Quality approved by SD BIOSENSOR / For *in vitro* diagnostics use only

STANDARD F

iFOB Control

REF C-F-FOB

STANDARD™ F iFOB Control

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION AND SUMMARY

[Intended use]

STANDARD F iFOB Control is designed to monitor the performance of STANDARD F iFOB FIA test and STANDARD F Analyzer. During operation of the STANDARD F Analyzer, at least two levels of an appropriate quality control reagent should be tested on a regular basis. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.

[Test principle]

Two different levels of control help monitoring the performance of STANDARD F iFOB FIA test. The range of each control is indicated on the bottle with a bar code which contains necessary information to process the quality control assessment. Both level 1 & level 2 tests should be separately performed in order, and results of the test should be within the given ranges.

ACTIVE INGREDIENTS OF MAIN COMPONENT

[Contents]

① STANDARD F iFOB Control – Level 1 : 10 tablets in the bottle. (Transparent tube)
② STANDARD F iFOB Control – Level 2 : 10 tablets in the bottle. (Red colored tube)
③ Instructions for use

[Reagents composition]

This product is composed of human Hemoglobin with other preservatives and stabilizers.
The range of control level is indicated on the label of the each bottle.

Components	Composition (per 1 tablet)
Level 1 control tablet	Low level of human hemoglobin
Level 2 control tablet	High level of human hemoglobin

[Materials required but not provided]

- STANDARD F Analyzer
- STANDARD F iFOB FIA test kit

KIT STORAGE AND STABILITY

1. Store the STANDARD F iFOB Control at 2-30°C / 36-86°F.
2. Avoid direct sunlight.
3. Do not freeze the test kit.
4. Kit materials are stable until expiration date printed on the outer box.

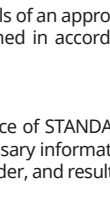
WARNINGS AND PRECAUTIONS

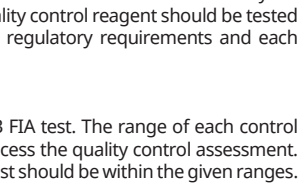
1. Check the expiration date on the test kit, and do not use expired product.
2. If there is the evidence of microbial contamination or excessive turbidity, discard the control bottle.
3. The control bottle itself is a dehumidifier. Cap the control bottle tightly to maintain the quality.

CONTROL TEST PROCEDURE

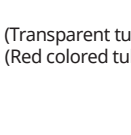
[Preparation]

1. Expose STANDARD F iFOB FIA test kit and STANDARD F iFOB Control at room temperature at least 30 minutes prior to the test.
2. Carefully read instructions to use.
3. Check the expiration date of the control on the bottle and of the test device on the pouch. Do not use expired controls or test devices.

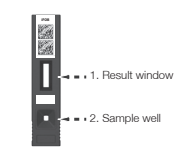




4. Open the foil pouch, and check the components. [Test device, Silica gel]



<Foil pouch>



<Test device>

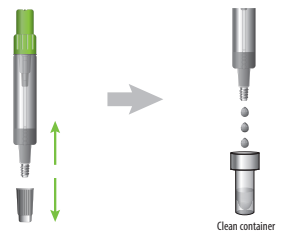
<Silica gel>

CAUTION

- Do not write on the bar code, or damage the barcode of the test device.

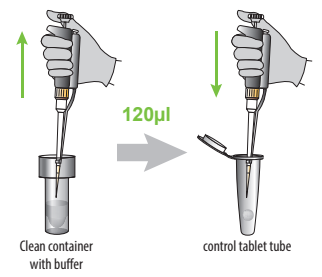
[Preparation of control]

