

OC-SENSOR PLEDIA



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1. SET-UP AND LOG IN

● Set Up OC-SENSOR PLEDIA

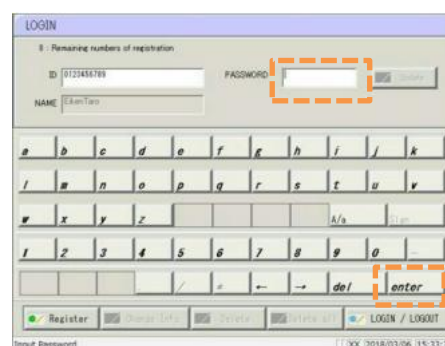
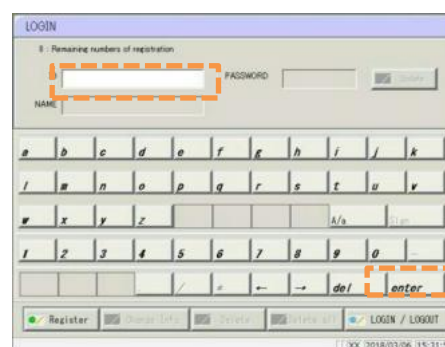
- (1) Set thermo-sensitive paper.
- (2) Turn the system power switch on (on the right side).
 - 【LOGIN】 screen will be displayed

● Set Up OC-SENSOR PLEDIA

- (1) Touch [ID] field, enter an ID and touch [enter].
 - Registered name will be shown in [NAME].
 - [PASSWORD] field will be enabled (will be white).
- (2) Touch [PASSWORD] field, enter password and touch [enter].
 - [Register][Delete] will be enabled.
- (3) Touch [LOGIN / LOGOUT] button.
 - “OK” dialog will be shown.
- (4) Select [LOGIN].
 - 【MENU】 screen will be displayed.
 - The ID will be shown.

● Remarks

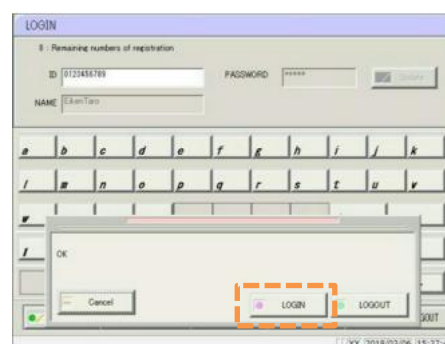
- If [LOGIN/LOGOUT] > [LOGOUT] is selected in 【LOGIN】 screen, only [Prep functions], [Help] and [Close] will be enabled as below.



- The other buttons cannot be selected.

- In order to login, touch [Please LOGIN] to show 【LOGIN】 screen, and login as above procedure.

- In order to change user (logout)
 - Touch [ID] field in 【MENU】 screen to show 【LOGIN】 screen.
 - Select >[LOGOUT].
 - Login as above procedure.



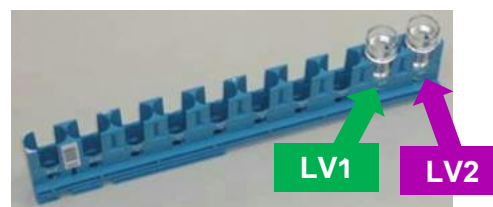
2. SET REAGENTS AND SAMPLES

• Set Reagents

- (1) Check the level of purified water and wash solution.
 - Refill purified water and wash solution if not enough.
 - If bubbles are in the tanks, hit the side of tank to remove them.
 - See [How To Set The Purified Water] and [How To Set The Wash Solution] [<P.7>](#)
- (2) Check that drain tank is not full.
 - Dispose of wasted fluid if needed.
- (3) Check that OC-SENSOR DIANA Buffer (BUFFER) is set.
 - Replace with a new one if not enough.
 - See [How To Set BUFFER] [<P.7>](#)
- (4) Check that OC-SENSOR Latex reagent (LATEX) is set.
 - See [How To Set LATEX] [<P.7>](#)

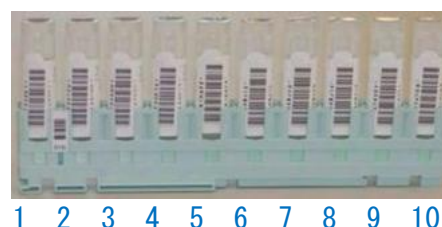
• Set Samples/QC(Control)

- (1) Set QC (OC-Control LV1/LV2) on a rack (blue rack).
 - Pour OC-Control LV1 and LV2 in sample cups.
 - Dead volume is 100 uL.
 - Pour needed amount of solution according to the number of replications.
 - Ex.) 1 replication: 4 drops, 2 replications: 5 drops
 - *See [How To Set The Replication Number of QC] [<P.10>](#)



□ Check that there's no bubbles

- ||||| ● Set QC on No.9 and No.10 of STD/QC rack (Blue rack).
- ||||| ● In case of measuring both OC-Control LV1 and LV2, set them in the same order every time.
- ||||| ● QC will be numbered differently from Sequence No. to distinguish from samples.



- (2) Set samples on a sample rack. (Light blue rack)
 - Set sampling bottles from the 1st side in turn with aluminum seals as the top.
 - Check that the green caps are closed tightly.
 - Barcode labels must be on the side of rack barcode label.

- (3) Set racks on the rack supply unit. (Right side).



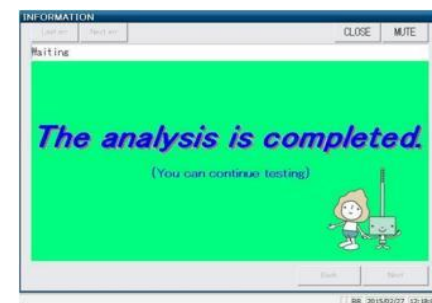
• Remarks

- With "Numbering Mode 2", allocate sequence No. evenly to positions in which samples are not set.
- If the Endring is set after the last sampling bottle, numbering will stop at the position of Endring.

3. TEST WORK

● Start Testing

- (1) Go to Test screen.
 - Press [Test] button on the [MENU] screen.
- (2) Check the settings of [Test] screen.
 - See [Test Mode]. [<P.9>](#)
- (3) Check the settings of LATEX and calibration curves.
 - See [Settings Of Latex / Calibration Curve]. [<P.10>](#)
- (4) Start test.
 - Press [Start] button.
 - If the temperature of the reaction table, reagent or buffer solution is not high enough, test will only start automatically after the temperature rises.
 - After sampling, racks will be discharged to the rack discharge unit (Left side).
 - The result data will be displayed.
 - If "Output to printer" is "YES", the result data will be printed.
- (5) Testing is completed.
 - [The analysis is completed] screen will be displayed.
 - Press [Close] button.
 - The screen will go back to [Test] screen.
 - Press [Completed] button and then press [Close] button.
 - [MENU] screen will be displayed.



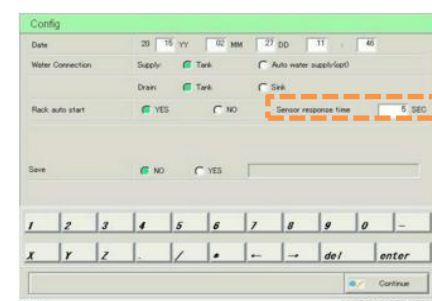
● Addition Of Sample Racks - 1

< Test under the same conditions >

- (1) Set racks on rack supply unit during test.
 - Sample-guide will move toward you.
- (2) Measure mode is recognized by rack barcode automatically.

Light Blue	Sample rack
Blue	STD/QC rack
Yellow-Green	Retest rack
Orange	Dilute retest rack

- The "Light Blue rack" and the "Yellow-Green rack" can set only sampling bottle



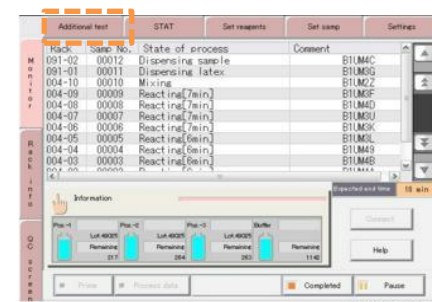
● Remarks

- Settings the time between rack installation and operation.
 - [Settings] → ([System settings]) → [Config]
 - Input the time of "Sensor response time". (0 to 60 sec)

● Addition Of Sample Racks - 2

<Test samples with different settings>

- (1) Press [Additional test] button during test.
- (2) Set items to change.
 - [Rack No.]: Input first rack number
 - [Rack]: Input the number of racks of additional tests.
 - After testing, the settings will return to the original.
 - In case [Rack] is "*", analysis will continue with the changed settings.
 - Press [Continue] button and then press [Register] button.
- (3) Press [Continue] button and then press [Register] button.
- (4) Set racks and press [Continue] button.



•STAT

4. STAT TESTING

- (1) Press [STAT] button during testing.
 - After sampling of analyzing rack, the <Fig. A> is displayed.
 - Only sample racks (light blue) or STD/QC racks (blue rack) are available.
 - Retest rack (Yellow-Green rack) and dilute retest rack (Orange rack) are unavailable with STAT mode.
- (2) After <Fig. B> is displayed, set the rack as the screen shows.
 - Rack barcode must be toward you.
- (3) Press [Start] button.
 - <Fig. C> will be displayed.
 - <Fig. D> will be displayed.
 - Sequence No. is from S-00001.
- (4) After STAT is finished, <Fig. B> will be displayed.
 - Take the rack out and press [Cancel] button to close.
 - Unless the above operation is done, next test won't start.

