



## BSE/TSE STATEMENT

### To Whom it may concern

According to the documents below :

- Monograph of European Pharmacopoeia chapter 5.2.8 "*Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products*"
- "*Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products*" (EMA/410/01 Rev.3 – March 2011).
- FDA's Code of Federal Regulations Title 9 section 94.18

Quality Manager declares :

- That all products listed in appendix 1 contains materials derived from animals that comes from countries with negligible BSE risk according to OIE Resolution n° 18, 84<sup>th</sup> General Session, 22 - 27<sup>th</sup> may 2016,
- Certify that the processing facility of bioMérieux site doesn't receive, store or process any infectious bovine or ruminant material (except : gelatin, tallow derivatives, milk / milk products, hides, and / or vitamin D3 derived from sheep wool grease) originated from any affected BSE country.

bioMérieux would like to point out that the above mentioned product is intended for in vitro diagnostic use and/or for laboratory microbiological controls, and should not be used as manufacturing material (e.g. seed stock culture preparation, industrial scale fermentations, etc...), and that it is responsibility of our customers to validate and implement a cleaning procedure for their equipment after the use of this product.

Given this statement the Quality Manager hereby attest that all products manufactured on bioMérieux site present no risk of BSE/TSE to the final customer.

Validated date of this document : 3 years

Craponne, May 2017

ARMAND Héloïse  
Responsable Qualité BioMérieux Craponne



## DECLARATION ESB/EST

### Cette déclaration concerne :

Selon les documents ci-dessous :

- Monographie de la pharmacopée Européenne chapitre 5.2.8 « réduction du risque de transmission des agents des encéphalopathies spongiformes animales par les médicaments à usage humain et vétérinaire »
- "Note explicative concernant la réduction du risque de transmission des agents des encéphalopathies spongiformes animales par les médicaments à usage humain et vétérinaire » (EMA/410/01 Rev.3 – March 2011).
- FDA's Code of Federal Regulations Title 9 section 94.18

Le responsable Qualité :

- Déclare que tous les produits listé en annexe1 et qui contiennent des matières premières d'origine animale proviennent d'animaux de pays à risque négligeable d'ESB conformément à la résolution n° 18, 84ème Session générale, 22 -27 mai 2016,
- Certifie que les locaux de fabrication du site de bioMérieux ne reçoivent pas, ne stockent pas, ne mettent pas en œuvre de composants infectieux de bovins ou de ruminants (à l'exception : de la gélatine, des dérivés de suif, du lait/ produits laitiers, les cuirs et/ou vitamines D3 dérivées de la graisse de laine de mouton) provenant de pays où des cas d'ESB ont été déclarés.

BioMérieux souhaite préciser que les produits mentionnés en annexe 1 sont destinés à un usage de diagnostic in vitro et / ou à des laboratoires de contrôles microbiologiques, et ne doivent pas être utilisés comme matériau de fabrication (par exemple semences, préparation stock culture, fermentations à l'échelle industrielle, etc ...), et qu'il est de la responsabilité de nos clients de valider et de mettre en œuvre une procédure de nettoyage pour leurs équipements après l'utilisation de ce produit.

Suite à cette déclaration, le responsable qualité atteste que toute la production sur le site ne présente aucun risque de ESB/EST pour ses clients.