1. Transfer an appropriate amount of buffer to a clean container.

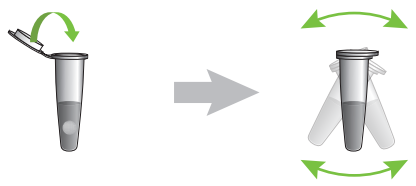


2. Open the level 1 control bottle, and take a control tablet tube out.

3. Using a micropipette, dispense 120µl of buffer into the control tablet tube.

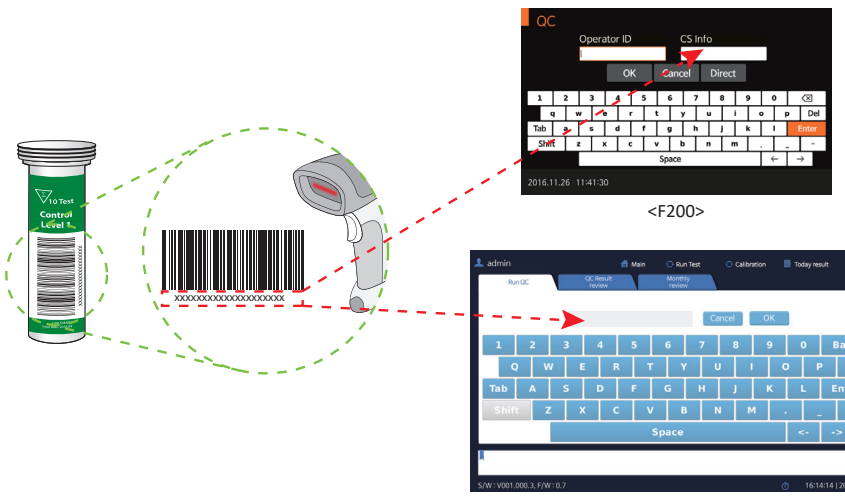


4. Close the control tube lead, and then shake several times to mix thoroughly. **Check if the control tablet is mixed well after shaking.**



[Analysis of control]

- **Using a 'QC' mode**
  - **Applying QC sample to STANDARD F100, F200 and F2400 analyzers**
    1. Prepare a STANDARD F Analyzer and select the "QC" mode according to the analyzer's manual. In case of STANDARD F100 Analyzer, select the 'STANDARD TEST' mode, and then press the right(▶) button to conduct the QC test.
    2. In case of STANDARD F200 and F2400 analyzers, select "Control ID" column, and then scan the barcode on the control bottle or manually enter the barcode number on the control bottle.

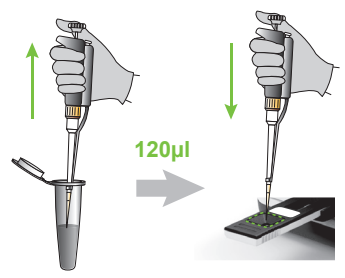


<F200>
<F2400>

3. Take the test device out of the foil pouch.

4. Insert the test device into the test slot.

5. Dispense 120µl of control mixture into the sample well of the test device.



6. After applying the sample, immediately press the 'TEST START' button.

<F100>

<F200>

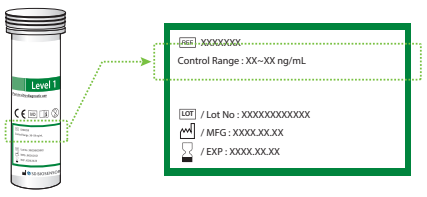
<F2400>

7. The analyzer will automatically display the QC result within 5 minutes.

8. **[F100 Analyzer]**
Compare the final result to the given range listed on the control bottle.

[F200, F2400]
The test result will be concluded "Pass" or "Fail" with a quantitative value.

If the result is out of range(Failed), repeat the test. If the re-test value is also unacceptable, please contact the customer service center.



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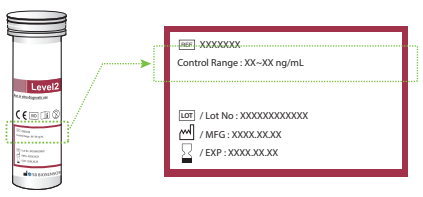
9. Perform the same test with a Level 2 control tablet to evaluate the performance of a high value.



Product Disclaimer
Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning
The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

CE IVD

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IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
To indicate the temperature limitations in which the transport package has to be kept and handled.
Note
Do not re-use.
Use by
LOT Batch code
Manufacturer
Date of manufacture
CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices