VIDAS® UP *Salmonella* (SPT)

For microbiological control only

Based on a novel recombinant phage protein-based technology, VIDAS® UP *Salmonella* is an automated qualitative test for use on the instruments of the VIDAS® family for the detection of *Salmonella* in human and animal food products, and production environmental samples.

SUMMARY AND EXPLANATION

Salmonella is one of the main causes of food poisoning. *Salmonella* detection using time-consuming protocols, can take up to 5 days to confirm a sample is negative (1). Enzyme immunoassay (EIA)-based screening techniques have the potential to simplify and accelerate this detection.

Salmonella are antigenically complex with over 2 400 serovars differentiated by somatic (O) lipopolysaccharide and flagellar (H) protein antigens (2).

Thanks to an innovative technology involving recombinant phage proteins, the VIDAS® UP *Salmonella* (SPT) assay enables the specific detection of *Salmonella* in human and animal food products and production environmental samples. Both motile and non-motile *Salmonella* can be detected.

PRINCIPLE

VIDAS® SPT is an enzyme immunoassay for use on the instruments of the VIDAS® family (see Operator's Manual) for the detection of *Salmonella* receptors using the ELFA method (Enzyme Linked Fluorescent Assay).

The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device. The interior of the SPR® is coated with proteins specific for *Salmonella* receptors. 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 enrichment broth is dispensed into the reagent strip. The *Salmonella* receptors present will bind to the interior of the SPR®. Unbound components are eliminated during the washing steps. The proteins conjugated to the alkaline phosphatase are cycled in and out of the SPR® and will bind to any *Salmonella* receptors, which are themselves bound to the SPR® wall.

A final wash step removes unbound conjugate.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR®. The conjugate enzyme 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, results are automatically analyzed by the instrument which calculates a test value for each sample. This value is then compared to internal references (thresholds) and each result is interpreted (positive, negative).

CONTENT OF THE KIT(60 tests)

60 SPT Strips	STR	Ready-to-use.
60 SPT SPR®s	SPR	Ready-to-use. Interior of SPR®s coated with proteins specific for *Salmonella* receptors.
Standard SPT (1 x 6 ml)	S1	Ready-to-use. Purified and inactivated *Salmonella* receptors + preservative + protein stabilizer. The confidence interval is indicated on the MLE card after the following mention: "Standard (S1) RFV Range".
SPT Positive Control (1 x 6 ml)	C1	Ready-to-use. Purified and inactivated *Salmonella* receptors + preservative + protein stabilizer. The confidence interval is indicated on the MLE card after the following mention: "Control C1 (+) Test Value Range".
Negative Control (1 x 6 ml)	C2	Ready-to-use. TRIS buffered saline (TBS) (150 mmol/l) - Tween pH 7.6 + preservative. The maximum acceptable value for the test is indicated on the MLE card after the following mention: "Control C2 (-) Test Value Range".
1 MLE Card (Master Lot Entry)		Specifications for the factory master data required to calibrate the test: to read the MLE data, please refer to the Operator's Manual.
1 Package insert provided in the kit or downloadable from www.biomerieux.com/techlib		

The SPR®

The interior of the SPR® is coated during production with proteins specific for *Salmonella* receptors.
Each SPR® is identified by the "SPT" code. Only remove the required number of SPR®s from the pouch and **reseal the pouch correctly after opening.**

The Reagent Strip

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly 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 SPT strip

Wells	Reagents
1	Sample well: dispense 0.5 ml of enrichment broth, standard or control.
2	Pre-wash solution (400 µl): Buffer pH 7.8 + preservative.
3 - 4 - 5 - 7- 8 - 9	Wash solution (600 µl): TRIS buffered saline (150 mmol/l) – Tween pH 7.6 + preservative.
6	Conjugate (400 µl): alkaline phosphatase-labeled proteins specific for *Salmonella* receptors + 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.

