VN

Read this insert carefully before performing the assay and make sure you are using the most recent version of the package insert. The reliability of assay procedures other than those described in this package insert cannot be guaranteed.

28Y07TE - 01VN Oct. 2024 (ver. 1)
☆Note Change

In Vitro Diagnostic Use

Chemiluminescent Enzyme Immunoassay Reagent

Lumipulse® G 25-OH Vitamin D Calibrators

■ NAME

Lumipulse G 25-OH Vitamin D Calibrators

■ INTENDED USE

Lumipulse G 25-OH Vitamin D Calibrators are for *in vitro* diagnostic use in the calibration of Lumipulse G 25-OH Vitamin D on the LUMIPULSE G System. This product is for professional use only.

■ SUMMARY AND EXPLANATION OF THE ASSAY

Vitamin D is a fat-soluble steroid hormone precursor present in two forms, vitamin D_2 (ergocalciferol) and vitamin D_3 (cholecalciferol). Vitamin D_3 is endogenously synthesized in the skin by exposure to sunlight while vitamin D_2 is taken up from dietary sources.

In the human circulatory system, biologically inert vitamin D_2 and vitamin D_3 are bound to the vitamin D binding protein and are transported to the liver to undergo hydroxylation on carbon 25 generating 25-hydroxyvitamin D (25-OH vitamin D) followed by hydroxylation on carbon 1 in the kidney to generate the biologically active form 1,25-dihydroxyvitamin D (1,25-$(OH)_2$ vitamin D).[1-2)]

Circulating 25-OH vitamin D is widely acknowledged as the indicator of vitamin D status for several reasons. It is the major storage form of vitamin D in blood with a half-life around 2-3 weeks while the biologically active form (1,25-$(OH)_2$ vitamin D) has shorter lifetime in serum and is present in levels approximately a thousand-fold less than 25-OH vitamin D. Further, as a patient becomes vitamin D deficient the renal production of 1,25-$(OH)_2$ vitamin D may increase as a result of increased secretion of parathyroid hormone (PTH) making 1,25-$(OH)_2$ vitamin D clinically irrelevant for the assessment of vitamin D sufficiency.[3)] Vitamin D deficiency was associated with the bone deforming disease rickets in children almost a century ago, and is also well known to impair bone metabolism and to cause musculoskeletal disease such as osteomalacia, osteoporosis and muscle weakness.[2-3)]

More recent research has shown that most cells and tissues in the body have a vitamin D receptor and more than 200 genes have been found to be directly or indirectly regulated by vitamin D.[4)]

It is required that 25-OH vitamin D assays measure both 25-OH vitamin D_2 and 25-OH vitamin D_3 since the proportion of 25-OH vitamin D_2 to 25-OH vitamin D_3 vary between individuals.[1,3,5-7)] The Lumipulse G 25-OH Vitamin D Assay specifically measures 25‐OH vitamin D and shows equimolar sensitivity for 25-OH vitamin D_2 and 25-OH vitamin D_3.

■ PRINCIPLE OF THE PROCEDURE

Lumipulse G 25-OH Vitamin D is an assay system, including a set of immunoassay reagents, for the quantitative determination of 25-OH vitamin D in specimens based on CLEIA technology[8)] by a two-step sandwich immunoassay method on the LUMIPULSE G System.

The 25-OH vitamin D concentration of a specimen is automatically calculated from the calibration curve, which is also automatically created from calibration data. The result of the calculation is reported in ng/mL.

☆ ■ MATERIALS PROVIDED

Lumipulse G 25-OH Vitamin D Calibrators : CAL Liquid, 1 × 6 Concentrations REF 298336