Date de validité du document : 3 ans

Craponne, mai 2017

ARMAND Héloïse  
Responsable Qualité bioMérieux Craponne



## ANNEXE 1

## BSE/TSE STATEMENT

| Product reference | Container | Product name                   |
|-------------------|-----------|--------------------------------|
| 41054             | Bottles   | LEGIONELLA AGAR BCYE 6X200ML   |
| 41146             | Bottles   | TRYPCASE SOY BROTH 6X100ML     |
| 41286             | Bottles   | COLUMBIA CNA AGAR 6X100ML      |
| 41314             | Bottles   | DRIGALSKI AGAR 6X200ML         |
| 41336             | Bottles   | E.M.B.(TEAGUE) AGAR 6X100ML    |
| 41466             | Bottles   | TRYPCASE SOY AGAR 6X200ML      |
| 41467             | Bottles   | TRYPCASE SOY AGAR 6X100ML      |
| 41536             | Bottles   | CHOCOLATE AGAR 6X100ML         |
| 41864             | Bottles   | MULLER HINTON 2 AGAR 6X200ML   |
| 41936             | Bottles   | SCHAEDLER AGAR 6X100ML PS      |
| 41995             | Bottles   | PORTAGERM 10VIALS              |
| 42018             | Tubes     | CLEAR-THIO 20 T                |
| 42031             | Tubes     | AGAR SAB GENTA CHLORAM 2 20 T  |
| 42037             | Tubes     | AGAR SABOURAUD 2 20 T          |
| 42038             | Tubes     | AGAR SABOURAUD CHLOR 2 20 T    |
| 42041             | Bottles   | PORTAGERM PYLORI 8VIALS        |
| 42044             | Bottles   | RINSING SOLUTION(0,1% PEPTONE) |
| 42066             | Bottles   | AGAR SABOURAUD 2 6X100         |
| 42067             | Bottles   | AGAR SAB CHLOR 2 6X100         |
| 42070             | Tubes     | ÉUGON LT 100 BOUILLON 20TUBES  |
| 42073             | Tubes     | RAPPAPORT VASILIDIS BROTH      |
| 42074             | Tubes     | THIOGLYCOLATE BROTH+RESAZURIN  |
| 42080             | Tubes     | MANNITOL SALT AGAR 20 TUBES    |
| 42081             | Tubes     | BRAIN-HEART INFUSION 20T       |
| 42082             | Tubes     | COLETSOS MEDIUM 20 TUBES       |
| 42083             | Tubes     | D-COCCOSEL AGAR 20 TUBES       |
| 42085             | Tubes     | PEPTONE WATER 20 TUBES         |
| 42086             | Tubes     | ESCULIN AGAR 20 TUBES          |
| 42089             | Tubes     | LOWENSTEIN-JENSEN MEDIUM 20T   |
| 42091             | Tubes     | RAPPAPORT BROTH 20 TUBES       |
| 42094             | Tubes     | SABOURAUD CHLOR.ACTID.AGAR 20T |
| 42097             | Tubes     | SCHAEDLER BROTH+0,02%AG+VK320T |
| 42098             | Tubes     | SCHAEDLER BROTH 0,2%+VK3 20T   |
| 42099             | Tubes     | SELENITE-F BROTH 20 TUBES      |