*** IRRITANT reagent:**
- **R 36**: Irritating to eyes.
- **S 26**: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

For further information, refer to the Material Safety Data Sheet available on request.

REAGENTS, MATERIALS AND CONSUMABLES REQUIRED BUT NOT PROVIDED

- Instrument of the VIDAS® family.
- Disposable pipettes and/or micropipettes to dispense the appropriate volumes
- VIDAS® Heat and Go (bioMérieux ref. 93554 or 93555 or 93556: Contact your bioMérieux representative) or a water-bath (95-100°C) or an equivalent system
- Stomacher®-type mixer
- Stomacher®-type bag with filter
- *Salmonella* Supplement (*Salmonella* SUPP) (bioMérieux ref.42650)
- SX2 Broth (bioMérieux ref. 42121, 20 tubes)
- chromID™ *Salmonella* Agar (SM2) (bioMérieux ref. 43621 or 43629)
- Vancomycin
- Strip
  - API® 20E (bioMérieux ref. 20 100)
  - or ID 32 E (bioMérieux ref. 32400)
  - or rapid ID 32 E (bioMérieux ref. 32700)

The following references are given as a guide.
- Buffered Peptone Water
  - 3-liter bag (bioMérieux ref. 42629)
  - 225 ml bottle (bioMérieux ref. 42043)
  - 225 ml mini-bag (bioMérieux ref. 42729)
  - 90 ml bottle (bioMérieux ref. 42042)
  - 9 ml tube (bioMérieux ref. 42111).
- Nonfat dry milk
- Neutralizing agent (e.g: Dey-Engley)
- Selective agar:
  Examples:
  - Hektoen Agar (bioMérieux ref. 43111)
  - XLD Agar (bioMérieux ref. 43563)
  - XLT4 Agar (bioMérieux ref. 43701)
  - Bismuth Sulfite (Wilson-Blair Agar)

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 ISO 7218) (3)
- During the enrichment and plating steps, this method may generate pathogenic organisms in levels sufficient to cause illness in humans. Therefore, take appropriate safety precautions when handling samples that may contain pathogenic organisms.
- 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.
- 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.
- 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 risk phrase "R" and the precautions "S" 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 CONDITIONS

- Store the VIDAS® SPT 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.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPR®s 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.

SPECIMENS (PREPARATION)

The following protocols are recommended.
Allow the enrichment broths to come to room temperature (18-25°C) before use.
Frozen samples must be thawed beforehand.

Method certified NF VALIDATION (BIO-12/32-10/11)

Standard procedure for all human (excluding raw milk cheese) and animal food products and production environmental samples

- In a Stomacher®-type bag with filter, aseptically place:
  - X g (X ml) of sample.
  - 9X ml of Buffered Peptone Water.
    For certain matrices, it is recommended to follow the specific preparation techniques described in the standards EN ISO 6887-1 to 6887-5 and EN ISO 6579 (4-9) and to add the *Salmonella* Supplement to the enrichment.
    Note 1: for cocoa and products containing cocoa, do not add brilliant green.
    Note 2: for acid products, it is not recommended to add a color indicator.
    Note 3: for environmental samples, the collection device should first be dampened with a sterile diluent (e.g., Buffered Peptone Water) containing a suitable neutralizing agent (e.g., Lecithin-Polysorbate-L.Histidine-Sodium thiosulfate mixture), if necessary. After collection, place the device in a suitable volume of supplemented Buffered Peptone Water (e.g., swab in 10 ml, sampling pad in 90 ml).
    Note 4: In the context of NF VALIDATION, no test samples over 25 g were tested.
- Mix using a Stomacher®-type mixer.
- Add Y ml of *Salmonella* Supplement (Ref. 42650) corresponding to:

$$Y\,(ml) = \frac{\text{volume of Buffered Peptone Water (ml)}}{225\,(ml)}$$

  Examples:
  - 1 ml for 225 ml of Buffered Peptone Water
  - 400 µl for 90 ml of Buffered Peptone Water.