Fig. A

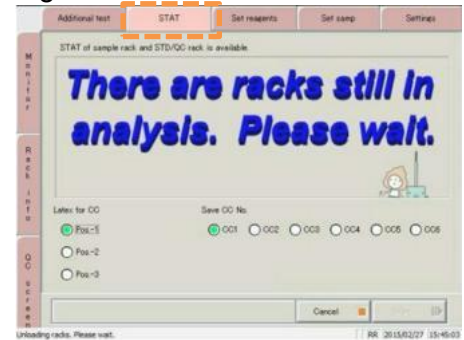


Fig. B

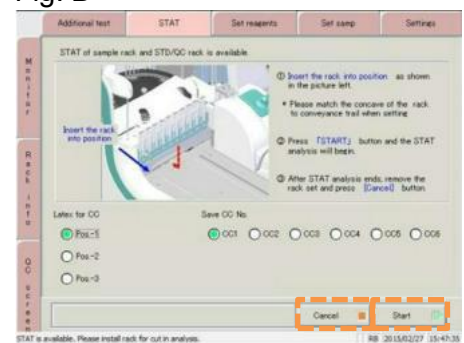


Fig. C

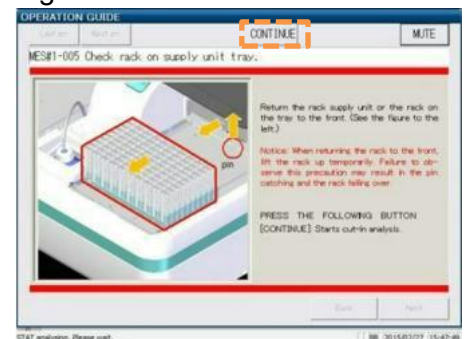
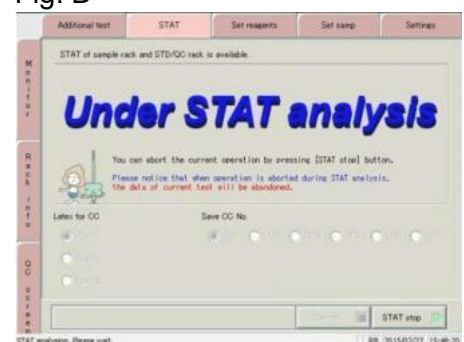


Fig. D



5. CLOSING AND SHUTTING DOWN

● Dispose Samples

- (1) Dispose samples.
 - Remove tested samples from the rack discharge unit and dispose of them.
- (2) Keep LATEX.
 - Close the caps of LATEX bottles and keep the bottles in a refrigerator or the latex storage.



● Close OC-SENSOR PLEDIA

- (1) 【MENU】 → 【Close】
- (2) Select the settings < Recommended mode >

Weekday and Weekend

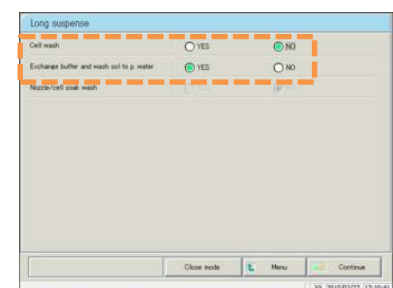
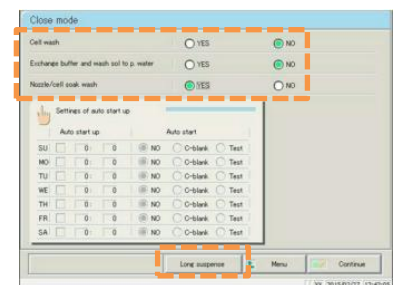
- Close mode ☐ YES ☒ NO
- Cell wash ☐ YES ☒ NO
- Exchange to p. water ☐ YES ☒ NO
- Soak washing ☒ YES ☐ NO

Suspension for more than 7 days

- Close mode ☐ YES ☒ NO
- Cell wash ☐ YES ☒ NO
- Exchange to p. water ☒ YES ☐ NO
- Soak wash ☒ YES ☐ NO

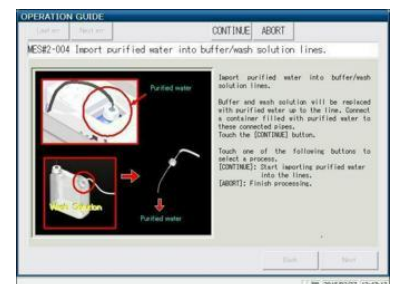
Suspension for more than 3 months

- Long suspension ☐ YES ☒ NO
- Cell wash ☐ YES ☒ NO
- Exchange to p. water ☒ YES ☐ NO



- (3) Press [Continue] button and then press [Start] button.
(Closing action will start)

- After closing, OC-SENSOR PLEDIA will be turned off the power automatically.
- If "exchange to p. water" is "YES", "Operation guide" will be displayed.
- If "Long suspension" is selected, "Operation guide" will be displayed.
- After "Exchange to p. water" is done, next time the system is turned on, BUFFER and wash solution are set according to the displayed guidance.



● Settings of auto start up

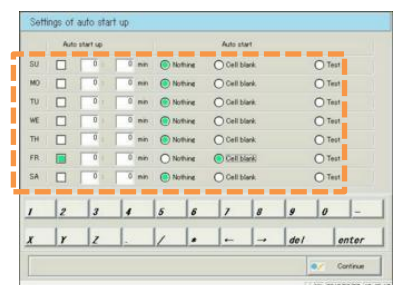
- Press [Setting of auto start up] button at 【Close mode】 screen.

(1) Auto start up

- Put ■ on the days to use [Auto start up] and set time.
- Change this setting a day before a public holiday.

(2) Auto start

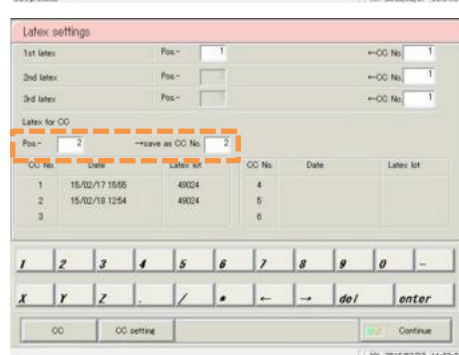
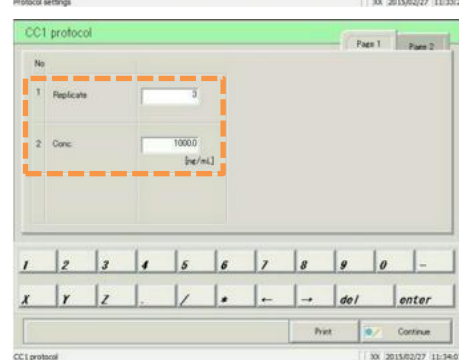
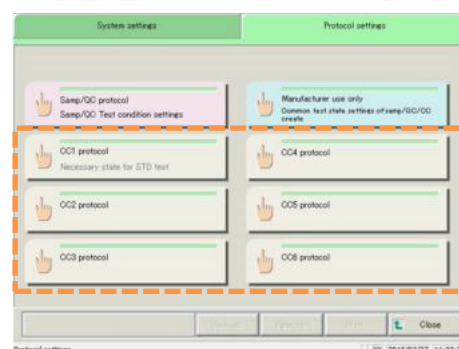
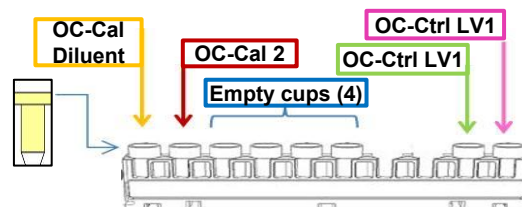
- You can set operations after starting up.
- Put ● on the items for auto start.
 - [Nothing]: After starting up, 【MENU】 screen will be displayed.
 - [Cell blank] : After starting up, cell blank will be checked.
 - [Test] cannot be selected.



6. CALIBRATION

● Calibration Curve Creation

- (1) Pour 2ML (or more) of OC-Calibrator Diluent into a sample cup
 - Check that there's no bubble.
- (2) Put 11 drops of OC-Calibrator 2 into a sample cup.
 - Check that there's no bubble.
- (3) Set sample cups on a rack.
 - Set sample cups on a STD/QC rack (blue rack) as right figure.
 - Set QC-samples on 9th and 10th if needed.
- (4) Input the concentration of OC-Calibrator 2.
 - MENU → [Settings] → [Protocol settings]
 - Select [CC protocol settings] to use.
 - Input the number of replication.
 - Input the concentration of OC-Calibrator 2 written on the label of the vial.
 - [Continue] → [Register]
- (5) Set the rack. (see [●TEST WORK <P.3>]).
 - [MENU] → [Test]
 - Set the rack on the rack supply unit.
- (6) Press [Latex settings] button.
 - Set LATEX # to make calibration curve.
 - Set CC No. to register
- (7) Press [Start] button.
 - OC-Calibrator 2 will be diluted in sample cups automatically.
 - Diluted solution will be dispensed and measured.
 - When LATEX not registered is set, [No CC] comment will be displayed as below figure. Press [Continue] button to continue.



XX 2015/02/27 11:34:07



RR 2015/02/27 12:38:13

- 8) Test Completed)
 - After test, [Check CC] screen will be displayed..
 - Check the result and press [Register] button.
 - <JUDGEMENT>
 - > It is acceptable with white square (□) at the side of "STD-#", not turned red.
 - > See [●Addition of Samples -1 or -2 <P.3>] to continue the test.

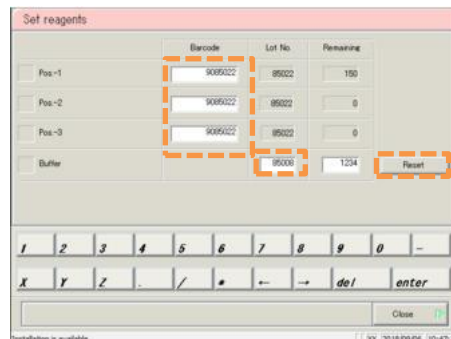
● Remarks

- Calibration Curve creation is acceptable anytime during test.

