SURE-VUE™ signature

Cryptosporidium/Giardia Control Set

REF 23-200-278

IVD *In vitro* Diagnostic Medical Device

℞ only

INTENDED USE
The **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Control Set is designed for use with the **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Test Kit as unassayed control material to monitor test performance.

SUMMARY AND EXPLANATION OF THE TEST
The **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Control Set consists of one bottle each of *Cryptosporidium* Positive Control and *Giardia* Positive Control. These controls are intended for use with **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Test Kit. The positive *Cryptosporidium* control should generate grey or black lines at the CRYP and CONT positions of the **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* test card demonstrating that all test reagents including the test card are active at the time of testing, the test was performed correctly (incubation time and temperature), and the control material flowed correctly. Similarly, the positive *Giardia* control will generate grey or black lines at the GIAR and CONT positions when all testing criteria have been met.

Each positive control reagent also functions as the negative control for the other antigen. For example, the *Giardia* Positive Control will generate a positive result for Giardia and a negative result for *Cryptosporidium;* while the *Cryptosporidium* Positive Control will generate a positive result for *Cryptosporidium* and a negative result for *Giardia.*

REAGENTS/MATERIALS PROVIDED
The **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Control Set includes one vial of each of the following controls ready for use:

- *Cryptosporidium* Positive Control: *Cryptosporidium* cell-wall antigen (derived from supernatant fluid of infected mouse stool) in buffer and 1.0% formaldehyde as a preservative. Store at 2-8°C when not in use. **DO NOT FREEZE.**
- *Giardia* Positive Control: *Giardia* cell-wall antigen (a combination of antigen generated in a *Giardia* lamblia cell line and the supernatant of infected gerbil stool, viable organisms removed by filtration) in buffer and 1.0% formaldehyde as a preservative. Store at 2-8°C when not in use. **DO NOT FREEZE**.
- The volume of each reagent is listed on container and package labels.

MATERIALS REQUIRED BUT NOT PROVIDED

1. **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Rapid Test Kit, Catalog # 23-200-277.

2. Interval timer.

3. Disposable gloves that should be used during the handling of patient samples.

PRECAUTIONS

1. All reagents are for *in vitro* diagnostic use only.

2. Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

2. Potential biohazard. Handle as if potentially infectious. "Universal Precautions" should be followed in handling all items contaminated with blood or other body fluids.[1,2]

3. Do not use controls beyond their labeled expiration date.

4. After completion of the test, all test components should be disposed of as bio-hazardous waste.

5. Disposable gloves should be worn when using the controls and performing the test. All materials that come in contact with the controls should be handled as potentially infectious.

6. These controls contain formaldehyde, which may cause sensitization when it comes in contact with skin. Use copious amounts of water to flush if the controls contact the skin.

HAZARD AND PRECAUTIONARY STATEMENTS

Warning

Danger

Hazard Statements:
H315: May cause an allergic skin reaction.
H350: May cause cancer.

Precautionary Statements:
P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.
P280+P281: Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P308 + P313: If exposed or concerned: Get medical advice/attention.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P321: Specific treatment (see First aid on the SDS).
P362+P364: Take off contaminated clothing and wash before reuse.
P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

TEST PROCEDURE

Test *Cryptosporidium* and *Giardia* Positive Controls as you would a patient sample by the procedure described in the package insert for **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Test Kit. Read all procedural instructions, including precautions and limitations before proceeding with testing. Mix the controls by inverting the vials just prior to use. Use a new transfer pipette for each control tested. Use caution when recapping to avoid cross-contamination of the controls.

INTERPRETATION OF RESULTS

- Visible test lines in any shade of grey or black only should be read as positive. Test lines in shades of yellow or brown should not be read as positive, but considered invalid.
- The intensity of the control line (CONT) should not be used as a reference for the evaluation of the quality control test line (GIAR or CRYP).
- Positive result: A grey or black line of any intensity at a test line and at the CONT position.
- Negative *Cryptosporidium* result: A grey or black line of any intensity at the CONT position and no line at the CRYP position.
- Negative Giardia result: A grey or black line of any intensity at the CONT position and no line at the GIAR position.

EXPECTED RESULTS

- *Cryptosporidium* Positive Control: A grey or black line of any intensity at the CRYP and CONT positions at the test window of the **SureVue™ *Signature*** *Cryptosporidium/Giardia* test card. No grey or black line should be observed at the GIAR position in the test window.
- *Giardia* Positive Control: A grey or black line of any intensity at the GIAR and CONT positions at the test window of the **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Rapid test card. No grey or black line should be observed at the CRYP position in the test window.

Invalid Results:
When results other than the expected results are obtained, the control tests should be repeated. If invalid results are replicated, all test results obtained with the **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Test Kit should be considered suspect. Test results should not be reported until the cause of the control failure has been identified and/or corrected. If invalid results occur repeatedly with a control reagent, contact Sekisui Diagnostics Technical Services at 1-800-332-1042.

LIMITATIONS OF THE PROCEDURE

The controls provided in the **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Control Set are designed for use only with the **Sure-Vue™ *Signature*** *Cryptosporidium/Giardia* Test Kit. The validity of the reactions they produce in other similar tests cannot be guaranteed.

REFERENCES
1. Bloodborne Pathogens. Code of Federal Regulations, Title 29, Part 1910. 1030, Federal Register. 1991. 56:64175-64182.

2. Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures. MMWR. 1991, Vol.40, No. RR-8.

ASSISTANCE:
For technical assistance, call Sekisui Diagnostics Technical Service at 800-332-1042.

RE-ORDER:
Sure-Vue™ *Signature* *Cryptosporidium/Giardia* Test Kit Catalog # 23-200-277
Sure-Vue™ *Signature* *Cryptosporidium/Giardia* Control Set Catalog # 23-200-278

Manufactured for:

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KEY TO COMPONENT LABELING


Use by YYYY-MM-DD

Batch code

Catalog number

In vitro diagnostic medical device


Temperature limitation


Do Not Freeze


Manufacturer


Consult instructions for use

Positive Control


Warning, consult SDS for further information


Danger, consult SDS for further information

Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner


This product fulfills the requirements of Directive 98/79/EC on In Vitro Diagnostics Medical Devices.