VIDAS® Staph enterotoxin II (SET2)

For microbiological control only

VIDAS® Staph enterotoxin II is an automated qualitative test for use on the VIDAS® family of instruments for the detection of staphylococcal enterotoxins in food products, using the ELFA technique (Enzyme Linked Fluorescent Assay).

SUMMARY AND EXPLANATION

Staphylococcal enterotoxins are among the most common causes of food poisoning. Seven distinct serological types have been identified and are designated by the symbols SEA, SEB, $SEC_{1,2,3}$, SED and SEE (1). These proteins are produced primarily by *Staphylococcus aureus*, although the newer species, *S. intermedius* and *S. hyicus,* have been reported to be enterotoxigenic (2, 3).

In general, coagulase-negative species such as *S. epidermidis* do not produce enterotoxin, however at least one outbreak has been reported to be due to this species (4). For this reason, coagulase-negative Staphylococci cannot be ignored if they are present in large numbers in food and should be checked for enterotoxin production.

Although staphylococci can be destroyed by heat treatment, the toxins are heat stable and can survive at high temperatures (5). Foods incriminated have included meat, poultry, canned mushrooms, dairy products, eggs and mayonnaise. The type of enterotoxin most frequently involved is SEA (about 75% of cases) followed by SED (6).

The VIDAS® SET2 assay provides a direct method for screening food for the presence of any of the seven toxins.

PRINCIPLE

VIDAS® Staph enterotoxin II is an enzyme-linked fluorescent immunoassay (ELFA) for use on the VIDAS® family instrument (see the Operator's Manual) for the specific detection of staphylococcal enterotoxins.

The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device. The interior of the SPR® is coated with anti staphylococcal enterotoxin antibodies. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR® several times. Part of the food extract is dispensed into the reagent strip. The antigens present will bind to the anti-enterotoxin antibodies which are coated on the interior of the SPR®. Unbound sample components are washed away. Alkaline phosphatase-labeled antibodies are cycled in and out of the SPR® and will bind to any Staphylococcal enterotoxins which are themselves bound to the antibodies on the SPR® wall. Further wash steps remove unbound conjugate.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR®. The bound enzyme conjugate catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm. At the end of the assay, the results are automatically analyzed by the instrument which calculates a test value each sample. This value is compared to internal references (thresholds) and each result is interpreted (positive, negative).

KIT COMPOSITION (30 tests)

30 SET2 Reagent Strips	STR	Ready-to-use.
30 SET2 SPR®s	SPR	Ready-to-use. Interior of SPR®s coated with anti-staphylococcal enterotoxin antibodies.
SET2 Standard (1 x 6 ml)	S1	Ready-to-use. Purified enterotoxin A (< 1.0 ng/ml) + preservative and protein stabilizers. MLE data indicate the confidence interval in Relative Fluorescence Value ("Standard (S1) RFV Range"). **CAUTION: HANDLE WITH CARE !**
SET2 Positive Control (1 x 6 ml)	C1	Ready-to-use. Purified enterotoxin A (< 1.0 ng/ml) + preservative and protein stabilizers. MLE data indicate the confidence interval in test value ("Control C1 (+) Test Value Range"). **CAUTION: HANDLE WITH CARE!**
Negative Control (1 x 6 ml)	C2	Ready-to-use. TRIS Buffered Saline (TBS) (150 mmol/l) - Polysorbate pH 7.6 + preservative. MLE data indicate the maximum acceptable value in Test Value ("Control C2 (-) Test Value Range").
SET2 Concentrated Extraction Buffer (1 x 55 ml)	R1	2.5 mol/l TRIS* - 10 g/l Polysorbate - 10 g/l MIT pH 8.0.
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit. or • MLE bar code printed on the box label.		
1 package insert downloadable from www.biomerieux.com/techlib		

* Signal Word: **WARNING**

Hazard statement

H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Precautionary statement

P280: Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
For further information, refer to the Material Safety Data Sheet.

The SPR

The interior of the SPR® is coated during production with staphylococcal anti-enterotoxin antibodies. Each SPR® is identified by the SET2 code. Only remove the required number of SPR®s from the pouch and **carefully reseal the pouch after opening.**

The Reagent Strip

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which indicates the assay code, kit lot number and expiration date.
The foil of the first well is perforated to facilitate the introduction of the sample.
The last well of each strip is a cuvette in which the fluorometric reading is performed.
The wells in the center section of the strip contain the various reagents required for the assay.

Description of the SET2 Reagent strip

Wells	Reagents
1	Sample Well: 500 µl of food extract, standard or control is dispensed in the well.
2	Pre-wash solution (400 µl): TRIS-NaCl (150 mmol/l) - Polysorbate pH 7.6 - protein stabilizer + preservative.
3 - 4 - 5 - 7 - 8 - 9	Wash solution (600 µl): TBS (150 mmol/l) - Polysorbate pH 7.6 + preservative.
6	Conjugate (400 µl): alkaline phosphatase-labeled anti-staphylococcal enterotoxin antibodies + preservative.
10	Reading cuvette with substrate (300 µl): 4 Methyl-umbelliferyl-phosphate (0.6 mmol/l) + diethanolamine* (DEA) (0.62 mol/l or 6.6%, pH 9.2) + preservative.

* Signal Word: **DANGER**

Hazard statement

H318 : Causes serious eye damage.

Precautionary statement

P280: Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
For further information, refer to the Material Safety Data Sheet.

REAGENTS, MATERIALS AND DISPOSABLES REQUIRED BUT NOT PROVIDED

- VIDAS® family instrument
- Disposable Pipette and/or micropipettes to dispense appropriate volumes.
- Paddle blender (example: SMASHER™ ref. AESAP1064 or SMASHER™ XL ref. AESAP1100).
- Blender bag
- Centrifugation tubes (50 ml).
- Syringes (20 ml).
- pH paper.
- Trichloroacetic acid (TCA) 90% (5.5N).
- TRIS buffer (0.3M pH 8.0).
- Sodium hydroxide 1N and 4 N.
- Hydrochloric acid 5N.

For other specific materials and disposables, please refer to the Instrument Operator's Manual.

WARNINGS AND PRECAUTIONS

- **For professional use only.**
- **Place the instrument in a room designed for microbiological analysis.**
- Comply with Good Laboratory Practice (e.g., standard EN ISO 7218) (7).
- **This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).**
- Do not use the SPR®s if the pouch is pierced or if the dot sealing a SPR has come unstuck.
- Do not use visibly deteriorated STRs (damaged foil or plastic).
- Do not use reagents after the expiration date indicated on the label.
- Do not mix reagents (or disposables) from different lots.
- ***The positive control and standard contain purified staphylococcal enterotoxin. Handle with great care and use protective devices (coat, gloves and glasses). Consult a physician immediately if accidentally ingested.***
- Kit reagents contain sodium azide which can react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- The substrate in well 10 contains an irritant agent (diethanolamine 6.6%). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Concentrated extraction buffer contains irritating components (TRIS). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped up thoroughly after treatment with liquid detergent or a solution of household bleach containing at least 0.5% sodium hypochlorite. See the Operator's Manual for cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
- The instrument should be regularly cleaned and decontaminated (see the Operator's Manual).

STORAGE

- Store the VIDAS® SET2 kit at 2-8°C.
- **Do not freeze reagents.**
- **Store all unused reagents at 2-8°C.**
- After opening the kit, check that the SPR® pouch is correctly sealed and undamaged. If not, do not use the SPR®s.
- **To maintain the stability of the SPR®s, carefully reseal the pouch after use with the desiccant inside, using the clip seal provided, and return the complete kit to 2-8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label.

SAMPLE PREPARATION

Detection of staphylococcal enterotoxins types SEA to SEE in all types of human food matrices according to the European screening method or the method recommended by the Direction Générale de l'Alimentation (General Directorate for Food)

Refer to the documents "European screening method of EU-RL for coagulase positive *Staphylococci*, including *Staphylococcus aureus*" (8) and "Recherche des enterotoxines staphylococciques de type SEA à SEE dans les aliments – Dispositions relatives aux méthodes d'analyses pour les analyses officielles – note de service DGAL en vigueur" (9).

AOAC Official Method of Analysis (no. 2007.06) validated protocols.

Preparation of the extraction buffer

Dilute the whole R1 extraction buffer with sterile demineralized water to obtain 1 liter of ready-to-use solution. Mix. Store at 2-8°C for up to 3 months.
The R1 buffer can also be diluted in different volumes depending on frequency of use (dilution rate = 1/18).

Preparation of the 90% trichloroacetic acid solution

Dissolve 90 g of trichloroacetic acid in 40 ml of demineralized water. Adjust the final volume to 100 ml using demineralized water.
The solution can be stored for 1 month at 18-25°C.

pH adjustment of food extracts

For pH adjustment of food extracts it is recommended to use a strip paper with 3 color bands and a precision of at least 0.5 pH units.

General extraction protocol

- To 25 g of food, add 25 ml of reconstituted extraction buffer diluted as indicated previously, in a blender bag.
- Blend at high speed for 3 minutes to obtain a homogeneous suspension.
- Let stand for 15 minutes at 18-25°C.
- Centrifuge the blended sample in the extraction solution for 15 minutes at 3000-5000 *g* at 18-25°C. Pump the supernatant through a moistened absorbent cotton placed in a syringe, using the plunger.
- Check the filtrate pH and adjust it to between 7.5 and 8.0 if necessary, using 1N NaOH.
- Recover 500 µl of the filtrate and place in the sample well of a VIDAS® SET2 Reagent strip before initiating the assay.

Liquid food

- Dilute the concentrated food product as indicated by the manufacturer.
- Check the filtrate pH and adjust it to between 7.5 and 8.0 if necessary, using 1N NaOH.
- In the case of a precipitate, centrifuge and filtrate the suspension as described in the general extraction protocol.
- Recover 500 µl of the filtrate and place in the sample well of a VIDAS® SET2 Reagent strip before initiating the assay.

Dehydrated food

- Rehydrate the food product with an equivalent volume of distilled water or according to the manufacturer's instructions.
- Leave the rehydrated sample for one hour at 18-25°C.
- Weigh 25 g of rehydrated food and add 25 ml of reconstituted extraction buffer.
- Proceed then as described in the general extraction protocol (for Non-fat Dry Milk (NFDM), proceed as described in the "Dairy products" protocol).

Canned food (post retort contamination)

- Blend the whole canned food or a representative aliquot to obtain a homogeneous suspension.
- To 25 g of food add 25 ml of reconstituted extraction buffer.
- Proceed then as described in the general extraction protocol.

Raw meat products, seafood and delicatessen meats

- Blend 25 g of food **in 25 ml of demineralized water** at high speed for 3 minutes to obtain a homogeneous suspension. If the suspension is too dense add an additional 25 ml of demineralized water and re-blend.
- Recover the whole extract.
- Check the pH and adjust it to 4.0 using 5N HCl.
- Let stand for 15 to 30 minutes at 18-25°C.
- Centrifuge the blended sample in the extraction solution for 15 minutes at 3000-5000 *g* at 18-25°C. Pump the supernatant through a moistened absorbent cotton placed in a syringe, using the plunger.
- Check the filtrate pH and adjust it to between 7.5 and 8.0 if necessary, with 1N NaOH.
- In the case of a precipitate, centrifuge an aliquot as described previously.
- Recover 500 µl of the filtrate and place in the sample well of a VIDAS® SET2 Reagent strip before initiating the assay.

Dairy products

Protocol without concentration

- To 25 g of food add 40 ml of demineralized water pre-incubated at 38 ± 2°C.
- Blend at high speed for 3 minutes to obtain a homogeneous suspension.
- Let stand for 30 minutes at 18-25°C.
- Check the pH and adjust it to between 3.5 and 4.0 using 5N HCl.
- Centrifuge this suspension for 15 minutes at 3000-5000 *g* at 18-25°C.
- Recover the supernatant and adjust the pH to between 7.5 and 8.0 using 1N NaOH.
- Centrifuge for 15 minutes at 18-25°C at 3000-5000 *g* and filter if necessary.
- Recover 500 µl of the filtrate and place in the sample well of a VIDAS® SET2 Reagent strip before initiating the assay.

For liquid products (i.e. milk)

Adjust the pH of 25 ml of the product to between 3.5 and 4.0 using 5N HCl. Proceed then as previously described.

Trichloroacetic acid concentration (TCA)

This protocol is recommended for increasing the concentrations of the toxins for all dairy products and suppressing rare interference found with some raw milk cheeses (e.g. Roquefort).

The method of preparation for the trichloroacetic acid solution is described in the section "Preparation of the 90% trichloroacetic acid solution":

- Proceed as described in the dairy product protocol until the end of the first centrifugation.
- Recover the supernatant in a centrifugation tube and measure its volume V.
- Add to the supernatant a volume Y of a TCA solution (at 90% in water) to obtain a 5% final concentration: Y = V x 5/100.
- Mix using a vortex-type mixer and precipitate the proteins for 30 minutes at 18-25°C.
- Centrifuge for 30 minutes at 3000-5000 *g* at 18-25°C.
- Carefully discard the supernatant.
- **Dissolve the protein pellet** in a volume of TRIS 0.3M pH 8.0 corresponding to 1/10 of the starting volume V of the supernatant treated with TCA.
- If necessary, adjust the pH to between 7.5 and 8.0 using 4N NaOH. At this pH, the milky solution becomes clear. If the solution shows particles in suspension, centrifuge again for 15 minutes at 3000-5000 *g* at 18-25°C.
- Recover 500 µl of the filtrate and place in the sample well of a VIDAS® SET2 Reagent Strip before initiating the assay.

Extract storage

The VIDAS® SET2 assay must be performed immediately after extraction. Extracts of food products other than dairy products, may be stored for 7 days at –25 ± 6°C. It is recommended that specific matrices be validated for stability of extracts when stored at –25 ± 6°C for 7 days.

INSTRUCTIONS FOR USE

For complete instructions, see the Operator's Manual.

Reading MLE data

When opening a new lot of reagents, enter the specifications (or factory master data) into the instrument using the MLE data. If this operation is not performed **before initiating the tests**, the instrument will not be able to print results.
It is possible to enter the MLE data manually or automatically depending on the instrument (refer to the User's Manual).
Note: the master lot data need only be entered once for each lot.

Calibration

Calibration, using the standard provided in the kit, must be performed upon receipt of a new lot of reagents after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.
The standard, identified by S1, must be tested in **duplicate** (see Operator's Manual). The standard value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

Procedure

1. **Only remove the required reagents from the refrigerator and allow them to come to room temperature for at least 30 minutes.**
2. Use one VIDAS® "SET2" strip and one VIDAS® "SET2" SPR® for each sample, control or standard to be tested. **Make sure the storage pouch has been carefully resealed after the required SPR®s have been removed.**
3. The test is identified by the "SET2" code on the instrument. The standard must be identified by "S1", and tested in duplicate. If the positive control is to be tested, it should be identified by "C1". If the negative control needs to be tested, it should be identified by C2.
4. If necessary, mix the standard, controls and samples using a vortex-type mixer.
5. Pipette 500 µl of standard, sample, or control into the sample well.
6. Insert the SPR®s and strips into the instrument. Check to make sure the color labels with the assay code on the SPR®s and the Reagent Strips match.
7. Initiate the assay as directed in the Operator's Manual. All the assay steps are performed automatically by the instrument. The assay will be completed within approximately 80 minutes.
8. After the assay is completed, remove the SPR®s and strips from the instrument.
9. Dispose of the used SPR®s and strips into an appropriate biohazard receptacle in accordance with applicable local regulations.