  Note 1: Mix the supplement using a vortex-type mixer, before each use.
  Note 2: if the 1/10 dilution in Buffered Peptone Water is also used for the enumeration of quality indicator organisms, follow the recommendations in the standard ISO 7218 (3). Take this sampling portion into account when initially weighing the sample. Sampling should be performed before adding the *Salmonella* supplement.
  Note 3: the supplement can be added directly to the Buffered Peptone Water if the enumeration of quality indicator organisms is not performed using the same test sample.
- Mix the contents of the Stomacher®-type bag manually.
- Incubate for 18-24 hours at 41.5 ± 1°C.
- After incubation, mix the contents of the Stomacher®-type bag manually.
  If the VIDAS® Heat and Go is used, transfer 0.5 ml of the enrichment broth into the sample well on the strip. Heat for 5 ± 1 minutes (see the VIDAS® Heat and Go Operator's Manual). Remove the strip and leave to cool for at least 10 minutes.
  Note: Do not use the VIDAS® Heat and Go for egg products and poultry samples.
  If a water-bath is used, transfer 2-3 ml of the enrichment broth into a tube. Seal the tube. Heat for 5 ± 1 minutes at 95-100°C. Cool the tube. Mix the boiled broth using a vortex-type mixer and transfer 0.5 ml into the sample well on the VIDAS® strip.
- Perform the VIDAS® assay.
  Note: The non-heated enrichment broth can be stored for 72 hours at 2-8°C before the VIDAS® test is performed.
- Confirm the positive results.
  Note: If confirmation is not initiated immediately after a positive VIDAS® test, store the enrichment broth at 2-8°C. Confirmation must be initiated within 72 hours following the end of incubation.

Method outside the scope of NF VALIDATION

Procedure for dairy products (including raw milk cheese)

- In a Stomacher®-type bag with filter, aseptically place:
  - X g (X ml) of sample.
  - 9X ml of Buffered Peptone Water.
    For certain matrices, it is recommended to follow the specific preparation techniques described in the standard EN ISO 6887-5 (8) and to add the *Salmonella* Supplement to the enrichment.
    Note 1: For acid products, it is not recommended to add a color indicator.
    Note 2: No test samples over 25 g were tested.
- Mix using a Stomacher®-type mixer.
- Add Y ml of *Salmonella* Supplement (Ref. 42650) corresponding to:

$$Y\,(ml) = \frac{\text{volume of Buffered Peptone Water (ml)}}{225\,(ml)}$$

  Example: 1 ml for 225 ml of Buffered Peptone Water.
  Note 1: Mix the supplement using a vortex-type mixer, before each use.
  Note 2: if the 1/10 dilution in Buffered Peptone Water is also used for the enumeration of quality indicator organisms, follow the recommendations in the standard ISO 7218 (3). Take this sampling portion into account when initially weighing the sample. Sampling should be performed before adding the *Salmonella* Supplement.
  Note 3: the supplement can be added directly to the Buffered Peptone Water if the enumeration of quality indicator organisms is not performed using the same test sample.
- Mix the contents of the Stomacher®-type bag manually.
- Incubate for 18-24 hours at 41.5 ± 1°C.
- After incubation, mix manually and transfer 1 ml of suspension into 10 ml of SX2 broth **pre-warmed at 41.5 ± 1°C** (enrichment broth).
- Incubate for 6-8 hours at 41.5 ± 1°C.

- After incubation, mix the enrichment broth.
  If the VIDAS® Heat and Go is used, transfer 0.5 ml of the enrichment broth into the sample well on the strip. Heat for 5 ± 1 minutes (see the VIDAS® Heat and Go Operator's Manual). Remove the strip and leave to cool for at least 10 minutes.
  If a water-bath is used, transfer 1-2 ml of the enrichment broth into a tube. Seal the tube. Heat for 5 ± 1 minutes at 95-100°C. Cool the tube. Mix the boiled broth using a vortex-type mixer and transfer 0.5 ml into the sample well on the VIDAS® strip.
- Perform the VIDAS® assay.
- Confirm the positive results.

