



## Customer letter for Clinical customer

To the Laboratory Manager  
To the attention of the Healthcare center Chairman  
To the attention of the Reactovigilance correspondent

Address  
City, Date

<b>Our reference:</b>	chromID Salmonella Agar (ref. 43621) Lots #1002234210 and #1002300040
<b>IMPORTANT:</b>	Field Safety Notice

Dear Valued bioMérieux Customer,

You are a user of chromID Salmonella Agar (ref. 43621), and we thank you for choosing bioMérieux solutions. Our records indicate that you have received the following batches:

Reference	Batch	Expiry date
43621	1002234210	03-SEP-2013
	1002300040	01-OCT-2013

### Description of Issue:

bioMérieux has registered some complaints for non-characteristic color colonies of Salmonella on chromID Salmonella that could lead to non-detection of Salmonella. Salmonella strains grow on the medium without given the characteristic color of colonies as described in the package insert: the Salmonella colonies are white (instead of pale pink to mauve).

The investigations performed by our Quality Control Laboratory have confirmed that the microbiologic performances of a part of these batches are not conform to the product specifications. The investigations are still on-going in order to determine the root cause. According to this information, we cannot guarantee the characteristic coloration (from pale pink to mauve) of the Salmonella colonies.

### Impact to customer:

The chromID Salmonella agar can be used alone after an enrichment broth or directly from stool specimens. The potential risk is to have a false negative result for Salmonella.

However, in case of clinical symptoms, a symptomatic treatment based on rehydration + glucose and electrolytes (oral or parenteral) will be implemented. Antibiotics are only prescribed in more severe Salmonella cases.

If clinical signs of infection are present, the treatment could even be prescribed on an empiric way, before microbiology result being available. The diagnostic evaluation is coupled with the clinician's independent judgment and additional information (patient demographics, medical history, patient status, symptoms, and other tests performed by the clinician ...).

The package insert described some "Warning and precautions": " interpretation of the test results should be made taking into consideration the patient's history, clinical status of the patient (symptoms), the source of the specimen, colonial and microscopic morphology and, if necessary, the results of any other tests performed".



Additionally, as described in the paragraph "Limitation of methods" of the package insert, "depending on the specimens analyzed, it is recommended to use chromID Salmonella agar in conjunction with additional media intended for fecal culture (such as Campyloset, Yersinia, Clostridium difficile agars).

**Required actions:**

As a consequence, we ask you to:

1. Ensure this letter and guidance has been distributed and reviewed by all appropriate personnel within your organization.
2. If you are still in possession of some kits of chromID Salmonella (ref. 43621), batches 1002234210 and/or 1002300040, discontinue to use them and destroy the kits. Contact your local bioMérieux representative for product replacement.
3. Fill out and return the Acknowledgement Form by fax for product replacement. Enter Local Contact: XXXXX.
- 4 Consider the need to review patient results given with the 2 concerned batches and to investigate further (e.g. final diagnosis and clinical status of the patient) if you suspect that that an erroneous result may have occurred.

bioMérieux is committed to providing our customers with the highest quality product possible, and we sincerely apologize for any inconvenience this issue may cause your laboratory. Should you need any additional information, please, feel free to contact our Customer Relation Center.

Yours sincerely,  
Customer Service



## ACKNOWLEDGEMENT FORM - DESTRUCTION CERTIFICATE

TO BE RETURNED TO YOUR CUSTOMER SERVICE

fax : .....

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux letter informing about a non-detection of Salmonella on chromID Salmonella Agar - **Reference 43621 – batches (see below)** and that I have to destroy the kits still in my stock.

Product : chromID Salmonella Agar (ref. 43621) Batches #1002234210 and #1002300040	
Reference 43621 – Lot 1002234210	Number of kits destroyed _____
Reference 43621 – Lot 1002300040	Number of kits destroyed _____

DATE .....

SIGNATURE : .....



