Document No. : INS-VDC-EN (Rev.06)
Revision Date : November 7, 2017

ichroma™ Vitamin D Control

INTENDED USE

ichroma™ Vitamin D Control is intended for *in vitro* diagnostic use in the quality control test and calibration of ichroma™ Vitamin D Assay Kit.

This material can be used to monitor the control of the accuracy and reproducibility of ichroma™ Vitamin D Assay Kit. The user can compare the test results with the expected ranges as a means of assuring the consistent performance of ichroma™ Reader and Vitamin D Assay Kits.

For *in vitro* diagnostic use only.

SUMMARY AND PRINCIPLE

The use of ichroma™ Vitamin D Control may be considered as an objective assessment of the precision of ichroma™ Vitamin D Assay Kits and is an integral part of Good Laboratory Practices.

ichroma™ Vitamin D Control is provided in ball-type lyophilized form to maximize stability.

SAFETY PRECAUTIONS AND WARNINGS

- For *in vitro* diagnostic use only.
- Do not pipette by mouth.
- Exercise proper precautions that would be normally required for handling laboratory reagents.
- ichroma™ Vitamin D Control should not be used past the expiration date.
- ichroma™ Vitamin D Control is solely designed to monitor the accuracy of ichroma™ Readers and ichroma™ Vitamin D Assay Kits. Any test of ichroma™ Vitamin D Control on other instruments than ichroma™ Product may produce the values that may vary from the expected values thereof.
- Human source materials from which ichroma™ Vitamin D Control is derived were tested at a donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg) and Hepatitis C Virus (HCV) antibody, and found to be NON-REACTIVE. FDA-approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, these human source materials and all patient samples should be handled as though capable of transmitting infectious diseases and should be disposed of as hazardous wastes.

STORAGE AND STABILITY

- Opened: Store refrigerated (+2 to +8 °C). Once reconstituted, stable for 7 days at (+2 to +8 °C) if kept capped in original container and free from contamination. After use, any residual product should not be returned to the original tube.
- Unopened: Store refrigerated (+2 to +8 °C).
- ichroma™ Vitamin D Control is stable to expiration date on the label.
- Bacterial contamination of reconstituted ichroma™ Vitamin D Control will cause reductions in the stability of many components. If bacterial contamination is suspected, the tube should be discarded and a fresh tube needs to be reconstituted.

INSTRUCTIONS FOR USE

ichroma™ Vitamin D Control is supplied as ball shape lyophilized form.

1. Carefully reconstitute a tube of lyophilized serum with exactly 150 µL of sterilized distilled water at +15 to +25 °C.
2. Close the bottle and allow to stand for 30 minutes before use. Ensure the contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to the package, contact the **Boditech Med Inc.'s Technical Services.**

PROCEDURE OF SPOT CALIBRATION

If measured concentration is out of the range, ichroma™ Reader should be set up newly.

1. If 39 ng/mL result which is 30 % increased value from the mean value, 30 ng/mL.
2. Select the setting mode in the ichroma™ Reader.
3. Select calibration.
4. Select the Vitamin D by using IN or Select key.
5. Set -30 % by using Down key.

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MATERIALS SUPPLIED

ichroma™ Vitamin D Control (Tube)	1
Instruction For Use	1

CONTROL VALUE

The assigned ranges for ichroma™ Vitamin D Control is based on replicate assays of the representative samples by use of ichroma™ Reader and Vitamin D Assay Kits.
The control range is equivalent to the assigned mean ± 25 %.
The expected values may vary slightly depending on users.

Cat. No.	Lot No.	Exp. Date
CFPO-79	VDCNK23	2018.11

Analytes	Unit	Mean Value	Range	
			Low	High
Vitamin D	ng/mL	35	26.25	43.75

For Technical Assistance
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