Confirmation of positive results obtained using the method certified NF VALIDATION and the specific procedure for dairy products

All positive results obtained with VIDAS® SPT must be confirmed.
Confirmation should be performed from the **non-boiled** enrichment broth **stored at 2-8°C**, and initiated within 72 hours following the end of incubation.

- Isolate on a selective chromogenic *Salmonella* agar.
- Incubate the agar following the instructions in the package insert. Then perform one of the following procedures:
  1. Identify between 1 and 5 typical colonies using the conventional tests described in the methods standardized by the CEN or ISO (including the purification step) (9).
  2. The presence of typical *Salmonella* colonies is sufficient to confirm the presence of *Salmonella*.
  3. Test isolated colonies directly using a bioMérieux strip (without a purification step).

In the event of discordant results (positive with the alternative method, non confirmed by the tests described above), the laboratory must follow the necessary steps to ensure the validity of the results obtained.

It is recommended, for example, to perform the following additional protocol:

- Transfer 0.1 ml of enrichment broth in 10 ml of SX2 broth.
- After incubation for 16-24 hours at 41.5 ± 1°C, isolate onto a selective chromogenic *Salmonella* agar.
- Identify the colonies using one of the 3 procedures indicated above.

AOAC RI approved protocols (N° 071101)

Standard procedure for a 25 g test portion for a variety of foods, and for environmental surfaces

- In a Stomacher®-type bag with filter, aseptically place:
  - 25 g (25 ml) of sample.
  - 225 ml of Buffered Peptone Water.
    Note: for environmental samples, the collection device should first be dampened with a sterile diluent (e.g., Buffered Peptone Water) containing a suitable neutralizing agent (e.g., Dey-Engley), if necessary. After collection, place the device in a suitable volume of Buffered Peptone Water (e.g., swab in 10 ml, sampling pad in 90 ml).
- Mix for 2 minutes using a Stomacher®-type mixer.
- Add the *Salmonella* Supplement (Ref. 42650) as indicated below:
  - 1 ml for 225 ml of Buffered Peptone Water.
  - 0.044 ml for 10 ml of Buffered Peptone Water
  - 0.4 ml for 90 ml of Buffered Peptone Water.
    Note 1: Mix the supplement using a vortex-type mixer, before each use.
    Note 2: the supplement can be added directly to the Buffered Peptone Water if the enumeration of quality indicator organisms is not performed using the same test sample.
- Mix the contents of the Stomacher®-type bag manually.
- Incubate for 18-24 hours at 42 ± 1°C.
- After incubation, mix the contents of the Stomacher®-type bag manually.
  If a water-bath is used, transfer 2-3 ml of the enrichment broth into a tube. Seal the tube. Heat for 5 ± 1 minutes at 95-100°C. Cool the tube. Mix the boiled broth using a vortex type mixer and transfer 0.5 ml into the sample well on the VIDAS® strip.
  If the VIDAS® Heat and Go is used, transfer 0.5 ml of the enrichment broth into the sample well on the strip. Heat for 5 ± 1 minutes (see the VIDAS® Heat and Go Operator's Manual). Remove the strip and leave to cool for at least 10 minutes.
  Note: Do not use the VIDAS® Heat and Go for egg products and poultry samples.
- Perform the VIDAS® assay.
- Confirm the positive results.

Procedure for heat-treated liquid eggs and powdered eggs for a 25 g test portion

- In a Stomacher®-type bag with filter, aseptically place:
  - 25 g (25 ml) of sample.
  - 225 ml of Buffered Peptone Water **pre-warmed at 42 ± 1°C.**
- Mix for 2 minutes using a Stomacher®-type mixer.
- Incubate for 16-24 hours at 42 ± 1°C.
- After incubation, mix the contents of the Stomacher®-type bag manually.
  Transfer 2-3 ml of the enrichment broth into a tube (for powdered eggs transfer 10 ml of the enrichment broth into a tube). Seal the tube. Heat in a water-bath for 5 ± 1 minutes at 95-100°C. Cool the tube. Mix the boiled broth using a vortex type mixer and transfer 0.5 ml into the sample well on the VIDAS® strip.
- Perform the VIDAS® assay.
- Confirm the positive results.

Procedure for bagged lettuce for a 25 g test portion

- In a Stomacher®-type bag with filter, aseptically place:
  - 25 g of sample.
  - 225 ml of Buffered Peptone Water + vancomycin (8 mg/l) **pre-warmed at 42 ± 1°C.**
- Mix for 2 minutes using a Stomacher®-type mixer.
- Incubate for 18-24 hours at 42 ± 1°C.
- After incubation, mix the contents of the Stomacher®-type bag manually.
  If a water-bath is used, transfer 2-3 ml of the enrichment broth into a tube. Seal the tube. Heat for 5 ± 1 minutes at 95-100°C. Cool the tube. Mix the boiled broth using a vortex type mixer and transfer 0.5 ml into the sample well on the VIDAS® strip.
  If the VIDAS® Heat and Go is used, transfer 0.5 ml of the enrichment broth into the sample well on the strip. Heat for 5 ± 1 minutes (see the VIDAS® Heat and Go Operator's Manual). Remove the strip and leave to cool for at least 10 minutes.
- Perform the VIDAS® assay.
- Confirm the positive results.

Procedure for raw beef, instant nonfat dry milk, bagged lettuce, dark chocolate and dry dog food for a 375 g test portion

- In a Stomacher®-type bag with filter, aseptically place:
  - 375 g of sample.
  - 1125 ml of Buffered Peptone Water **pre-warmed at 42 ± 1°C**.
    Note: for dark chocolate, replace Buffered Peptone Water with reconstituted nonfat dry milk **pre-warmed at 42 ± 1°C**.
- Mix for 2 minutes using a Stomacher®-type mixer.
- Add 5 ml of *Salmonella* Supplement (Ref. 42650).
  Note: Mix the supplement using a vortex-type mixer, before each use.
- Mix the contents of the Stomacher®-type bag manually.
- Incubate for 22-26 hours at 42 ± 1°C.
- After incubation, mix the contents of the Stomacher®-type bag manually.
  Transfer 2-3 ml of the enrichment broth into a tube. Seal the tube. Heat in a water-bath for 5 ± 1 minutes at 95-100°C. Cool the tube. Mix the boiled broth using a vortex type mixer and transfer 0.5 ml into the sample well on the VIDAS® strip.
- Perform the VIDAS® assay.
- Confirm the positive results.

Confirmation of positive results obtained with the AOAC RI approved protocols

All positive results obtained with VIDAS® SPT must be confirmed. Confirmation should be performed using the **non-heated** enrichment broth**,** as described in the appropriate reference method (i.e. USDA-FSIS MLG (10) and FDA BAM (11)).

INSTRUCTIONS FOR USE

For complete instructions, see the Operator's Manual.

VIDAS® PTC protocol data entry

When using the assay for the first time, **and before reading the MLE data,** scan the bar code(s) (at the end of the package insert) using the instrument's external bar code reader. This reading will allow VIDAS® PTC protocol data to be transferred to the instrument software for its update. These data should only be read the first time the assay is used.

Master lot data entry

Note: When using the assay for the first time, enter the VIDAS® PTC protocol (bar codes at the end of the package insert) before reading the MLE data. If the MLE data have been read before the VIDAS® PTC protocol, read the MLE data again.
Before each new lot of reagents is used, specifications (or factory master calibration curve data) must be entered 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. The master lot data need only be entered once for each lot.
It is possible to enter the MLE data manually or automatically depending on the instrument (refer to the Operator's Manual).

Calibration

Calibration, using the standard provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 28 days. This operation provides instrument-specific calibration information 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 the 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.**
2. Use one "SPT" strip and one "SPT" 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 "SPT" 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 and controls using a vortex-type mixer and then dispense **500 µl** into the sample well.
   Note: Do not heat the standard and controls.
5. For the heating step and for the transfer of the sample into the strip, refer to the procedure used.
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 results are obtained within approximately 48 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 from each sample is interpreted by the instruments as follows:

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

Thresholds and Interpretations

Test Value Threshold	Interpretation
< 0.25	Negative
≥ 0.25	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 less than the threshold value indicates that the sample does not contain *Salmonella* or contains *Salmonella* at a concentration below the detection limit.

A result with a test value greater than or equal to the threshold value indicates a sample contaminated with *Salmonella*. In this case, refer to the corresponding section “Confirmation of positive results”.

Invalid results are reported:
- when the background reading is above a pre-determined cut-off (indicating low-level substrate contamination).
  In this case, repeat the assay with the heated 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

A positive control and a negative control are included in each VIDAS® SPT kit.
These controls must be performed each time a new lot of reagents is received 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 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.

Caution

The VIDAS® SPT assay has been tested on a large number of products. Given the wide 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® SPT results.

The VIDAS® Heat and Go system has been evaluated on a large number of food matrices. Given the wide variety of food matrices and manufacturing procedures, when commissioning the system, it is recommended to verify that the heating step does not result in a substantial coagulation or precipitation of the sample in the sample well of the VIDAS® strip as this could lead to an incorrect volume of sample being taken into the SPR®.

PERFORMANCE

In the context of NF VALIDATION mark, the following results were obtained during the preliminary study:
- Inclusivity: 56 out of 57 *Salmonella* strains tested were detected.
- Relative detection level: the 50% detection limit is between 0.3 and 1.3 cells / 25 g for VIDAS® SPT and between 0.3 and 1.1 cells / 25 g for the EN ISO 6579 reference method (9).
- Comparative study: 379 samples were tested in parallel using VIDAS® SPT and the EN ISO 6579 method (9):
  - sensitivity of the VIDAS® SPT method: 96.8%
  - sensitivity of the EN ISO 6579 reference method (9): 96.3%

The performance data were obtained using bioMérieux culture media.

The VIDAS® UP Salmonella (SPT) method has been certified NF VALIDATION as an alternative method for the analysis of all human (excluding raw milk cheese) and animal food products and production environmental samples.
This validation has been obtained by comparison with the reference method described in the international standard EN ISO 6579 (9) according to the standard EN ISO 16140 (12).
The BIO - 12/32-10/11 validation certificate can be obtained from our Technical Assistance or from AFNOR Certification. The date of end of validity for the NF VALIDATION is indicated on the certificate.

BIO - 12/32-10/11
ALTERNATIVE ANALYTICAL METHODS FOR AGRIBUSINESS
Certified by AFNOR Certification
www.afnor-validation.org
www.afnor-validation.com

The VIDAS® UP Salmonella (SPT) method has been validated and certified by the AOAC Research Institute as a Performance Tested Method (Certificate N° 071101) for the detection of Salmonella in a variety of foods and environmental surfaces.

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE
LICENSE NUMBER 071101
PERFORMANCE TESTED METHOD
Certified by AOAC Research Institute
www.aoac.org

The following matrices were included in the AOAC validation: raw ground beef, deli roast beef, liquid eggs, powdered eggs, vanilla ice cream, instant nonfat dry milk, American processed cheese, bagged lettuce, peanut butter, black pepper, cooked shrimp, raw cod, dark chocolate, dry dog food, stainless steel (collected with a swab), plastic (collected with a sponge) and ceramic (collected with a swab).

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 as well as 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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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
	Manufacturer
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests

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