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|-------------------|-----------|---------------------------------------|
| 42100             | Tubes     | TRYPCASE SOYA BROTH 20TUBES           |
| 42101             | Tubes     | TRYPCASE SOYA AGAR 20TUBES            |
| 42103             | Tubes     | R:3 PHOSPH-BUFFER 20TUBES             |
| 42104             | Tubes     | R2 BENZAL-CHLOR. 20TUBESX10ML         |
| 42105             | Tubes     | PORTAGERM 20TUBES                     |
| 42106             | Tubes     | SCHAEDLER BROTH+VIT.K3 20T            |
| 42107             | Tubes     | LOWENSTEIN-JENSEN+TCH 20T             |
| 42108             | Tubes     | SABOURAUD LIQUID BROTH 20T            |
| 42110             | Tubes     | RVS BROTH 20TUBES                     |
| 42116             | Tubes     | TODD HEWITT BROTH + ATB               |
| 42605             | Bottles   | CHROMID 0157:H7 6X200ML               |
| 42608             | Bottles   | LACTOSE BROTH 6X90ML                  |
| 42609             | Bottles   | BUFFERED PEPT SOL PH7.0 6X90ML        |
| 42613             | Bottles   | EUGON LT100 BROTH 6X50ML              |
| 42614             | Bottles   | TRYPCASE SOY BROTH 6X90ML             |
| 42616             | Bottles   | RINSING SOL.(FLUIDA) 4X300ML          |
| 42620             | Bottles   | SABOURAUD DEXT CHLORAM 6*200ML        |
| 42621             | Bottles   | MOSEL BROTH 6*100ML                   |
| 42622             | Bottles   | MAC CONKEY BROTH 6*100ML              |
| 42623             | Bottles   | PEPTONE SOL. NEUTRALIZ. 6x90ML        |
| 42624             | Bottles   | FLUID D 4x300ML                       |
| 42630             | Bottles   | CHROMID 0157:H7 5X20 ML               |
| 42633             | Bottles   | TSB CLEAN ROOMS BOTTLES X6            |
| 42634             | Bottles   | CLEAR TIO CLEAN ROOMS BOTTLES 6x100ml |
| 42640             | Bottles   | FLUID A CLEAN ROOM BOTTLES X6         |
| 42641             | Bottles   | SABOURAUD DEXT AGAR 6X200 ML          |
| 42644             | Bottles   | FLUID D CLEAN ROOM BOTTLES X6         |
| 43001             | Plates    | TRYPCASE SOY AG.5% SH.BL.20 PL        |
| 43003             | Plates    | A7 AGAR MYCOPLASMA 10 PL              |
| 43004             | Plates    | CHROMID VRE ID AGAR 20 PLT            |
| 43009             | Plates    | TRYPCASE SOY AG+SH.BL. 100PLTE        |
| 43011             | Plates    | TRYPCASE SOY AGAR 20 PL               |
| 43013             | Plates    | LEGIONELLA BCYE WITH CYST. 10B        |
| 43019             | Plates    | GELOSE TRYPCASE-SOJA 100 PLA.         |



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| Product reference | Container | Product name                       |
|-------------------|-----------|------------------------------------|
| 43021             | Plates    | PURPLE LACTOSE AGAR 20 PL          |
| 43023             | Plates    | LEGIONELLA BCYE W/o CYST. 10B      |
| 43031             | Plates    | LEGIONELLA (GVPC) MEDIUM 20P       |
| 43032             | Plates    | LEGIONELLA GVPC MEDIUM 100 PLT     |
| 43041             | Plates    | COLUMBIA 5% SHEEP BL. 20 PLA.      |
| 43049             | Plates    | G.COLUMBIA 5%SG MOUTON 100 BOX     |
| 43050             | Plates    | COLUMBIA AGAR+5%HORSE BLOOD20P     |
| 43059             | Plates    | COLUMBIA+5% HORSE BLOOD 100BTE     |
| 43061             | Plates    | TRYPCASE SOY AG.5% HOR.BL20PLT     |
| 43071             | Plates    | COLUMBIA CNA 5% SHEEP BD 20PLT     |
| 43079             | Plates    | G.COLUMBIA CNA 5%SG MT 100PLAT     |
| 43081             | Plates    | EOSIN METHYLENE BL.AGAR 20PLT      |
| 43091             | Plates    | SALMONELLA SHIGELLA AGAR 20PLT     |
| 43099             | Plates    | G.SS 100BTES                       |
| 43101             | Plates    | CHOCOLATE AGAR+POLYVITEX 20PL.     |
| 43109             | Plates    | G.CHOCOLAT POLYVITEX 100PLATES     |
| 43111             | Plates    | HEKTOEN ENTERIC AGAR 20 PLT        |
| 43119             | Plates    | G.HEKTOEN 100BTES                  |
| 43141             | Plates    | MC CONKEY CRYSTAL VIOLET 20PLT     |
| 43149             | Plates    | GELOSE MAC CONKEY 100 PLATES       |
| 43151             | Plates    | D-COCCOSEL 20PLT                   |
| 43169             | Plates    | TSA 3P IRR 100 PLT                 |
| 43209             | Plates    | G.YERSINIA CIN 100BTES             |
| 43231             | Plates    | ENDO 20PLT                         |
| 43239             | Plates    | G.ENDO 100BTES                     |
| 43271             | Plates    | VRBGL AGAR 20 PLT                  |
| 43279             | Plates    | G.SCHAEDLER 5% SG MOUTON 100       |
| 43281             | Plates    | LT 100 20PLT                       |
| 43287             | Plates    | TSA 3P IRR BETALACTAMASE           |
| 43288             | Plates    | COUNTTACT 3P IRR BETALACTAMASE X20 |
| 43321             | Plates    | M.HINTON 2 SHEEP BLOOD 90 20PL     |
| 43329             | Plates    | MUELLER HINTON2+5% SH.BL. 100P     |
| 43331             | Plates    | CLED 20PLT                         |
| 43339             | Plates    | CLED AGAR 100 BTES                 |