7. SETTING THE REAGENTS

● How To Set LATEX

- (1) 【MENU】 → 【Set latex】
- (2) Press the white frame of [Barcode] to set.
 - The barcode reader will flash.
- (3) Pull down the green unit.
- (4) Place barcode label of LATEX toward you and set LATEX bottle in the entry.
 - Barcode number will be displayed.
- (5) Take LATEX bottle and push back the green unit to the original position.
- (6) Invert LATEX bottle several times gently and open the cap.
- (7) Open the Front cover of reaction part.
- (8) Open the cover of latex storage and set LATEX bottle with the barcode label toward you and close the cover.
 - To set another latex bottle, repeat (2) to (6).
 - Check that there's no bubble.
- (9) Close the cover of latex storage and Front cover.
- (10) Press [Close] button.
 - Volume of latex will be detected automatically.



● How To Set BUFFER

- (1) Replace BUFFER bottle with new one.
 - Please don't lose the spacer.
- (2) Close the cap.
- (3) Select 【MENU】 → 【Set latex】 .
- (4) Enter [Lot No.].
- (5) Select [Reset] → [Close].
 - Prime will start automatically.



● How To Set The Purified Water

- (1) Open the cap of purified water tank and refill
 - Please do not lose the cap spacer.
- (2) Close the cap
- (3) Normal prime operation
 - see [●Prime Operation] [<P.8>](#)



For making a 0.15% solution;

By using a 3% stock solution, you need 250 mL of stock solution of NaClO and 4750 mL of water.

By using a 5% stock solution, you need 150 mL of stock solution of NaClO and 4850 mL of water.



● How To Set The Wash Solution

- (1) Make Wash solution.(0.15% NaOCl solution)
- (2) Open the cap of wash solution tank and refill.
 - Please do not lose the cap spacer.
- (3) Close the cap.
- (4) Normal prime operation
 - see [●Prime Operation] [<P.8>](#)

|| Refresh the purified water every day.



8. (NOTE 1): PRIME & CELL BLANK

● Prime Operation

- (1) 【MENU】 → 【Prep Functions】 → 【Prime】
- (2) Select [Normal prime] and [●Yes] of items needed.
 - Select [Volume reset] and BUFFER volume will be reset.
- (3) Press [Start] button.
 - Prime will start automatically.

● Cell Blank Check

- (1) 【MENU】 → 【Prep Functions】 → 【Cell blank】
- (2) Select [●Wash cells] and press [Start] button.
 - Cell blank check will be started.
 - After cell blank check, result will be shown on the screen.
- ||||| ● Cells in red color are unusable.
 - Unusable cells are not used for analysis.
 - When unusable cells are more than 10, all the cells (5 units) must be exchanged.



9. (NOTE 2): TEST MODE & DILUTE RETEST

● Test Mode

(1) Sample No.

- [G] : Group No.
➢ This is for controlling by groups. Input “*” if not needed.
- [SEQ]: Sequence No.

(2) Numbering

- When sampling bottles are set with empty rack position, number only sampling bottles (skip empty rack position).
➢ Mode 1 : Numbering only sampling bottles
➢ Mode 2 : Numbering all rack position (both of sampling bottles and empty rack position)

(3) Sample barcode

- Read barcodes of sampling bottles or not.

(4) Method

- Select [1 day], [2 day] or [3 day].
- Regarding how to set the rack of each method, please check the “Operation Manual”.

(5) Measure mode

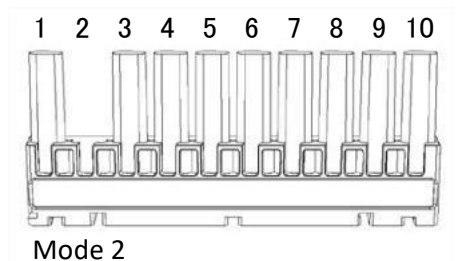
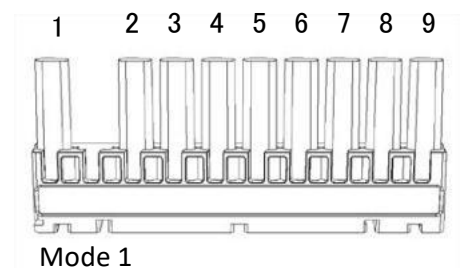
- Test: Measure mode is recognized by rack barcode automatically
➢ Light blue rack: Sampling bottles will be punctured.
➢ Yellow-Green rack: Sampling bottles will not be punctured.
- Retest: Sampling bottles will not be punctured even with light blue rack.

(6) Test start point

- Test will start from this position of first rack which is set in this mode.

(7) Key mark

- Yellow : Settings **cannot** be changed.
- Gray : Settings can be changed.



● Dilute Retest

(1) This mode is for diluting samples and retesting. (for OR and PRC samples)

- Dilute rates are <15 times> and <250 times>
- At most, 3 samples are available for dilute test by one rack.
- The sample solution can set in sample cups.

(2) How to measure

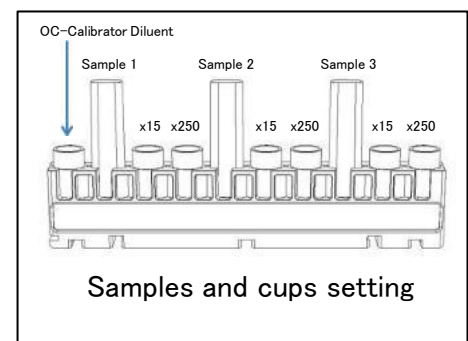
- Set OC-Calibration Diluent (included in OC-Calibration 2 kit) on 1st position of dilute retest rack. (2 mL or more).
- The sampling bottles or sample solution will be in the position 2, 5, 8 on the rack.

15 times

- Set sample cups on the position 3, 6, 9 on the dilute retest rack like right figure.

250 times

- Set sample cups on the position 3&4, 6&7, 9&10 on the dilute retest rack like right figure.



10. SETTING CALIBRATION CURVE & CUT-OFF

● Setting Of Latex / Calibration Curve

- (1) **[MENU] → [Test] → [Latex settings]**
- (2) **[1st latex]**
 - Input LATEX position No. (1, 2 or 3) for test.
 - Input calibration curve No. (1 to 6) of the 1st LATEX.
- (3) **[2nd latex]** (1st spare latex)
 - Input calibration curve No. (1 to 6) of the 2nd LATEX.
- (4) **[3rd latex]** (2nd spare latex)
 - Input calibration curve No. (1 to 6) of the 3rd LATEX.
- (5) **[Latex for CC]**
 - Input latex position No.(1, 2 or 3) for calibration curve creation.
 - Input calibration curve No. (1 to 6) for registration.

● How To Set The Replicate Number of QC

- (1) **[MENU] → [Settings] → [Protocol settings] → [Sample/QC protocol]**
- (2) **[QC Replicate]**
 - Input the replication number of QC test.
- (3) **[Continue] → [Register]**

● How To Set The Concentrate Range of QC

- (1) **[MENU] → [Settings] → ([System Settings]) → [STD/QC process] → [Page 2]**
- (2) Input the concentrate range of OC-Control LV1, LV2 written on the package insert.
- (3) Press **[Continue]** button and then press **[Register]** button.

● How to Set The Cut-off Value

- (1) **[MENU] → [Settings] → [Protocol settings] → [Sample/QC Protocol]**
- (2) Input cut-off value of
 - ☐ [3 Cut off 1]
 - ☐ [4 Cut off 2]
 - ☐ [5 Cut off 3]
 - From 0 ng/mL and [cut-off 1] or less
 - [cut-off 1] + 1 or above and [cut-off 2] or less
 - [cut-off 2] + 1 or above and [cut-off 3] or less
 - [cut-off 3] + 1 or more
 - If only positive or negative (- or +) needed, input the value only on [cut-off 1] and input “*” on cut-off 2 and 3.
- (3) Press **[Continue]** button and then press **[Register]** button.

The image displays four screenshots of the device's menu system, showing the steps to set calibration curves and cut-off values.

CC1 protocol screen: Shows the 'No.' field set to 1, 'Replicate' set to 3, and 'Conc.' set to 10000 [ng/mL]. The 'Print' and 'Continue' buttons are visible at the bottom.

Protocol settings screen: Shows the 'Sample/QC protocol' and 'Sample/QC Test condition settings' sections. The 'CC1 protocol' is highlighted, and the 'QC4 protocol' is also visible.

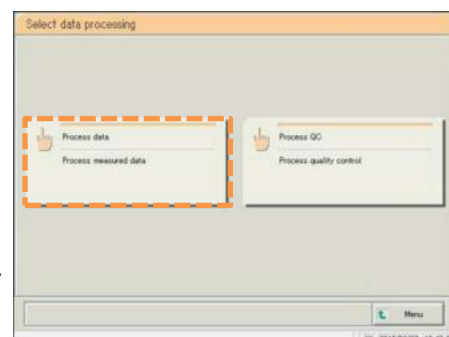
Sample/QC protocol screen: Shows the 'No.' field set to 1, 'Replicate' set to 3, and 'Cut off 1' set to 100 [ng/mL]. The 'Print' and 'Continue' buttons are visible at the bottom.

STD/QC process settings screen: Shows the 'Min limit[ng/mL]' and 'Max limit[ng/mL]' fields for QC1, QC2, QC3, and QC4. The 'QC set' field is set to 45204. The 'SD coefficient' is set to 3 SD.