CAL1	0 ng/mL 25-OH Vitamin D calibrator (1 × 1.5 mL) (0 nmol/L 25-OH Vitamin D calibrator (1 × 1.5 mL))
CAL2	10 ng/mL 25-OH Vitamin D calibrator (1 × 1.5 mL) (25 nmol/L 25-OH Vitamin D calibrator (1 × 1.5 mL))
CAL3	20 ng/mL 25-OH Vitamin D calibrator (1 × 1.5 mL) (50 nmol/L 25-OH Vitamin D calibrator (1 × 1.5 mL))
CAL4	50 ng/mL 25-OH Vitamin D calibrator (1 × 1.5 mL) (125 nmol/L 25-OH Vitamin D calibrator (1 × 1.5 mL))
CAL5	100 ng/mL 25-OH Vitamin D calibrator (1 × 1.5 mL) (250 nmol/L 25-OH Vitamin D calibrator (1 × 1.5 mL))
CAL6	150 ng/mL 25-OH Vitamin D calibrator (1 × 1.5 mL) (375 nmol/L 25-OH Vitamin D calibrator (1 × 1.5 mL))

Contains calcifediol in sodium chloride in HEPES buffer with protein stabilizer.

Preservative: sodium azide

Traceability

The calibrators for use with Lumipulse G 25-OH Vitamin D are prepared gravimetrically and are traceable to internal reference calibrator concentrations determined by UV spectrophotometric analysis and verified by Reference Method Procedure (University of Ghent) .[9)]

■ MATERIALS REQUIRED BUT PROVIDED SEPARATELY

Refer to the ■ **MATERIALS REQUIRED BUT NOT PROVIDED** in the package insert of Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges. The required materials are the same except the 25-OH Vitamin D Calibrators which is listed in ■ **MATERIALS PROVIDED** here.

■ MATERIALS REQUIRED BUT NOT PROVIDED

1.Purified water

2.Micropipettes

3.Recommended sample cups or sample tubes; refer to the LUMIPULSE G System Operation Manual.

☆ ■ WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only.

1. SAFETY PRECAUTIONS

Please refer to the safety data sheet (SDS) and product labeling for information on potentially hazardous components. Please make a contact with local distributors when you need the most recent SDS version.

EUH032: Contact with acids liberates very toxic gas.

2. PRECAUTIONS FOR HANDLING

1). Lumipulse G 25-OH Vitamin D Calibrators contain biological materials. No given tests can completely guarantee that infected materials are absent. Accordingly, such materials should be considered potentially infectious.

To avoid a risk of infection when handling these reagents and human specimens, wear disposable gloves to avoid direct contact. Do not perform pipetting by mouth and follow appropriate biosafety practice.[10)]

2). Lumipulse G 25-OH Vitamin D Calibrators contain 0.1% sodium azide as a preservative. Avoid contact with skin, eyes or mouth.

Wash Solution: 1.0% (w/v) (before dilution)
Substrate Solution: 0.05% (w/v)
Antibody-Coated Particle Solution: 0.1% (w/v)
Enzyme-Labeled Antibody Solution: 0.1% (w/v)
Specimen Diluent 1: 0.1% (w/v)

3). Lumipulse G Substrate Solution is an alkaline solution (pH 10). Handle carefully to avoid contact with skin, eyes, or mouth.
4). In the event of accidental contact of any reagent with skin, eyes, or mouth immediately rinse thoroughly with water and seek medical attention if necessary.

3. PRECAUTIONS FOR USE

1). Follow the procedures described in this package insert, the package insert of Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges and the LUMIPULSE G System Operation Manual. Incorrect use of the reagents, instruments, or other consumables may result in unreliable data or accident hazard.
2). Do not use expired reagents.
3). To ensure measurement accuracy, always use freshly purified water.
4). Avoid using the 25-OH Vitamin D Calibrators which may have been stored in an improper way.
5). Use new sampling tips and new sample cups or sample tubes as specified by the LUMIPULSE G System. Refer to the LUMIPULSE G System Operation Manual.
6). Bring the 25-OH Vitamin D Calibrators to room temperature (15-25 °C). Mix the calibrators by gentle inversion.
7). Bubbles in sample cup or sample tube sometimes make sampling errors. If large amounts of bubbles appear in the dispensing droplets of the 25-OH Vitamin D Calibrators, the volume of the calibrating solution may be insufficient to perform the assay. Please use new 25-OH Vitamin D Calibrators.
8). When handling these calibrators, avoid contamination. Cap the bottle immediately after use.
9). Start the 25-OH Vitamin D assay immediately after sample setup to avoid evaporation of the specimen or 25-OH Vitamin D Calibrators.
10). Avoid removing the Substrate Solution until it is time to replace it. The Substrate Solution cannot be used if it is contaminated with alkaline phosphatase (ALP). Use new gloves when replacing the Substrate Solution. Ensure the substrate cap seal is properly installed to avoid air entering the system.
11). Replace the Soda lime on the LUMIPULSE G System according to the LUMIPULSE G System Operation Manual.
12). Sometimes a small amount of ingredients of the calibrators may precipitate. However, they do not influence measurement results.