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| Product reference | Container | Product name                   |
|-------------------|-----------|--------------------------------|
| 43341             | Plates    | DRIGALSKI 20PLT                |
| 43361             | Plates    | CAMPYLOSEL 20PLATES            |
| 43371             | Plates    | CHROMID S AUREUS 20 PLATES     |
| 43391             | Plates    | GELOSE CT SMAC 20 PLATES       |
| 43401             | Plates    | SCHAEDLER 5% SHEEP BLOOD AGAR  |
| 43411             | Plates    | GARDNERELLA AGAR 20 PLTS       |
| 43421             | Plates    | YERSINIA CIN AGAR 20 PLTS      |
| 43431             | Plates    | CLOSTRIDIUM D. AGAR 20 PLTS    |
| 43451             | Plates    | CHROMID MRSA 20 PLT            |
| 43459             | Plates    | CHROMID MRSA 100 PLT           |
| 43461             | Plates    | CHROMID STREPTO B 20 PLT       |
| 43462             | Plates    | CHROMID P.AERUGINOSA 20 PLATES |
| 43464             | Plates    | CHROMID CANDIDA SABOURAUD 20PL |
| 43465             | Plates    | CHROMID SALMONELLA HEKTOEN 20P |
| 43466             | Plates    | CHROMID MRSA S. AUREUS 20 PLT  |
| 43467             | Plates    | GRANADA/COL CNA AGAR           |
| 43470             | Plates    | CHROMID ESBL / CHROMID VRE     |
| 43471             | Plates    | CAMPYFOOD AGAR 20 PLATES       |
| 43474             | Plates    | MACCONKEY/COL CAN 20 PLATES    |
| 43481             | Plates    | CHROMID ESBL 20 PLT            |
| 43491             | Plates    | COUNT TACT IRRADIATED          |
| 43501             | Plates    | COUNT-TACT 20PLT               |
| 43551             | Plates    | R2A - GELOSE 20PLATES          |
| 43554             | Plates    | G.SABOURAUD GLUCOSE IRR        |
| 43555             | Plates    | SABOURAUD DEXTROSE AGAR        |
| 43556             | Plates    | TRYPCASE SOYA AGAR IRRAD.140MM |
| 43557             | Plates    | TSA IRRADIATED 90MM PLATE X100 |
| 43561             | Plates    | CHOCOL. HAEMOPHILUS AGAR 20 PL |
| 43562             | Plates    | TSA+NEUTRALISERS IRR.90MM 100P |
| 43563             | Plates    | XLD AGAR                       |
| 43564             | Plates    | XLD AGAR 100PLATES             |
| 43565             | Plates    | CETRIMIDE AGAR                 |
| 43580             | Plates    | SABOURAUD DEXTROSE CONTACT     |
| 43581             | Plates    | SABOURAUD DEXTROSE CONTACT IRR |