11. OUTPUT OF MEASURED DATA

● How To Output Measured Data

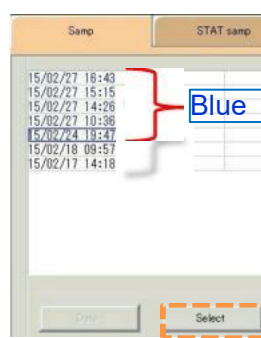
- (1) 【MENU】 → 【Data processing】 → 【Process data】
- (2) The Process data screen is displayed.
- (3) Touch the tab of the measured data for output (print).
 - Select the measurement date and time of the start point.
 - Press [Select-s] button.
 - Selected [Date/Times] will be in blue color.
 - [Select-s] button will be changed to [Select] button.
 - Select the measurement date and time of the end point.
 - Date and time between start point and end point will be in blue color.
 - Press [Select] button
 - Selected data will be displayed.
 - [Select] button will be changed to [Clear] button



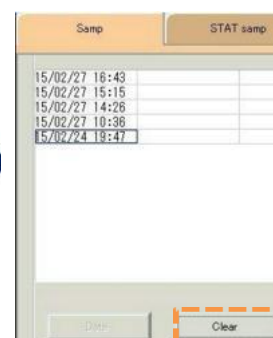
【Samp】 screen



【Select start】



【Selecting】



【Select end】

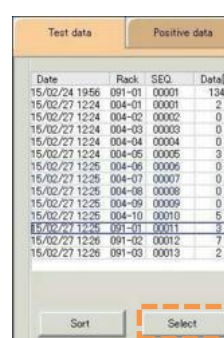
- (4) Press [Test data] button.
- (5) The measurement data in the selected range will be displayed.
 - Select the measurement data of the start point.
 - Press [Select-s] button.
 - Selected [Data] will be displayed in blue color.
 - [Select-s] button will be changed to [Select] button.
 - Select the measurement data of the end point.
 - Measurement data between start point and end point will be in blue color.
 - Press [Select] button.
 - Selected data will be display.
 - [Select] button will be changed to [Clear] button



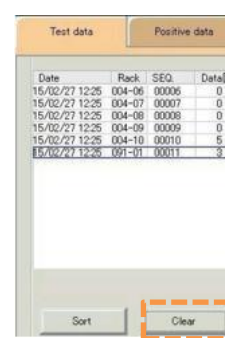
【Test data】 screen



【Select start】

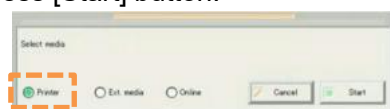


【Selecting】



【Select end】

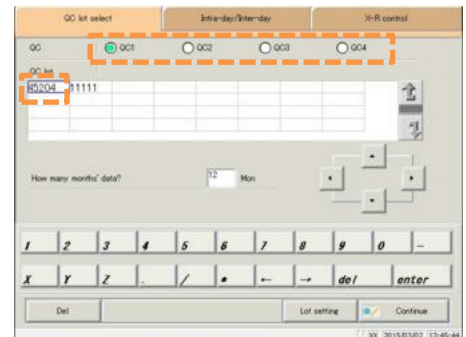
- (6) Press [Output] button.
 - Select the output destination.
 - Select [Printer], [External media] or [Online].
- (7) Press [Start] button.



12. QC SCREEN & SETTING RACK BARCODE

● Check QC Screen (during Analysis)

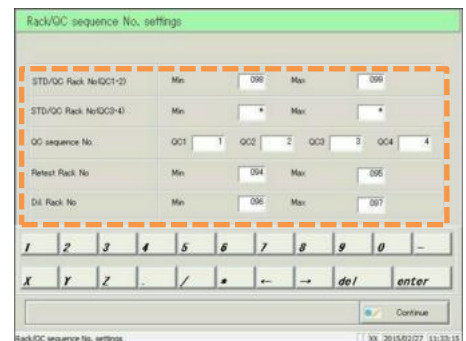
- (1) Press [QC screen] of during test.
- (2) Select QC lot.
 - Select QC No. (1 to 4) to check.
- (3) Select item tabs to check.
- (4) 【Intra-day / Inter-day data】 and 【X-R control】 is available to check.
- (5) To go back to 【Test】 screen, press [Close] button



● How To Set The Rack Barcode

- ▽ Measure mode will be distinguished by rack barcode.
- ▽ All the racks, except for [STD/QC rack No.(QC1 • QC2)], [STD/QC rack No.(QC3 • QC4)], [Dil (Dilute retest) rack No.], [Dilute retest rack No.], will be used as sample racks.

- (1) 【MENU】 → 【Settings】 → 【System settings】 → 【Rack No./QC No.】
- (2) Input the rack number.
 - If only QC(LV1/LV2) is used, input “*” in [Min] of [STD/QC rack No.(QC3•QC4)].
 - [Max] will be marked by “*” automatically.
 - Same No. can't be input
- (3) Press [Continue] button and then press [Register] button.



● Rack Information

- ▽ Information of tested samples can be checked/printed in this function.

- (1) 【MENU】 → 【Test】 → 【Rack info】
- (2) Print/Check rack info.
 - Rack info will be displayed.
 - Rack info will be cleared by pressing [clear] button.
- (3) Rack info can be printed/checked during test.
 - Press [Stop unloading racks] button.
 - After print/check, press [Restart unloading racks] button and analysis will start.
 - Press [Monitor] tab and return to 【Test】 screen.



13. OPERATOR ID

How to Set Operator ID

- (1) Select [Register] in LOGIN screen.
 - [ID], [NAME], [PASSWORD] will be enabled.
- (2) Enter [ID], [NAME], [PASSWORD].
 - ID (Operator ID): 1 to 20 digits, Alphanumeric > Upper and lower case will be distinguished.
 - NAME (Operator Name): 1 to 20 digits, Alphanumeric
 - PASSWORD: (Operator Password): 5 to 10 digits, Alphanumeric
- (3) Select [Update].
- (4) Select [OK].

Remarks

- First registered operator will be set as administrator. The others will be normal operator.
- Up to 11 operators can be registered.
- Normal operator can change / delete own ID information.
- Administrator can delete other normal operators.

LOGIN

5 : Remaining numbers of registration

ID: [] PASSWORD: []

NAME: []

Alphanumeric keypad with letters a-z and numbers 0-9.

Buttons: Register, Show Info, Delete, Cancel, LOGIN / LOGOUT

Footer: [] [] XX 2018/03/06 15:26:08

LOGIN

5 : Remaining numbers of registration

ID: [] PASSWORD: []

NAME: []

Alphanumeric keypad with letters a-z and numbers 0-9.

Buttons: Register, Show Info, Delete, Cancel, LOGIN / LOGOUT

Footer: [] [] XX 2018/03/06 15:26:58

LOGIN

5 : Remaining numbers of registration

ID: 8123456789 PASSWORD: *****

NAME: LiemYaro

Alphanumeric keypad with letters a-z and numbers 0-9.

Buttons: Register, Show Info, Delete, Cancel, Update, LOGIN / LOGOUT

Dialog box: Register the entered information. Buttons: Cancel, OK, EXIT

Footer: [] [] XX 2018/03/06 15:29:54

14. PREPARATION OF REAGENTS (F-Hb, IFU)

● OC-SENSOR FIT Latex Reagent (V-PZ01)

- Before use, bring it to room temperature (20-25 °C) and invert the bottle gently several times to assure uniform suspension.
- Stable for 4 weeks if stored back in a refrigerator after use with cap closed.
- Stable for 4 weeks on-board with cap closed after use on PLEDIA.
 - Do not mix reagent with another bottle.

● OC- SENSOR FIT Buffer (V-PZ03)

- Before use, bring the buffer to room temperature (20-25 °C).
- Stable for 4 weeks on-board.
 - Do not mix buffer from another bottle.
 - Do not use precipitated buffer, as precipitate may cause problems on the analyser.

● OC-FIT Calibrator (V-PH52)

OC-FIT Calibrator is stable for 2.5 months (10 weeks) after opening.

- The stability for this period is maintained if it is capped properly and put back in the refrigerator when not in use.

A new calibration curve should be created:

- When the lot (batch) of latex reagent is changed.
- When the measurement value of OC-FIT Control (LV1/LV2/LV3) is not within the control range.
- When opened latex reagent is used over 2 weeks.
- After maintenance support procedures.

● OC-FIT Control LV1 & LV2 (V-PH53, V-PH54)

OC-FIT Control is stable for 2 months after opening.

- The stability for this period is kept if it is capped properly and put back in the refrigerator when not in use.
- Minimum requirement is to analyse the OC-FIT Control LV1 and LV2 before sample analysis on a daily basis.

OC-SENSOR PLEDIA IFU's





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IFU on our website / IFU sul nostro sito web / IFU en nuestro sitio web / IFU sur notre site web / IFU auf unserer Website
<https://www.eiken.co.jp/en/ifu>

SSP available in EUDAMED

English

OC-SENSOR FIT Latex Reagent

for OC-SENSOR DIANA, PLEDIA

for OC-SENSOR io

for OC-SENSOR MICRO

OC-SENSOR FIT Buffer

for OC-SENSOR DIANA, PLEDIA

for OC-SENSOR MICRO, io

OC-SENSOR FIT

for OC-SENSOR Ceres

REF V-PZ01

REF V-PH18

REF V-PH33

REF V-PZ03

REF V-PH46

REF V-PH01

INTENDED USE

OC-SENSOR FIT reagents are *in vitro* diagnostic reagents intended for the quantitative measurement of human haemoglobin in faeces. OC-SENSOR FIT reagents aid in the diagnosis of colorectal cancer, neoplasia, dysplasia, polyps, and other disorders associated with gastrointestinal bleeding in conjunction with other clinical findings. The test can be utilized in colorectal cancer screening for asymptomatic population as well as in diagnostic aid and monitoring for symptomatic patients. The test is noninvasive, using stool/faeces as test sample. The reagents are used on the dedicated automated analysers by qualified personnel in clinical laboratories and hospitals.