RESULTS AND INTERPRETATION

Once the assay is completed, results are analyzed automatically by the computer.
Fluorescence is measured twice in the Reagent Strip's reading cuvette for each sample tested.
The first reading is a background reading of the substrate cuvette before the SPR® is introduced into the substrate.
The second reading is taken after incubating the substrate with the enzyme remaining on the interior of the SPR®.

The RFV (Relative Fluorescence Value) is calculated by subtracting the background reading from the final result. This calculation appears on the result sheet.
The RFV obtained for each sample is interpreted by the instrument as follows:

$$\text{Test value} = \frac{\text{Sample RFV}}{\text{Standard RFV}}$$

Thresholds and interpretations

Test value	Interpretation
< 0.13	Negative
≥ 0.13	Positive

The printed report includes:

- the type of test performed,
- the sample identification,
- the date and time,
- the lot number and expiration date of the kit,
- the RFV, Test Value and interpreted result for each sample.

A result with a test value that is less than the threshold value indicates that the sample does not contain staphylococcal enterotoxin or contains staphylococcal enterotoxin at a concentration below the detection limit.

A result with a test value that is greater than or equal to the threshold value indicates a sample contaminated with enterotoxin.

Invalid results are reported:
- when the background reading is above a pre-determined cut-off (indicating substrate contamination). In this case, repeat the assay with the broth or the reagent used (S1, C1, or C2).
- If there is no standard available for the lot number of the sample test strip.
  In this case, run a standard in duplicate in strips with the same lot number as the invalid sample test. The sample test result can then be recalculated using the new stored standard. See the Operator's Manual for complete information.

QUALITY CONTROL

One positive control and one negative control are included in each VIDAS® SET2 kit.
These controls must be performed each time a new lot of reagents is opened to verify the calibration (see section “Calibration”). It is also recommended to perform the controls each time new kits are received to ensure that reagent performance has not been altered.
The instrument will only be able to check the control values if it they are identified by C1 and C2.
Results cannot be validated if the control values deviate from the expected values.

Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

LIMITATIONS OF THE METHOD

Any change or modification in the procedure may affect the results.

Rare interference has been observed with some blue-veined-type raw milk cheeses (e.g. Roquefort). The trichloroacetic acid concentration method enables the suppression of this interference.

Caution

The VIDAS® SET2 assay has been evaluated on a large number of food matrices: milk, cheese, raw and cooked meat, delicatessen meats, seafood, vegetables, etc. However, since this test is used directly on the food product, non immunological interferences linked to matrix effect may occur (e.g. raw products containing a high concentration of endogenous alkaline phosphatase).
Given the large variety of food products and manufacturing procedures, it is recommended to check that the composition of the matrices tested does not affect the reliability of VIDAS SET2 results.
When performing an enterotoxin test on a product not yet tested, it is recommended that the absence of matrix interference and the extraction efficacy be checked by testing a known negative sample of this product type.

PERFORMANCE

Limit of detection tested with purified toxins:

Toxins A, B, C1, C2, C3, D and E are detected with a detection limit ≥ 0.25 ng/ml.

The results concerning the detection limit with spiked food and the specificity were obtained using the protocols described in the package insert for each category of food product. For dairy products, the results were obtained using the trichloroacetic acid concentration protocol.