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| Product reference | Container | Product name                        |
|-------------------|-----------|-------------------------------------|
| 43582             | Plates    | TRYPCASE SOYA AGAR CONTACT          |
| 43595             | Plates    | SAB DEXT CHL IRRAD AGAR 20PLT       |
| 43596             | Plates    | SAB DEXTROSE CHL AGAR 20PLT         |
| 43601             | Plates    | BRILLANT GREEN AGAR 20PLATES        |
| 43611             | Plates    | CHOCOLATE AGR POLYVITEX VCAT3       |
| 43621             | Plates    | CHROMID SALMONELLA 20 PLATES        |
| 43629             | Plates    | CHROMID SALMONELLA 100 PLATES       |
| 43631             | Plates    | CHROMID CANDIDA 20 PLATES           |
| 43639             | Plates    | CHROMID CANDIDA 100 PLATES          |
| 43651             | Plates    | SABOURAUD GENTA.CHLOR 2 20 PLT      |
| 43659             | Plates    | SABOURAUD GENTA.CHLOR 2 100PLT      |
| 43661             | Plates    | CHROMID LMONO 20 PLTS               |
| 43671             | Plates    | CHAPMAN 2 MEDIUM 20 PLATES          |
| 43681             | Plates    | CHOCOLAT HAEMOPH. 2 MEDIUM 20P      |
| 43689             | Plates    | CHOCOLAT HAEMOPH.2 MEDIUM 100P      |
| 43691             | Plates    | COUNT-TACT IRR 3P X20               |
| 43699             | Plates    | COUNT-TACT IRR 3P X100              |
| 43711             | Plates    | TSA 3P IRR 20 PLATES                |
| 43741             | Plates    | CHROM ID SAKAZAKII 20 PLATES        |
| 43761             | Plates    | CHROM ID VIBRIO 20 PLATES           |
| 43762             | Plates    | CHROMID VIBRIO CE AGAR 20 PLT       |
| 43811             | Plates    | TSA 3P IRR NEUTRALIZERS X20         |
| 43812             | Plates    | CT SAB DEX 3P IRR NEUTRALIZERS      |
| 43814             | Plates    | SAB DEX 3P IRR NEUTRALIZERS         |
| 43819             | Plates    | TSA 3P IRR NEUTRALIZERS X100        |
| 43831             | Plates    | LEGIONELLA MWY AGAR                 |
| 43841             | Plates    | CHROMID MRSA 20 PLT US              |
| 43851             | Plates    | CHROMID VRE 20 PLT US               |
| 43861             | Plates    | CHROMID CARBA AGAR 20 PLT           |
| 43871             | Plates    | CHROMID C.DIFFICILE 20 PLT          |
| 43901             | Plates    | M.HINTON HORSE BLOOD NADX20PLT      |
| 43904             | Plates    | M.HINTON HORSE BLD NAD 120X120 20PL |
| 43919             | Plates    | M.HINTON HORSE BLD NADX100BTS       |
| 44001             | Bottles   | THIOGLYCOLATE BROTH 12 BOTTLES      |



