

# HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

*Tài liệu được xác nhận bằng chữ ký số*

*Hà Nội, ngày 18 tháng 10 năm 2022*

**Người đại diện hợp pháp của cơ sở**

**GIÁM ĐỐC**

**Nguyễn Thị Minh Phương**

# QUANTA Flash<sup>®</sup> SS-B Calibrators



For *In Vitro* Diagnostic Use. Complexity: Moderate

**REF** 701151

**Rx Only**

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## Intended Use

QUANTA Flash SS-B Calibrators are intended for use with the QUANTA Flash SS-B Reagents for the determination of IgG anti-SS-B autoantibodies in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate unit values.

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## Summary and Principles of the Procedure

The QUANTA Flash SS-B CIA utilizes a predefined lot specific Master Curve that is stored in the reagent cartridge barcode. The QUANTA Flash SS-B Calibrators are designed to produce an instrument specific Working Curve from the parameters of the Master Curve, with a decision point based on the performance characteristics and clinical evaluation of the QUANTA Flash SS-B CIA. Calibrators are tested on multiple instruments with multiple lots of reagents prior to value assignment.

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## Reagents

1. QUANTA Flash SS-B Calibrator 1: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human antibodies to SS-B in stabilizers and preservatives.
2. QUANTA Flash SS-B Calibrator 2: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human antibodies to SS-B in stabilizers and preservatives.

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## Warnings

1. All human source material used in the preparation of calibrators for this product has been tested and found negative with FDA cleared methods for antibody to HIV and HCV, and for HBsAg No test method however can offer complete assurance that HIV, HBV, HCV or other infectious agents are absent. Therefore, the QUANTA Flash SS-B Calibrators should be handled in the same manner as potentially infectious material.<sup>1</sup>
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.

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## Precautions

1. This product is for *In Vitro* Diagnostic Use.
2. The QUANTA Flash SS-B Calibrators are for use with the QUANTA Flash SS-B assay.
3. Do not transfer the calibrator reagents to secondary tubes. The barcodes on the tubes are used by the instrument to match the calibrators to the proper assay type.
4. Once a calibrator tube is opened, it is good for up to 8 hours kept uncapped, onboard the instrument, after which the reagent must be discarded.

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

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1. Store unopened calibrators at 2-8°C. Do not freeze. Reagents are stable until the expiration date when stored and handled as directed.
2. Opened calibrators must be discarded after 8 hours kept uncapped, onboard the instrument.

## Materials Provided

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- 2 QUANTA Flash SS-B Calibrator 1
- 2 QUANTA Flash SS-B Calibrator 2

## Additional Materials Required But Not Provided

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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

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1. Each new lot of reagent cartridge must be calibrated prior to first time use. The software will not allow a new lot to be used until it is calibrated.
2. Each calibrator must be gently mixed before use to insure homogeneity. Avoid foam formation, as bubbles may interfere with the instrument's liquid level detection. Uncap each calibrator 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 calibrator 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.
3. The instrument will run each calibrator in triplicate. After the Calibrators have been run, the software will require the calibration to be validated. From the **Instrument Summary** screen, click the **Choose more options – Ctrl-M (▼)** arrow button. Select **Calibration Ctrl-F3**. In the **Calibration** window, highlight the desired assay, and click **Details**.
4. In the new **Calibration Details** window, select the calibration that was just performed. The Master Curve appears as a dashed line, while the new Working Curve appears as a solid line. If the calibration results are valid, a validation button will appear in the lower left of the screen. Click the **Validate Calibration** button.
5. Once the calibration is validated, the reagent cartridge lot on which the calibration was performed is ready for use. It is recommended that the QUANTA SS-B Controls (sold separately – part number 701152) be run after a reagent cartridge lot is calibrated.

## Traceability

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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

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These calibrators are designed for 4 calibrations. The total time the calibrator tubes can be uncapped onboard the instrument is 8 hours. If the calibrators are left uncapped, onboard, for any longer period of time, they should be discarded. Using the same calibrator tubes for more than 8 hours can result in improper calibration of the assay, which in turn could give erroneous results.

## Performance Characteristics/Expected Values

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


## References

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

## Symbols Used

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 *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

 Calibrator 1

 Calibrator 2

 Recycle paper box

 This end up

 European Conformity

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