

HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Tài liệu được xác nhận bằng chữ ký số

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Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

Nguyễn Thị Minh Phương

QUANTA Flash[®] SS-B

Controls

For *In Vitro* Diagnostic Use. Complexity: Moderate

REF 701152

Rx Only

Intended Use

QUANTA Flash SS-B Controls are intended for quality control in the determination of IgG anti-SS-B autoantibodies in human serum.

Summary and Principles of the Procedure

The QUANTA Flash SS-B Controls are made up of a Negative Control and a Positive Control. Each contains a different amount of anti-SS-B antibodies. The Negative Control and Positive Control are used to monitor the analytical performance of the QUANTA Flash SS-B chemiluminescent immunoassay.

Reagents

1. QUANTA Flash SS-B Negative Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human antibodies to SS-B in stabilizers and preservatives.
2. QUANTA Flash SS-B Positive Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human antibodies to SS-B in stabilizers, and preservatives.

Warnings

1. All human source material used in the preparation of controls for this product has been tested and found negative for antibody to HIV, HBsAg, and HCV by FDA cleared methods. No test method however can offer complete assurance that HIV, HBV, HCV or other infectious agents are absent. Therefore, the QUANTA Flash SS-B Controls should be handled in the same manner as potentially infectious material.¹
2. Use appropriate personal protective equipment while working with the reagents provided.
3. Spilled reagents should be cleaned up immediately. Observe all federal, state and local environmental regulations when disposing of wastes.

Precautions

1. This product is for *In Vitro* Diagnostic Use.
2. The QUANTA Flash SS-B Controls are for use with the QUANTA Flash SS-B assay.
3. Do not transfer the control reagents to secondary tubes. The barcodes on the tubes are used by the instrument to identify the control.
4. Once opened, each control tube is good for up to 15 uses with an average time of 10 minutes onboard the instrument per use, for a total of 2 ½ hours.
5. Chemical contamination of the reagents can result from improper cleaning or rinsing of the instrument. Residues from common laboratory chemicals such as formalin, bleach, ethanol, or detergent can cause interference in the assay. Be sure to follow the recommended cleaning procedure of the instrument as outlined in the BIO-FLASH operator's manual.

Storage Conditions

1. Store unopened controls at 2-8°C. Do not freeze. Reagents are stable until the expiration date when stored and handled as directed.
2. Opened controls can be used for up to 15 times, with an average time of 10 minutes onboard the instrument per use. The total time the control tubes can be uncapped, onboard the instrument is 2 ½ hours. If the controls are left uncapped, onboard, for a total time greater than 2 ½ hours, they should be discarded.
3. For optimal stability, remove controls from the system immediately after sampling and store them at 2-8°C capped in the original vial.

Materials Provided

- 2 QUANTA Flash SS-B Negative Control
- 2 QUANTA Flash SS-B Positive Control

Additional Materials Required But Not Provided

BIO-FLASH instrument with operating computer
BIO-FLASH System Rinse (Part Number: 3000-8205)
BIO-FLASH Triggers (Part Number: 3000-8204)
BIO-FLASH Cuvettes (Part Number: 3000-8206)
QUANTA Flash SS-B Reagents (Part Number: 701153)
QUANTA Flash SS-B Controls (Part Number: 701152)

Procedure

To Create New QC Materials for the SS-B Assay:

1. Prior to using QUANTA Flash SS-B Controls for the first time on the instrument, enter the name, lot, expiration, value (or dose), and target standard deviation (SD) information into the software.
2. From the **Instrument Summary** screen, click the **Choose more options – Ctrl-M (▼)** arrow button. Select **QC Ctrl-F2**. Click the **New QC Material** button.
3. A lot specific data sheet is included with each Control kit. First enter the name, lot number, expiration from this data sheet into the software. Next, click the **Add Assay** button. In the new window, make sure the **Show All Assays** box is checked. Select the SS-B assay from the list and click **Add**. Finally, enter in the target dose and target SD. Click **Save**. Perform this process for both controls.

To Create a New Lot for Existing QC Materials:

1. Prior to using a new lot of QUANTA Flash SS-B Controls for the first time, enter the lot, expiration, value (or dose), and target SD information into the software.
2. From the **Instrument Summary** screen, click the **Choose more options – Ctrl-M (▼)** arrow button. Select **QC Ctrl-F2**. Highlight the SS-B assay in the column on the left. Then highlight the appropriate control material on the right (either “SSBN” for the Negative Control or “SSBP” for the Positive Control). Click the **New QC Lot** button.
3. A lot specific data sheet is included with each Control kit. Enter the information from this data sheet into the software. This should include the lot number, expiration, target dose, and target SD. If necessary, click the **Add Assay** button. In the new window, make sure the **Show All Assays** box is checked. Select the SS-B assay from the list and click **Add**. Click **Save**. Perform this process for both controls.

It is recommended that the QUANTA Flash SS-B Controls be run once every day that the assay is used; however, users should also consider national/local regulatory requirements.

Each control must be gently mixed before use to insure homogeneity. Avoid foam formation, as bubbles may interfere with the instruments liquid level detection. Uncap each control tube and place both into a sample rack, with the barcodes facing forward through the gaps in the rack. Place the sample rack into the sample carousel of the BIO-FLASH instrument, and close the door. The instrument will read the barcodes on the control tubes, and identify the required reagent cartridge. Refer to the operator's manual provided with the BIO-FLASH system for detailed operating instructions of the BIO-FLASH chemiluminescent analyzer and the BIO-FLASH software.

Traceability

No international standard serum for anti-SS-B antibodies is available that allows for the standardization of anti-SS-B antibody assays.

The Reference sera IS2073 ANA #2 and IS2074 ANA #3 from the Center of Disease Control and Prevention have been tested and showed a concentration of 1634.9 CU and 284.1 CU, respectively.

Limitations

These controls are designed for 15 uses. The label of each control tube has a row of 15 boxes that may be checked off so as to track the number of uses. The total time the control tubes can be uncapped onboard the instrument is 2 ½ hours. If the controls are left uncapped, onboard, for any longer period of time, they should be discarded.


Performance Characteristics/Expected Values

Refer to the QUANTA Flash SS-B Reagents directional insert (Part Number 621150) for performance characteristics.


References

1. Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition. **Centers for Disease Control/National Institute of Health**, 2009.

Symbols Used


 *In Vitro* diagnostic medical device


 Prescription only per US FDA


 Consult instructions for use

 Temperature limitation

 Do not reuse


 Biological risks


 Batch code

 Catalog number

 Use by


 Manufacturer


 Authorized representative

 Contains sufficient for < n > tests

 Positive Control

 Negative Control

 Recycle paper box

 This end up

 European Conformity

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Manufactured By:

Inova Diagnostics, Inc.
9900 Old Grove Road
San Diego, CA 92131
United States of America

Technical Service (U.S. & Canada Only) : 877-829-4745
Technical Service (Outside the U.S.) : 1 858-805-7950
support@inovadx.com

Australian Sponsor:

Werfen Australia Pty Ltd
59-61 Dickson Avenue
Artarmon NSW 2064 Australia
Tel. +61 2 9098 0200 / 1300 369 132
<http://au.werfen.com/>

Authorized Representative in the EU:

Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert, Germany
Tel.: +49-6894-581020
Fax.: +49-6894-581021
www.mt-procons.com

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