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| Product reference | Container         | Product name                   |
|-------------------|-------------------|--------------------------------|
| 44011             | Bottles           | TRYPCASE SOY BROTH 12 BOTTLES  |
| 44021             | Bottles           | CLEAR-THIO 12 FL               |
| 51009             | Dehydrated medium | BRAIN HEART INFUSION 500G      |
| 51015             | Dehydrated medium | MAC CONKEY BROTH 500G          |
| 51018             | Dehydrated medium | THIOGLYCOLLATE BROTH RES.500G  |
| 51019             | Dehydrated medium | TRYPCASE-SOY BROTH 500G        |
| 51020             | Dehydrated medium | AGAR SABOURAUD 2 500G          |
| 51021             | Dehydrated medium | AGAR SABOURAUD CHLOR 2 500G    |
| 51025             | Dehydrated medium | D-COCCOSEL AGAR 500G           |
| 51026             | Dehydrated medium | COLUMBIA AGAR 500G             |
| 51033             | Dehydrated medium | EOSIN METHYLENE BLUE AG. 500G  |
| 51035             | Dehydrated medium | PURPLE LACTOSE AGAR 500G       |
| 51036             | Dehydrated medium | MACCONKEY AG WITHOUT CVIO500G  |
| 51039             | Dehydrated medium | BLOOD AGAR BASE 500G           |
| 51043             | Dehydrated medium | SALMONELLA SHIGELLA AGAR 500G  |
| 51044             | Dehydrated medium | TRYPCASE-SOY AGAR 500G         |
| 51047             | Dehydrated medium | TRIPLE SUGAR IRON AGAR 500G    |
| 51049             | Dehydrated medium | XLD AGAR 500G                  |
| 51050             | Dehydrated medium | HEKTOEN ENTERIC AGAR 500G      |
| 51052             | Dehydrated medium | CLED AGAR 500G                 |
| 51053             | Dehydrated medium | MANNITOL SALT AGAR 500G        |
| 51072             | Dehydrated medium | STANDARD METHODS AGAR 500G     |
| 51075             | Dehydrated medium | MUELLER HINTON 2 AGAR 500G     |
| 51101             | Dehydrated medium | IRR TSB ANI PEPT 3P MFT 5KG    |
| 51102             | Dehydrated medium | IRR TSB ANI PEPT 3P MFT 500G   |
| 51103             | Dehydrated medium | IRRADIATED TSB 3P VP+CI 5KG    |
| 51104             | Dehydrated medium | IRRADIATED TSB 3P VP+CI 500G   |
| 51140             | Dehydrated medium | TRYPCASE SOY BROTH 5 KG PS     |
| 51280             | Dehydrated medium | COLUMBIA AGAR BASE 5 KG PS     |
| 410782            | Dehydrated medium | IRRADIATED TSB 3P VP 5KG       |
| 410783            | Dehydrated medium | IRRADIATED TSB 3P VP 500G      |
| 410927            | Plates            | CT3P+ENHANCED NEUTRALIZER X20  |
| 410928            | Plates            | TSA3P+ENHANCED NEUTRALIZER X20 |
| 410974            | Plates            | CT3P+ENHANCED NEUTRALIZER X100 |



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| Product reference | Container         | Product name                           |
|-------------------|-------------------|--|
| 411968            | Plates            | BRUCELLA BLOOD AGAR 20 PLT             |
| 412108            | Plates            | CHROMID SALMONELLA ELITE 20 PLTS       |
| 413050            | Plates            | CHROMID MRSA SMART 20 PLATES           |
| 413051            | Plates            | CHROMID MRSA SMART 100 PLATES          |
| 413093            | Bottles           | CHROMID EHEC 5X20ML                    |
| 413193            | Plates            | GELOSE PYLORI 20 PLT                   |
| 413194            | Plates            | SCHAEDLER NEO.VANC.5%SB 20PLT          |
| 413697            | Bottles           | CHROMID EHEC 6X200ML                   |
| 413822            | Plates            | MUELLER HINTON E AGAR 90 20PL          |
| 413823            | Plates            | MUELLER HINTON E AGAR 145 20P          |
| 413824            | Plates            | MUELLER HINTON E AGAR 90 100PL         |
| 413825            | Plates            | M HINTON E AGAR 120X120 20PL           |
| 414011            | Plates            | CHROMID OXA 48 20 PLTS                 |
| 414012            | Plates            | CHROMID CARBA US 20 PLTS               |
| 414524            | Plates            | CHROMID MRSA S. AUREUS US              |
| 414685            | Plates            | CHROMID CARBA SMART                    |
| 416172            | Plates            | CHROMID CPS ELITE TRANSLUCENT 100 PLT  |
| 416173            | Plates            | CHROMID CPS ELITE OPAQUE AGAR 100 PLTS |
| 418206            | Plates            | CHROMID CPS ELITE OPAQUE 20 PT         |
| 418229            | Plates            | CHROMID CPS ELITE / COL CNA            |
| 418284            | Plates            | CHROMID CPS ELITE TRANSLUCEN 20 PLT    |
| 419042            | Plates            | CHROMID S.AUREUS ELITE 20 PL           |
| 419751            | Plates            | CHROMID STREPTO B US 20 PLT            |
| 420984            | Dehydrated medium | LPT Broth (LPT-D) 500G                 |
| 420985            | Dehydrated medium | LPT Broth (LPT-D) 5KG                  |