SUMMARY

The amount of haemoglobin in faeces increases with illnesses that are accompanied by haemorrhagic lesions in the digestive tract, particularly in the lower digestive tract. Therefore, measuring the amount of haemoglobin in faeces is an effective means of screening for early detection and treatment of colorectal cancer and other lower digestive tract illnesses that are accompanied by haemorrhaging.^{1,2} OC-SENSOR FIT Reagents are immunoassay test reagents and used together with an automatic analyser for measurement of haemoglobin in faeces. OC-SENSOR FIT Latex Reagent contains the latex particles coated with anti-human haemoglobin A₂ (HbA₂) polyclonal antibodies for optical measurement of the latex agglutination reaction.

PRINCIPLE OF THE METHOD

The test method is based on a latex agglutination reaction. A latex reagent is prepared by coating polystyrene latex particles with anti-human HbA₂ antibodies. When this reagent is mixed with a sample, the anti-human HbA₂ antibodies on the latex particles react with the haemoglobin in the sample, and the latex aggregate is formed in the latex agglutination reaction. The change in absorbance per unit time resulting from the latex agglutination reaction is proportional to the concentration of haemoglobin in the sample. A dose response curve of the absorbance unit (OD) vs. concentration is generated using the results obtained from the calibrators. The concentration of haemoglobin in the patient sample is determined from this curve.

MATERIALS PROVIDED

Product code	Product name	Contents	Storage	Compatible analyser
V-PZ01	OC-SENSOR FIT Latex Reagent	5 x 15 mL	2-10 °C	DIANA, PLEDIA
V-PZ03	OC-SENSOR FIT Buffer	1 x 500 mL	2-10 °C	
V-PH18	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	io
V-PH33	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	MICRO
V-PH46	OC-SENSOR FIT Buffer	1 x 200 mL	2-10 °C	MICRO, io
V-PH01	OC-SENSOR FIT Latex Reagent Buffer	2 x 6 mL 2 x 20 mL	2-10 °C	Ceres

MATERIALS REQUIRED BUT NOT PROVIDED

Product code	Product name	Contents	Storage	Compatible analyser
V-PH51	OC-FIT Calibrator	1 x 3 mL	2-8 °C	MICRO, DIANA
V-PH52	OC-FIT Calibrator	1 x 3 mL	2-8 °C	io, PLEDIA
V-PH02	OC-FIT Calibrator	6 x 1 mL	2-8 °C	Ceres
V-PH53	OC-FIT Control LV1	2 x 5 mL	2-8 °C	
V-PH54	OC-FIT Control LV2	2 x 5 mL	2-8 °C	All
V-PH59	OC-FIT Control LV3	2 x 5 mL	2-8 °C	
V-PZ25	OC-Auto Sampling Bottle 3	100 bottles	1-30 °C	
V-PZ26	OC-Auto Sampling Bottle 3 without barcode	100 bottles	1-30 °C	All
V-PH19	OC-SENSOR Sample Diluent	3 x 45 mL	2-8 °C	DIANA, PLEDIA, MICRO, io
V-PH08		2 x 20 mL		Ceres

REQUIRED MATERIALS NOT PROVIDED BY THE MANUFACTURER

Prepare these materials before measurement

- Wash solution: Sodium hypochlorite 0.15% (0.10%-0.30% is acceptable)
- Purified water for wash: Distilled or de-ionized water (1.0-10.0 MΩcm is acceptable)
- Sample cups
- Printer paper: Thermal printer paper which fits the analyser

REAGENTS

Reagents are stable until the date printed on the label assuming the container remains unopened at a storage temperature of 2-10 °C.

Latex Reagent (Suspension of latex particles coated with anti-human HbA₂ rabbit IgG) for OC-SENSOR DIANA, PLEDIA 15 mL x 5 bottles; approx. 250 tests/bottle for OC-SENSOR Ceres 6 mL x 2 bottles; approx. 115 tests/bottle Stable for 4 weeks if stored back in a refrigerator after use with cap closed. Stable for 4 weeks on-board with cap closed after use on DIANA, PLEDIA, and Ceres.

for OC-SENSOR MICRO, io 7 mL x 2 bottles; approx. 100 tests/bottle Stable for 2 weeks on-board with cap closed after use on io and MICRO.

Buffer (50 mM N-2-Hydroxyethylpiperazine-N'-2-ethanesulfonic acid (HEPES))

for OC-SENSOR DIANA, PLEDIA 500 mL x 1 bottle

for OC-SENSOR MICRO, io 200 mL x 1 bottle

for OC-SENSOR Ceres 20 mL x 2 bottles; approx. 115 tests/bottle

Stable for 4 weeks on-board on all analysers.

Note: The number of tests per bottle varies depending on the usage.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Before performing measurement, be sure to read the instruction manual of the analyser.
- Fully prepare and adjust the analyser before measurement.
- Use OC-FIT Calibrator (REF V-PH51, V-PH52, V-PH02) suitable for the analyser to create calibration curve. Follow its instruction for use when to create a new calibration curve.
- If the measurement results exceed the measurement range, use Diluent of Calibrator or OC-SENSOR Sample Diluent (REF V-PH19, V-PH08) to dilute the sample and perform measurement again.
- Store the reagents at 2-10 °C and avoid freezing.
- Do not use reagents that have passed their expiration date.
- On-board stability can vary depending on the conditions of measurement, such as tests/day and laboratory environment. It is advised to close the bottle of Latex Reagent with a cap when the measurement is not in process, especially with OC-SENSOR MICRO and io.
- The test sample may contain pathogens. Handle with care. After use, all samples and other materials must be considered as medical waste and properly disposed of.
- Example of treatment: Soak for 1 hour or longer in a sodium hypochlorite solution (available chlorine concentration 1000 ppm or greater). (Neutralize any substances that contain acids before soaking.) Alternatively, treat in an autoclave at 121 °C for 20 minutes. (Do not treat any items which sodium hypochlorite have adhered to in this way.)
- Dispose of used reagents and containers as medical waste in accordance with local regulations.
- If the product is used in any way other than that specified here, the reliability of measurement results cannot be guaranteed. Be sure to follow the procedure.
- A clinical diagnosis based on the measurement results must be a comprehensive judgment made by the attending physician, including factors such as clinical symptoms and other test results.

LIMITATIONS

The test has not been validated for testing of patients with all existing haemoglobinopathies. Clinical consideration is recommended.³

SAMPLE COLLECTION

- Use the following designated sampling device for collecting specimens. OC-Auto Sampling Bottle 3 (REF V-PZ25, V-PZ26) : Sold separately
- Collect faecal samples by scraping the surface of the stools in different areas.
- Collect the amount necessary to cover the groove of the probe.
- Check that the faecal sample has become fully suspended in the buffer solution inside OC-Auto Sampling Bottle 3.

PREPARATION OF REAGENTS

OC-SENSOR FIT Latex Reagent for OC-SENSOR PLEDIA, DIANA, MICRO, io

Ready to use.

Before use, bring it to room temperature (20-25 °C) and invert the bottle gently several times to assure uniform suspension.

Do not mix reagent with another bottle.

OC-SENSOR FIT Buffer for OC-SENSOR DIANA, PLEDIA, MICRO, io

Ready to use.

Before use, bring the buffer to room temperature (20-25 °C).

Do not mix buffer from another bottles.

Do not use precipitated buffer, as precipitate may cause problems on analysers.

OC-SENSOR FIT Latex Reagent for OC-SENSOR Ceres

Ready to use.

Before use, invert the bottle gently several times to assure uniform suspension.

Do not mix reagent with another bottle.

OC-SENSOR FIT Buffer for OC-SENSOR Ceres

Ready to use.

Do not mix buffer from another bottle.

Note: OC-SENSOR Ceres is equipped with refrigerated reagent slots so that the reagents do not need to be brought to room temperature.

TEST PROCEDURE

Perform measurements according to the instruction manual of the analyser.

- Set the OC-SENSOR FIT Latex Reagent and Buffer on the designated locations in the analyser.
- Input the parameters into the analyser.
- Check water, wash solution and drain tank volumes.
- Create calibration curve.
- Set control materials, OC-FIT Controls as internal control and start measurement. Make sure the control values are within the acceptable range set by each laboratory.
- Set samples sampled with OC-Auto Sampling Bottle 3 and start measurement.

RESULTS

The reaction of each sample is compared to the calibration curve that has been created previously. The concentration of human haemoglobin (ng/mL) is calculated.

Conversion of units in OC-SENSOR systems is done in the following equation:

$$\mu\text{g Hb/g stool} = 0.2 \times (\text{ng Hb/mL buffer})$$



Instructions for Use

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INTERNAL QUALITY CONTROL

Each laboratory should establish a quality control program to monitor the performance of OC-SENSOR system. It is recommended to use OC-FIT Controls for the quality control in a laboratory.

OC-FIT Controls : Liquid, ready-to use controls sold separately
LV1 (REF) V-PH53 LV2 (REF) V-PH54 LV3 (REF) V-PH59

PERFORMANCE CHARACTERISTICS

1. Specificity

In comparison with haemoglobin A0, OC-SENSOR FIT reagents can measure human haemoglobin variants Hb-S and Hb-C. The reactivity of variants can vary.⁸

2. Accuracy

When control samples of known concentration were measured, the value obtained was within $\pm 15\%$ of the indicated value.

3. Cut-off value

It is recommended for each laboratory to establish the cut-off value suitable for purposes in screening programs or diagnostic use.^{1,2}

4. Repeatability and Precision

When the same samples were measured in 2 replicates, twice a day, for 20 days (2x2x20), the coefficient of variation (CV) for the values obtained was 10% or less, using ANOVA analysis. Examples of measurement of controls and faecal samples (N=80 each) using OC-SENSOR PLEDIA and Ceres are shown below.

