse G Myoglobin Calibrators                         |
| 48   | Lumipulse G hs Troponin I       | Lumipulse G hs Troponin I Immunoreaction Cartridges       |
|      |                                 | Lumipulse G hs Troponin I Calibrators                     |
| 49   | Lumipulse G CK-MB               | Lumipulse G CK-MB Immunoreaction Cartridges               |
|      |                                 | Lumipulse G CK-MB Calibrators set                         |
| 50   | Lumipulse G HBeAb-N             | Lumipulse G HBeAb-N Immunoreaction Cartridges set         |
| 51   | PIVKA-II and KL-6 Controls      | Lumipulse PIVKA-II and KL-6 Controls                      |
| 52   | B•R•A•H•M•S PCT Controls        | Lumipulse B•R•A•H•M•S PCT Controls                        |
| 53   | BNP Controls                    | Lumipulse BNP Controls                                    |
| 54   | HBcrAg Controls                 | Lumipulse HBcrAg Controls                                 |
| 55   | HBsAg Controls                  | Lumipulse HBsAg Controls                                  |
| 56   | HCV Controls                    | Lumipulse HCV Ab Controls                                 |
| 57   | HIVAg/Ab Controls               | Lumipulse HIV Ag/Ab Controls                              |
| 58   | HTLV-I/II Controls              | Lumipulse HTLV-I/II Controls                              |
| 59   | whole PTH Controls              | Lumipulse PTH Controls                                    |
| 60   | Lumipulse G Specimen Diluent 1  | Lumipulse G Specimen Diluent 1                            |
| 61   | Lumipulse G Substrate Solution  | Lumipulse G Substrate Solution                            |
| 62   | Lumipulse G Wash Solution       | Lumipulse G Wash Solution                                 |

| S/N. | Product name (simplified)      | Product Official Name                               |
|------|--------------------------------|---|
| 63   | Lumipulse G SARS-CoV-2 Ag      | Lumipulse G SARS-CoV-2 Ag Immunoreaction Cartridges |
|      |                                | Lumipulse G SARS-CoV-2 Ag Calibrators set           |
| 64   | Sample Extraction Solution set | Sample Extraction Solution set                      |
| 65   | SARS-CoV-2 Ag Controls         | Lumipulse SARS-CoV-2 Ag Controls                    |
| 66   | Lumipulse G TSH IFCC           | Lumipulse G TSH IFCC Immunoreaction Cartridges      |
|      |                                | Lumipulse G TSH IFCC Calibrators                    |
| 67   | Lumipulse G AMH                | Lumipulse G AMH Immunoreaction Cartridges           |
|      |                                | Lumipulse G AMH Calibrators                         |