4. PRECAUTIONS FOR WASTE

1). Lumipulse G 25-OH Vitamin D Calibrators as well as other reagents used in the calibration procedure contain 0.1% (w/v) sodium azide as a preservative. (See **2. PRECAUTIONS FOR HANDLING**). Follow any applicable regulations for disposal. If flushing down the drain, use generous amount of water when discarding to prevent the formation of explosive metal azides.
2). Handle any medical waste produced by this assay in compliance with waste-related regulations in each country or region.
3). When any liquid such as specimen or assay waste is splashed, wipe and disinfect the whole area with an appropriate disinfectant such as sodium hypochlorite or ethanol.

☆■ STORAGE INSTRUCTIONS

Store at 2-10 °C.

DO NOT FREEZE.

Product	Shelf life
Lumipulse G 25-OH Vitamin D Calibrators	12 months

The 25-OH Vitamin D Calibrators after first opening can be stored at 2-10 ℃ for a maximum of 12 month.

When stored and handled properly, the 25-OH Vitamin D Calibrators remains stable until the expiration date. Refer to the expiration date shown on the immediate container labels.

■ INSTRUMENT

The reagents are designed for a fully automated chemiluminescent enzyme immunoassay (CLEIA) on the LUMIPULSE G System. Refer to the LUMIPULSE G System Operation Manual for further information.

☆ ■ REAGENT PREPARATION

Ready-for-use Lumipulse G 25-OH Vitamin D Calibrators are supplied. Bring to room temperature (15-25 °C). Mix the calibrators by gentle inversion. Drip the required amount (more than 40 µL) of calibrators into the sample cup or sample tube, taking into account the dead volume which is at least 100 µL or 250 µL when using recommended sample cups or sample tubes for the LUMIPULSE G System respectively. The approximate drip volume per drop of solution is 45 µL. The drip volume fluctuates depending on how hard the container is pressed and if any bubbles are present in the calibrator. Refer to the LUMIPULSE G System Operation Manual for recommended sample cup or sample tubes, and the dead volume of each type of sample cup and sample tube.

For other reagent preparation refer to the package insert of the Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges.

■ CALIBRATION

1. Required Calibrators

Lumipulse G 25-OH Vitamin D Calibrators

2. Calibration Procedure

Refer to ■ **REAGENT PREPARATION**. For subsequent procedures follow the LUMIPULSE G System Operation Manual.

3. When to calibrate

Calibration is performed in the following cases:
1). On the first assay of the Lumipulse G 25-OH Vitamin D
2). When the Lumipulse G 25-OH Vitamin D Cartridges are replaced with a different lot.
3). When quality control results fall out of the range.
4). When 30 days have elapsed since the previous calibration. Update the calibration data whenever needed.

4. The calibrator must be tested in duplicate.

■ QUALITY CONTROL

1). Quality Control Material Preparation

Use control materials with at least two levels (e.g. low and high).

2). Quality Control Procedure

Refer to the package insert of control materials. Refer to Internal Quality Control Testing for further information. It is recommended to conduct Quality Control Testing at least once every 24 hours.

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11). Clinical and Laboratory Standards Institute. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline – Third Edition. CLSI Document C24-A3.

☆■ CONTACT

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☆■ GLOSSARY OF SYMBOLS

	Manufacturer	LOT	Batch Code
REF	Catalogue Number		Use by date
CAL	Calibrators		Temperature Limit
CAL 1	Calibrator (1-6)	MADE IN JAPAN	Made in Japan

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