## Customer letter for Industrial customer

Address  
City, Date

Our reference: chromID Salmonella Agar (ref. 43621)  
Lots #1002234210 and #1002300040

**IMPORTANT:** Field Safety Notice

Dear Valued bioMérieux Customer,

You are a user of chromID Salmonella Agar (ref. 43621), and we thank you for choosing bioMérieux solutions. Our records indicate that you have received the following batches:

Reference	Batch	Expiry date
43621	1002234210	03-SEP-2013
	1002300040	01-OCT-2013

### Description of Issue:

bioMérieux has registered some complaints for non-characteristic color colonies of *Salmonella* on chromID Salmonella that could lead to non-detection of *Salmonella*. *Salmonella* strains grow on the medium without given the characteristic color of colonies as described in the package insert: the *Salmonella* colonies are white (instead of pale pink to mauve).

The investigations performed by our Quality Control Laboratory have confirmed that the microbiologic performances of a part of these batches are not conform to the product specifications. The investigations are still on-going in order to determine the root cause. According to this information, we cannot guarantee the characteristic coloration (from pale pink to mauve) of the *Salmonella* colonies.

### Impact to customer:

**For food customers:** The risk is to have a false negative result could lead to a non-detection of contaminated food by *Salmonella*. Two methods can be used to detect the *Salmonella*.

### Traditional method:

According to the standard NF EN ISO 6579, the use of chromID Salmonella agar has to be performed in parallel with XLD agar after pre-enrichment in buffered peptone water, followed by enrichment in broth. So, if the users have discordant results from XLD medium (typical growth of *Salmonella*) and chromID Salmonella agar (no typical growth of *Salmonella*), additional investigations should be performed before giving the results for the food product tested. So the risk is defined as minor.

### VIDAS method:

In the case where the VIDAS method is performed, two kind of VIDAS products can be used:

- VIDAS Qualitative tests:

ChromID Salmonella is one of the possible culture media recommended to confirm a positive detection of *Salmonella* with VIDAS. In this case if the chromID Salmonella result is negative, additional investigations should be performed before giving the result for the food product tested. So the risk is defined as minor.

- VIDAS for selective enrichment of salmonella:

if the Immuno-Concentration Salmonella II test (VIDAS ICS2 reference 30708) is used, the detection of *Salmonella* can be done using chromID Salmonella agar only. In addition, there is no requirement to carry out systematically another medium in parallel or to use a confirmation method that would detect the sensitivity issue on chromID Salmonella. All isolated colonies on chromID Salmonella are not systematically identified by biochemical and/or immunological tests. So the risk is defined as major.

[Enter Local Contact Address and telephone]

[www.biomerieux.com](http://www.biomerieux.com)



**For use in pharmaceutical industry:**

The use of chromID Salmonella agar for the control of pharmaceutical products is not claimed in the package insert of the product reference 43621. Also, as you have received at least one of two batches, we ask you to implement corrective actions described below and to evaluate the risk based on your laboratory practices.

**Required actions:**

As a consequence, we ask you to:

1. Ensure this letter and guidance has been distributed and reviewed by all appropriate personnel within your organization.
2. If you are still in possession of some kits of chromID Salmonella (ref. 43621), batches 1002234210 and/or 1002300040 discontinue to use them and destroy the kits. Contact your local bioMérieux representative for product replacement.
3. Fill out and return the Acknowledgement Form by fax for product replacement. Enter Local Contact: XXXXX
4. Consider the need to review results given with the two concerned batches (notably in case of use of the protocol VIDAS ICS2 + ChromID Salmonella) and to investigate further if you suspect that an erroneous result may have occurred.

bioMérieux is committed to providing our customers with the highest quality product possible, and we sincerely apologize for any inconvenience this issue may cause your laboratory. Should you need any additional information, please, feel free to contact our Customer Relation Center.

Yours sincerely,  
Customer Service



## ACKNOWLEDGEMENT FORM - DESTRUCTION CERTIFICATE

TO BE RETURNED TO YOUR CUSTOMER SERVICE

fax : .....

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux letter informing about a non-detection of Salmonella on chromID Salmonella Agar - **Reference 43621 – batches (see below)** and that I have to destroy the kits still in my stock.

Product : chromID Salmonella Agar (ref. 43621) Batches #1002234210 and #1002300040	
Reference 43621 – Lot 1002234210	Number of kits destroyed _____
Reference 43621 – Lot 1002300040	Number of kits destroyed _____

DATE.....

SIGNATURE :.....