OC-SENSOR PLEDIA

Samples	Mean (ng/mL)	Repeatability		Between-Run		Between-Day		Precision	
		SD	CV	SD	CV	SD	CV	SD	CV
LV1	148.7	2.0	1.4%	2.4	1.6%	2.0	1.3%	3.7	2.5%
LV2	450.2	8.1	1.8%	1.2	0.3%	1.3	0.3%	8.3	1.8%
LV3	71.4	1.1	1.5%	0.6	0.9%	0.8	1.2%	1.5	2.1%
S1	73.6	1.7	2.3%	3.2	4.4%	1.4	1.9%	3.9	5.3%
S2	109.4	2.3	2.1%	3.6	3.3%	1.6	1.5%	4.5	4.1%
S3	474.3	5.3	1.1%	6.4	1.3%	0.8	0.2%	8.2	1.7%

OC-SENSOR Ceres

Samples	Mean (ng/mL)	Repeatability		Between-Run		Between-Day		Precision	
		SD	CV	SD	CV	SD	CV	SD	CV
LV1	145.7	1.6	1.1%	0.5	0.3%	1.7	1.2%	2.4	1.7%
LV2	453.0	3.4	0.8%	2.5	0.6%	5.4	1.2%	6.9	1.5%
LV3	73.9	0.9	1.2%	0.9	1.2%	1.1	1.5%	1.7	2.3%
S1	76.2	0.8	1.1%	1.4	1.8%	0.7	1.0%	1.8	2.3%
S2	124.3	1.0	0.8%	0.9	0.8%	1.1	0.9%	1.8	1.4%
S3	461.3	3.1	0.7%	3.4	0.7%	6.3	1.4%	7.8	1.7%

5. Measurement range

Up to 1000 ng/mL (200 µg/g stool)

Examples of measurement using OC-SENSOR PLEDIA result showed LOD of 9 ng/mL (1.8 µg/g), LOQ of 25 ng/mL (5 µg/g); OC-SENSOR Ceres showed LOD of 6 ng/mL (1.2 µg/g), and LOQ of 20 ng/mL (4 µg/g). The values can vary due to faecal samples and whether/how haemoglobin is spiked

6. Interference and Cross-reactivity

Following substances were added to sample and the test results showed no interference or cross-reactivity.

-Animal haemoglobin	600 ng/mL of bovine, equine, porcine, goat, sheep, rabbit, turkey and fish Hb	
-Animal meat extracts	2.0% from beef, pork, chicken, lamb, and fish	2.5% rabbit
-Toilet cleaners	10 mg/mL of Nupur	10 mg/mL Bleach
-Co-existing substances	25 mg/dL Bilirubin (free and conjugated)	2.5 g/dL Protein
	0.6% Lipids (Intralipids)	4.0 g/dL Glucose
	25 µg/mL Peroxidase	
-Supplements and drugs	2 µg/mL Ascorbic acid	3.1 µg/mL Iron
	25 mg/dL Barium sulphate	0.2 µg/mL Laxative
	2 mg/mL Glycerol in emula	

7. Sample Stability

Performance testing with the sample collection device demonstrated that samples stored at 2-10 °C for 28 days had 95±14.7%, at 25 °C for 7 days had 96±20.4%, for 14 days had 93±23.5%, and at 30 °C for 7 days had 89±20.5%, for 14 days had 84±23.6% of haemoglobin recovery (in-house data, recovery rate shown as mean±2SD). However, the haemoglobin in some samples may undergo rapid denaturation or degradation, resulting in decreased haemoglobin values or false negatives. Samples should be stored at 2-10 °C and analysed as soon as possible.

8. Comparison between analysers

When OC-SENSOR analysers, DIANA, MICRO, io and Ceres are compared with PLEDIA, there were no significant differences in measurement.

9. Traceability and Standard Material

WHO International Standard NIBSC code 98/708, Certified Reference Material (CRM) 522 is used as the standard material. The value was assigned using cyanmethemoglobin method from the standard material to the internal standard.

10. Clinical Performance

Reports from different screening programs using OC-Sensor systems are summarized.

Colorectal Cancer detection rate at cut-off 100 ng/mL (20 µg/g stool)

Country	Positive Rate (%)	PPV (%)	Detection Rate (per 1000)	N
Netherlands ¹³	5.5	8.6	2.3	10,322
France ¹⁴	3.5	7.2	2.2	19,797
Spain ¹⁵	6.6	5.1	3.1	11,162
Taiwan ¹⁶	3.8	6.8	2.1	747,076

Colorectal Cancer and Advanced Adenoma detection rate at cut-off 150 ng/mL (30 µg/g stool)

Country	PPV (%)	Detection Rate (per 1000)	N
France ¹⁷	8.5	2.3	88,796
	30.5	8.3	

One study showed the reference intervals are 25-45 ng/mL (N=739) in the population with normal colonoscopy findings, and 435-759 ng/mL (N=91) in that with cancer and advanced adenoma, respectively as 95% confidence interval.²

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NOTICE

In case of occurrence of any serious incident that has occurred in relation to the device shall be reported to the authorised representative, the manufacturer, and the competent authority of the Member State in which the user and/or the patient is established.

OC-SENSOR FIT Latex Reagent contains the following material.

ProClin300 CAS No. 55965-84-9



WARNING

May cause an allergic skin reaction.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves.
If on skin: Wash with plenty of soap and water.
If skin irritation or rash occurs: get medical attention.
Dispose of contents/container in accordance with local/regional/national/international regulations.

Eiken Chemical Co., Ltd.
4-19-9 Taisho, Taisho-ku, Tokyo, 110-8408 JAPAN
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EXPLANATION OF SYMBOLS

LOT	Batch code	Manufacturer	Consult instructions for use
EXP	Use by date	In vitro diagnostic medical device	Biological risks
REF	Catalog number	Temperature limitation	Contains sufficient for ≥ 2 tests

IVD **CE 0123**
Advena Ltd.
Tower Business Centre, 2nd Flr., Tower Street,
Sliema, BKR 4013 Malta

EIKEN CHEMICAL CO., LTD.
4-19-9 Taisho, Taisho-ku, Tokyo, 110-8408 JAPAN
<https://www.eiken.co.jp/en/>

Date of issuance: 2022-05-26

17. OC-SENSOR PLEDIA FIT CALIBRATOR IFU



Instructions for Use

380363-A

IFU on our website / IFU sul nostro sito web / IFU en nuestro sitio web / IFU sur notre site web / IFU auf unserer Website
<https://www.eiken.co.jp/en/ifu>

SSP available in EUDAMED

English

OC-FIT Calibrator

for OC-SENSOR MICRO, DIANA
for OC-SENSOR io, PLEDIA
for OC-SENSOR Ceres

REF V-PH51
REF V-PH52
REF V-PH02

INTENDED USE

OC-FIT Calibrator is intended for use as a calibrator used together with OC-SENSOR FIT reagents on the dedicated automated immunochemical analysers (OC-SENSOR series) to measure faecal haemoglobin. OC-SENSOR FIT reagents are *in vitro* diagnostic reagents intended for the quantitative measurement of human haemoglobin in faeces. OC-SENSOR FIT reagents aid in the diagnosis of colorectal cancer, neoplasia, dysplasia, polyps, and other disorders associated with gastrointestinal bleeding in conjunction with other clinical findings. The test can be utilized in colorectal cancer screening for asymptomatic population as well as in diagnostic aid and monitoring for symptomatic patients. The test is noninvasive, using stool/faeces as test sample. The reagents are used on the dedicated automated analysers by qualified personnel in clinical laboratories and hospitals.

MATERIALS PROVIDED

Product code	Product name	Contents	Storage	Compatible analyser
V-PH51	OC-FIT Calibrator	1 x 3 mL	2-8 °C	MICRO, DIANA
V-PH52	OC-FIT Calibrator	1 x 3 mL	2-8 °C	io, PLEDIA
V-PH02	OC-FIT Calibrator	6 x 1 mL	2-8 °C	Ceres

MATERIALS REQUIRED BUT NOT PROVIDED

Product code	Product name	Contents	Storage	Compatible analyser
V-PZ01	OC-SENSOR FIT Latex Reagent	5 x 15 mL	2-10 °C	DIANA, PLEDIA
V-PZ03	OC-SENSOR FIT Buffer	1 x 500 mL	2-10 °C	
V-PH18	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	io
V-PH33	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	MICRO
V-PH46	OC-SENSOR FIT Buffer	1 x 200 mL	2-10 °C	MICRO, io
V-PH01	OC-SENSOR FIT Latex Reagent Buffer	2 x 6 mL 2 x 20 mL	2-10 °C	Ceres
V-PH53	OC-FIT Control LV1	2 x 5 mL	2-8 °C	All
V-PH54	OC-FIT Control LV2	2 x 5 mL	2-8 °C	
V-PH59	OC-FIT Control LV3	2 x 5 mL	2-8 °C	
V-PZ25	OC-Auto Sampling Bottle 3	100 bottles	1-30 °C	All
V-PZ26	OC-Auto Sampling Bottle 3 without barcode	100 bottles	1-30 °C	
V-PH19	OC-SENSOR Sample Diluent	3 x 45 mL	2-8 °C	DIANA, PLEDIA, MICRO, io
V-PH08		2 x 20 mL		Ceres

REQUIRED MATERIALS NOT PROVIDED BY THE MANUFACTURER

- Prepare these materials before measurement
- Wash solution: Sodium hypochlorite 0.15% (0.10%-0.30% is acceptable)
- Purified water for wash: Distilled or de-ionized water (1.0-10.0 MΩcm is acceptable)
- Sample cups
- Printer paper: Thermal printer paper which fits the analyser

REAGENTS

OC-FIT Calibrator is liquid and ready to use requiring no preparation.