Limit of detection tested with spiked food:

Performance was tested on 44 food matrices spiked with toxins :
- 6 products tested according to the general protocol,
- 2 canned foods,
- 3 liquid products,
- 4 dehydrated products,
- 14 dairy products,
- 15 meat, delicatessen and seafood products.

According to the spiking level the following sensitivity of detection was observed :

	Toxin concentration (ng of toxin per g of products)			
	0.1 ng/g	0.25 ng/g	0.5 ng/g	1.0 ng/g
Toxin A	75%	93%	100%	-
Toxin B	80%	98%	100%	-
Toxin C2	-	84%	95%	100%
Toxin D	-	48%	82%	95%*
Toxin E	-	66%	93%	100%

* For ground veal and a cheese spread, the limit of detection was higher than 1.0 ng/g.

Specificity

Performance was tested on 143 food matrices during an external evaluation and 137 food matrices during an in-house evaluation:
- 43 products tested according to the general protocol,
- 19 canned foods,
- 15 liquid products,
- 17 dehydrated products,
- 87 dairy products,
- 99 meat, delicatessen and seafood products.

Number of false positive results: 1 (kidneys). Assay specificity was 99.6%.

The VIDAS® SET2 method is described as the official method for the detection of staphylococcal enterotoxins in all types of food matrices according to the documents *"European screening method of EU-RL for coagulase positive Staphylococci, including Staphylococcus aureus" (8) and "Recherche des enterotoxines staphylococciques de type SEA à SEE dans les aliments – Dispositions relatives aux méthodes d'analyses pour les analyses officielles – note de service DGAL en vigueur" (9).*

The VIDAS® SET2 method has been validated and certified by AOAC INTERNATIONAL as an Official Method of Analysis (Certificate No. 2007.06) for the detection of staphylococcal enterotoxins in a number of products.

The following matrices have been included in the AOAC validation: lasagna, chocolate eclairs, canned mushrooms, egg powder, roast beef, cooked chicken, ham, unpasteurized milk, cheddar, yoghurt, Italian salami, smoked salmon, potato salad, ice cream, powdered milk and pasteurized milk.

USE / VALIDATION STATEMENT

Performance characteristics for the System for any use outside the labeling, package insert or operator's manual have not been established. Customer therefore acknowledges and agrees that bioMérieux, Inc. makes no claims, representations, warranties or guarantees for use of the System other than as specifically set forth in the applicable package insert and/or operator's manual. bioMérieux specifically disclaims all warranties, express or implied, of MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE and disclaims all liability, whether direct, indirect or consequential, for any use other than as set forth in the applicable package insert and/or operator's manual. IN NO EVENT SHALL bioMérieux's LIABILITY TO CUSTOMER UNDER ANY CLAIM EXCEED A REFUND OF THE AMOUNT PAID TO bioMérieux FOR THE PRODUCT OR SERVICE WHICH IS THE SUBJECT OF THE CLAIM. Customer acknowledges and agrees that it is Customer's sole and exclusive responsibility to validate the System for any such intended use, and to determine whether the System is suitable for that intended use. The performance of any validation studies, and the subsequent use of the System based on Customer's studies shall be the Customer's sole risk and responsibility.

WASTE DISPOSAL

Dispose of used or unused reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious products.

It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

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9. Recherche des enterotoxines staphylococciques de type SEA à SEE dans les aliments – Dispositions relatives aux méthodes d'analyses pour les analyses officielles – note de service DGAL en vigueur

INDEX OF SYMBOLS

Symbol	Meaning
	Catalog reference
	Manufacturer
	Temperature limit
	Use by date
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Potential biohazard
	Date of manufacture

WARRANTY

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REVISION HISTORY

Change type categories :

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Note :*Minor typographical, grammar, and formatting changes are not included in the revision history.*

Release date	Part Number	Change Type	Change Summary
2015/01	12095I	Administrative	Index of symbols Creation of the revision history table
		Technical change	Kit composition Warnings and precautions

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