For OC-SENSOR MICRO, DIANA
OC-FIT Calibrator Hb 2000 ng/mL 1 x 3 mL
OC-FIT Calibrator Diluent 1 x 45 mL

For OC-SENSOR io, PLEDIA
OC-FIT Calibrator Hb 1000 ng/mL 1 x 3 mL
OC-FIT Calibrator Diluent 1 x 45 mL

For OC-SENSOR Ceres
OC-FIT Calibrator Hb 6 levels 6 x 1 mL
CAL1. 0 ng/mL CAL2. 62.5 ng/mL CAL3. 125 ng/mL
CAL4. 250 ng/mL CAL5. 500 ng/mL CAL6. 1000 ng/mL

STORAGE

OC-FIT Calibrator is stable until the date printed on the label when stored at 2-8 °C.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not freeze this product.
- Do not use expired products.
- Air bubbles on the surface of the product after being added into sample cups can cause an erroneous measurement. The bubbles should be removed.
- OC-FIT Calibrator uses material derived from human blood. Only blood testing negative for HBs antigens, HIV (HIV-1 and HIV-2) antibodies and HCV antibodies is used, but the presence of pathogens and infection risk cannot be completely ruled out. Therefore, the product should be handled carefully in the same manner as patient samples to ensure safety.
- Use specific calibrator dedicated to a type of analysers and follow instructions in the user manual.
- Avoid contamination and evaporation by sealing the bottle properly with a cap and put it back in the refrigerator after use. It is advised to minimize the time left in room temperature and keep the calibrator refrigerated when not in use. In-use stability can be altered if the instruction is not followed.

PROCEDURE

Create calibration curve in the manner described in the user manual of the automatic analysers.

[OC-SENSOR PLEDIA, OC-SENSOR DIANA, OC-SENSOR io]

Add 600 µL (12 drops or more) of OC-FIT Calibrator into a sample cup. Add 2 mL (or more) of OC-FIT Calibrator Diluent into another sample cup. Set these sample cups on a rack according to the user manual and create calibration curve.

[OC-SENSOR MICRO]

Add 400 µL (8 drops or more) of OC-FIT Calibrator into a sample cup. Add 2 mL (or more) of OC-FIT Calibrator Diluent into another sample cup. Set these sample cups on a rack according to the user manual and create calibration curve.

[OC-SENSOR Ceres]

Add 150 µL (3 drops or more) of 6 levels of OC-FIT Calibrator individually into 6 sample cups. Set these sample cups on a rack according to the user manual and create calibration curve.

Note: Volume of 1 drop from the vial of OC-FIT Calibrator is approximately 50 µL.

New calibration curve should be created;

- When the lot (batch) of latex reagent is changed.
- When the measurement value of OC-FIT Control (LV1/LV2/LV3) is not within the control range.
- When opened latex reagent is used over 2 weeks.
- After maintenance support procedures.

In-Use Stability

OC-FIT Calibrator is stable for 2.5 months (10 weeks) after opening. The stability for this period is kept if it is capped properly and put back in the refrigerator when not in use. In-use stability can be altered in case of contamination, evaporation and/or storage at improper temperatures.

NOTICE

In case of occurrence of any serious incident that has occurred in relation to the device shall be reported to the authorised representative, the manufacturer, and the competent authority of the Member State in which the user and/or the patient is established.

EXPLANATION OF SYMBOLS

Batch code	Manufacturer	Consult instructions for use
Use by date	In vitro diagnostic medical device	Biological risks
Catalog number	Temperature limitation	Contains sufficient for <=> tests

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Instructions for Use

380365-A

IFU on our website / IFU sul nostro sito web / IFU en nuestro sitio web / IFU sur notre site web / IFU auf unserer Website
<https://www.eiken.co.jp/en/ifu>

SSP available in EUDAMED

English

OC-FIT Control

LV1	REF V-PH53
LV2	REF V-PH54
LV3	REF V-PH59

INTENDED USE

OC-FIT Control LV1/LV2/LV3 are intended for use as an internal quality control in faecal immunochemical tests for haemoglobin. They are especially compatible with OC-SENSOR FIT reagents on the automated immunochemical analysers [OC-SENSOR series] to measure faecal haemoglobin.

OC-SENSOR FIT reagents are *in vitro* diagnostic reagents intended for the quantitative measurement of human haemoglobin in faeces. OC-SENSOR FIT reagents aid in the diagnosis of colorectal cancer, neoplasia, dysplasia, polyps, and other disorders associated with gastrointestinal bleeding in conjunction with other clinical findings. The test can be utilized in colorectal cancer screening for asymptomatic population as well as in diagnostic aid and monitoring for symptomatic patients. The test is noninvasive, using stool/faeces as test sample. The reagents are used on the dedicated automated analysers by qualified personnel in clinical laboratories and hospitals.

MATERIALS PROVIDED

Product code	Product name	Contents	Storage	Compatible analyser
V-PH53	OC-FIT Control LV1	2 x 5 mL	2-8 °C	All
V-PH54	OC-FIT Control LV2	2 x 5 mL	2-8 °C	
V-PH59	OC-FIT Control LV3	2 x 5 mL	2-8 °C	

MATERIALS REQUIRED BUT NOT PROVIDED

Product code	Product name	Contents	Storage	Compatible analyser
V-PZ01	OC-SENSOR FIT Latex Reagent	5 x 15 mL	2-10 °C	DIANA, PLEDIA
V-PZ03	OC-SENSOR FIT Buffer	1 x 500 mL	2-10 °C	
V-PH18	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	io
V-PH33	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	MICRO
V-PH46	OC-SENSOR FIT Buffer	1 x 200 mL	2-10 °C	MICRO, io
V-PH01	OC-SENSOR FIT Latex Reagent Buffer	2 x 6 mL 2 x 20 mL	2-10 °C	Ceres
V-PH51	OC-FIT Calibrator	1 x 3 mL	2-8 °C	MICRO, DIANA
V-PH52	OC-FIT Calibrator	1 x 3 mL	2-8 °C	io, PLEDIA
V-PH02	OC-FIT Calibrator	6 x 1 mL	2-8 °C	Ceres
V-PZ25	OC-Auto Sampling Bottle 3	100 bottles	1-30 °C	All
V-PZ26	OC-Auto Sampling Bottle 3 without barcode	100 bottles	1-30 °C	
V-PH19	OC-SENSOR Sample Diluent	3 x 45 mL	2-8 °C	DIANA, PLEDIA, MICRO, io
V-PH08		2 x 20 mL		Ceres

REQUIRED MATERIALS NOT PROVIDED BY THE MANUFACTURER

- Prepare these materials before measurement
- Wash solution: Sodium hypochlorite 0.15% (0.10%–0.30% is acceptable)
 - Purified water for wash: Distilled or de-ionized water (1.0–10.0 MQcm is acceptable)
 - Sample cups
 - Printer paper: Thermal printer paper which fits the analyser

REAGENTS

OC-FIT Control is liquid and ready to use requiring no preparation.

OC-FIT Control LV1	(Middle)	2 x 5 mL
OC-FIT Control LV2	(High)	2 x 5 mL
OC-FIT Control LV3	(Low)	2 x 5 mL

The haemoglobin concentration range is printed on the labels of a bottle.

STORAGE

OC-FIT Control is stable until the date printed on the label when stored at 2-8 °C.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not freeze this product.
- Do not use expired products.
- Air bubbles on the surface of the product after being added into sample cups can result in erroneous measurement. The bubbles should be removed.
- OC-FIT Control uses material derived from human blood. Only blood testing negative for HBs antigens, HIV (HIV-1 and HIV-2) antibodies and HCV antibodies is used, but the presence of pathogens and infection risk cannot be completely ruled out. Therefore, the product should be handled carefully in the same manner as patient samples to ensure safety.
- When used on the OC-SENSOR series analysers, OC-FIT Control must be used with OC-FIT Calibrator (**REF** V-PH51, V-PH52, V-PH02) dedicated to each analyser.
- Avoid contamination and evaporation by sealing the bottle properly with a cap and put it back in the refrigerator after use. It is advised to minimize the time left in room temperature and keep the control refrigerated when not in use. In-use stability can be altered if the instruction is not followed.

PROCEDURE

Minimum requirement is to analyse the OC-FIT Control LV1 and LV2 before sample analysis on a daily basis. Analyse OC-FIT Control LV3 as required. Follow the detailed measurement procedure in the user manual of the automatic analysers.

Add an appropriate amount of OC-FIT Control into a sample cup and then operate the automatic analyser according to its instructions. For a single measurement, it uses 150 µL (3 drops) of OC-FIT Control, including a dead volume of 100 µL of a sample cup. For a duplicated measurement, it uses 200 µL (4 drops).

When the measurement value of OC-FIT Control (LV1/LV2/LV3) is not within the control range set by each laboratory, new calibration curve should be created.

Note: Volume of 1 drop from the vial of OC-FIT Control is approximately 50 µL.

In-use stability

OC-FIT Control is stable for 2 months after opening. The stability for this period is kept if it is capped properly and put back in the refrigerator when not in use. In-use stability can be altered in case of contamination, evaporation and/or storage at improper temperatures.

NOTICE

In case of occurrence of any serious incident that has occurred in relation to the device shall be reported to the authorised representative, the manufacturer, and the competent authority of the Member State in which the user and/or the patient is established.

EXPLANATION OF SYMBOLS

LOT	Batch code	Manufacturer	Consult instructions for use
EXP	Use by date	IVD	Biological risks
REF	Catalog number	In vitro diagnostic medical device	Contains sufficient for ≥ 2 tests
		Temperature limitation	

IVD **CE** 0123

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Date of issuance: 2022-05-26

19. OC-SENSOR PLEDIA FIT SMP DILNT IFU



Instructions for Use

380364-A

IFU on our website / IFU sul nostro sito web / IFU en nuestro sitio web / IFU sur notre site web / IFU auf unserer Website
<https://www.eiken.co.jp/en/ifu>

SSP available in EUDAMED

English

OC-SENSOR Sample Diluent

for OC-SENSOR DIANA, PLEDIA, MICRO, io
for OC-SENSOR Ceres

REF V-PH19
REF V-PH08

INTENDED USE

OC-SENSOR Sample Diluent is intended for use as a high concentration sample diluent used together with OC-SENSOR FIT reagents and OC-FCa Reagent on the automated immunochemical analysers [OC-SENSOR series] to measure faecal haemoglobin and calprotectin.

OC-SENSOR FIT reagents are *in vitro* diagnostic reagents intended for the quantitative measurement of human haemoglobin in faeces. OC-SENSOR FIT reagents aid in the diagnosis of colorectal cancer, neoplasia, dysplasia, polyps, and other disorders associated with gastrointestinal bleeding in conjunction with other clinical findings. The test can be utilized in colorectal cancer screening for asymptomatic population as well as in diagnostic aid and monitoring for symptomatic patients.

OC-FCa Reagent is *in vitro* diagnostic reagent intended for the quantitative measurement of calprotectin, inflammatory protein, in faeces. The OC-FCa Reagent aids in diagnostic and monitoring of inflammatory bowel diseases (IBD; e.g. ulcerative colitis, and Crohn's disease) in conjunction with other clinical findings. The test can be utilized in diagnostic aid and in monitoring for symptomatic patients.

The tests are noninvasive, using stool/faeces as test sample. The reagents are used on the dedicated automated analysers by qualified personnel in clinical laboratories and hospitals.

MATERIALS PROVIDED

Product code	Product name	Contents	Compatible analyser
V-PH19	OC-SENSOR Sample Diluent	3 x 45 mL	DIANA, PLEDIA, MICRO, io
V-PH08	OC-SENSOR Sample Diluent	2 x 20 mL	Ceres

MATERIALS REQUIRED BUT NOT PROVIDED

For Haemoglobin Measurement
OC-SENSOR FIT Latex Reagent, Buffer
OC-FIT Calibrator
OC-FIT Control
OC-Auto Sampling Bottle 3

For Calprotectin Measurement
OC-FCa Reagent
OC-FCa Calibrator
OC-FCa Control
OC-Auto Sampling Bottle 3

COMPOSITION

OC-SENSOR Sample Diluent is liquid and ready to use.
It contains buffer solution (HEPES; N-2-hydroxyethyl piperazine-N'-2-ethanesulfonic acid).
The container is made of polyethylene (PE), the cap is made of polypropylene (PP), and the case is made of paper.

STORAGE

This product is stable up to the date printed on the label as long as it remains unopened at a storage temperature of 2-8 °C.

PROCEDURE

Dilution procedure should be followed in the manner described in the user manual of the automatic analysers.

[OC-SENSOR DIANA, OC-SENSOR PLEDIA]

Set a high concentration sample, an empty sample cup and a sample cup with 2 mL (or more) of the diluent on a dedicated rack. Dilution is performed automatically before measurement on the analyser.

[OC-SENSOR MICRO, OC-SENSOR io]

Manually dilute high concentration samples with the diluent, add the diluted sample in a sample cup and measure on the analyser.

[OC-SENSOR Ceres]

Set the diluent (REF V-PH08) in the dedicated reagent slot on the analyser with a cap open. Dilution is performed automatically before measurement on the analyser.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use OC-SENSOR Sample Diluent for any purpose other than dilution of high concentration samples.
- Do not freeze.
- Do not use OC-SENSOR Sample Diluent after the expiry date.
- Air bubbles on the surface can cause an erroneous measurement. The bubbles should be removed.
- The test sample may contain pathogens. Handle with care. After use, all samples and other materials must be considered as medical waste and properly disposed of.
- Dispose of used reagents and containers as medical waste in accordance with local regulations.

NOTICE

In case of occurrence of any serious incident that has occurred in relation to the device shall be reported to the authorised representative, the manufacturer, and the competent authority of the Member State in which the user and/or the patient is established.

EXPLANATIONS OF SYMBOLS

LOT	Batch code	Manufacturer	Consult instructions for use
Use by date		In vitro diagnostic medical device	Biological risks
Catalog number		Temperature limitation	Contains sufficient for <n> tests

IVD CE 0123

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Instructions for Use

341840A-A

OC-Auto Sampling Bottle 4 **REF** VAPZ55

(For OC-SENSOR series)

INTENDED USE

The OC-Auto Sampling Bottle 4 is designed as a specimen container for measurement of haemoglobin in faeces in using together with automated faecal occult blood analysers. Therefore it is ideally suited for use as a sample collection device that can be used to easily collect a constant amount of faeces.

PROCEDURE FOR SPECIMEN COLLECTION

1. Remove the green cap by turning to the left and pulling upwards.
2. Collect the faecal sample with the sampling probe by scraping from different areas of the surface of the faeces. Collect the amount enough to cover the groove of the probe.
3. Insert the sampling probe to the sample collection device and tighten the cap. Do not repeat more than once.
4. Shake the bottle vigorously up and down several times.

Note.

If the faeces is hard, moisten it with water before collecting the sample using the sampling probe.

STORAGE

The sample collection device is stable until the date printed on the label assuming the bottle remains unopened at a storage temperature of 1-30 °C.

STABILITY AFTER SAMPLING

Performance testing with the sample collection device demonstrated the stability of haemoglobin recovery (in-house data, recovery rate shown as mean±2SD). Details are shown in the table below. However, the haemoglobin in some samples may undergo rapid denaturation or degradation, resulting in false negatives. Therefore, samples should be stored at 2-10 °C and analysed as soon as possible.

Storage	Recovery rate	
2-10 °C	103 ± 4.5 % for 28 days	98 ± 5.3 % for 55 days
25 °C	89 ± 2.8 % for 28 days	83 ± 6.9 % for 55 days
30 °C	88 ± 3.6 % for 28 days	86 ± 4.0 % for 42 days
40 °C	91 ± 4.2 % for 14 days	84 ± 11.5 % for 28 days
50 °C	95 ± 4.5 % for 3 days	82 ± 10.1 % for 7 days

COMPOSITION AND DESCRIPTION

Sampling bottles contain buffer (HEPES; N-2-hydroxyethylpiperazine-N'-2-ethane- sulfonic acid, 2 mL). Sampling bottles are made of polypropylene (PP) and their bottoms sealed with two layers of aluminium. Sampling probes are made of acrylonitrile butadiene styrene (ABS) resin, and filters and collection bags are made of polyethylene (PE).

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not pour out any fluid in the sample collection device, or add water to it.
3. Do not break the aluminum seal.
4. Do not obtain faecal samples during menstruation.
5. Do not use the sample collection device by placing it in direct contact with the body.
6. Do not use the sample collection device for any purpose other than collecting faecal samples.
7. Store the sample collection device in a location that is out of the reach of children.
8. Perform the measurement as soon as possible after sample has been transported. If analysis is not immediately possible, store the sample collection device in the refrigerator at 2-10 °C and analyse as soon as possible.
9. After removing the sample from the refrigerator, be sure to completely return it to the room temperature before using.
10. Do not use the sample collection device that has passed its expiration date.
11. The test sample may contain microorganisms. Therefore use caution when handling. After use, all samples and other materials must be considered to carry a risk of infection and must be treated accordingly.
12. Dispose of used reagents and containers as medical waste in accordance with local regulations.
13. The buffer in the sampling bottles contains a toxic material, sodium azide (NaN₃ <0.1 %). Be sure not to contact with skin, eyes, and mouth. In case of exposure, wash vigorously with water and call a doctor for treatment advice.

PRODUCT CODE, PRODUCT NAME AND STORAGE

Product code	Product name	Contents	Storage
VAPZ55	OC-Auto Sampling Bottle 4 without barcode	100 bottles	1-30 °C

REFERENCE

1. T. Takeshita et al.: Journal of Coloproctology, 38: 780-783, 1985.

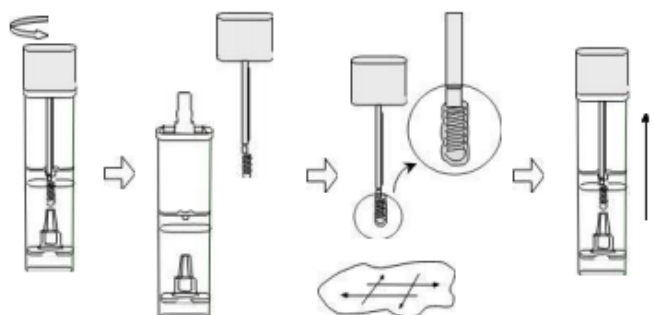


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(Date of revision: December 1, 2023)

OPERATOR CERTIFICATION

	MODULE	EXPL'D	DEMO'D	INITIAL'D
1	SET UP AND LOGIN			
2	SET REAGENTS AND SAMPLES			
3	TEST WORK			
4	STAT TESTING			
5	CLOSING AND SHUTTING DOWN			
6	CALIBRATION			
7	SETTING THE REAGENTS			
8	NOTE 1: PRME & CELL BLANK			
9	NOTE 2: TEST MODE & DILUTE RETEST			
10	SETTING CALIBRATION CURVE & CUT-OFF			
11	OUTPUT OF MEASURED DATA			
12	QC SCREEN & SETTING RACK BARCODE			
13	OPERATOR ID			
14	PREPARATION OF REAGENTS			
15	OC-SENSOR PLEDIA FIT IFU (1/2)			
16	OC-SENSOR PLEDIA FIT IFU (2/2)			
17	OC-SENSOR PLEDIA FIT CALIBRATOR IFU			
18	OC-SENSOR PLEDIA FIT CONTROL IFU			
19	OC-SENSOR PLEDIA FIT SMP DILNT IFU			
20	OC-SENSOR SAMPLE BOTTLE IFU			

	NAME & COMPANY	SIGNED	DATED
OPERATOR			
TRAINER			