



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

Address
City, Date

Mueller Hinton 2 Agar
References :
43301, 43302, 43309, 43511, 41864, 51075
All lots.
IMPORTANT: Field Safety Notice

Dear Madam, Dear Sir,
bioMérieux's records indicate that you use our products Mueller Hinton 2 Agar media and we thank you for choosing bioMérieux solution. We would like to inform you that we have observed a possible non-detection of low level methicillin-resistant *Staphylococcus aureus* (MRSA) with cefoxitin disk and the Mueller Hinton 2 agar – references:

Part Number	Media Description
43301	Mueller Hinton 2 (2X10 plates 90 mm)
43302	Mueller Hinton 2 (4X5 plates 145 mm)
43309	Mueller Hinton 2 (10X10 plates 90 mm)
43511	Mueller Hinton 2 (4X5 plates 120X120 mm)
41864	Mueller Hinton 2 (6X200 ml bottles)
51075	Mueller Hinton 2 (Dehydrated medium)

Description of Issue

Mueller Hinton 2 agar is intended for antimicrobial susceptibility testing by disc diffusion. The composition enables the growth of non-fastidious bacteria (*Enterobacteriaceae*, non-fermenting Gram (-) bacilli, *Staphylococci* and *Enterococci*) found in pathology. However, internal studies have shown that some strains of *Staphylococcus aureus* with a low level resistance to methicillin may be not detected when tested on Mueller Hinton 2 by using a cefoxitin disk and whatever the standards used.

In parallel, facing to a change in the epidemiology and in the implementation of new standard, bioMérieux has developed a Mueller Hinton E (MHE) medium which is EUCAST and CLSI compliant. This new medium allows MRSA detection even for the isolates expressing resistance at low level and whatever the genotype is (*mecA* or *mecC*). Therefore, based on our internal studies, we strongly advise you to use Mueller Hinton E in replacement of Mueller Hinton 2 agar.

The following Mueller Hinton E References are already available:

Part Number	Media Description
413 822	Mueller Hinton E (2X10 plates 90 mm)
413 823	Mueller Hinton E (4X5 plates 145 mm)
413 824	Mueller Hinton E (10X10 plates 90 mm)
413 825	Mueller Hinton E (4X5 plates 120X120 mm)

In the case you would not being able to use the Mueller Hinton E and if you are using the CA-SFM 2013 guidelines for MRSA detection, we ask you to test by an alternative method all the isolates that have a cefoxitin inhibition zone falling between 25 and 29 mm. If the inhibition zone is ≥ 30 mm, you do not need to confirm with other tests.

In the case you are using the EUCAST or the CLSI standard, we ask you not to use Mueller Hinton 2 agar anymore for MRSA detection purpose.



Impact

Based on the bioMérieux Health Risk Assessment, the two potential risks associated to this issue are:

1. Susceptibility testing of a clinical isolate (diagnosis of infection).

The non-detection of MRSA corresponds to a false sensitive result for the given antibiotic. Then, the risk is to prescribe an antibiotic that will not be efficient (inappropriate treatment) and to delay the correct treatment.

2. Confirmation of methicillin resistance when MRSA has been isolated during a screening process.

This is a confirmation of a positive screening test. So, a false negative test will alert the microbiologist and will lead to additional testing because the false sensible result (obtained with the Mueller Hinton 2 medium) will be in discordant with the first screening positive result (usually obtained with a screening medium as chromID MRSA).

Actions

Please complete the following actions:

1. Take immediately into account the reported issue described above as soon as you receive this customer letter and each time, you use the Mueller Hinton 2 Agar- References: 43301, 43302, 43309, 43511, 41864, 51075.
2. Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
3. If you wish to have more information on tests done by our quality department lab or the Mueller Hinton E, please contact your local bioMérieux Customer Service representative. (Phone number:xxxxx)
4. In addition, we recommend that you discuss with the Laboratory Director to evaluate the impact and determine if any retrospective analysis of results is required.
5. Please complete and return the Attachment A: Acknowledgement Form to your local bioMérieux Customer Service representative. (FAX number: xxxxx)

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours sincerely,

Customer Service



Attachment A: Acknowledgement Form

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 possible non-detection of resistance to ceftazidime in methicillin-resistant *Staphylococcus aureus* , low level of resistance (*MRSA mecA* gene) with the Mueller Hinton 2 agar by using a ceftazidime disk and whatever the standards used – references:

Part Number	Media Description
43301	Mueller Hinton 2 (2X10 plates 90 mm)
43302	Mueller Hinton 2 (4X5 plates 145 mm)
43309	Mueller Hinton 2 (10X10 plates 90 mm)
43511	Mueller Hinton 2 (4X5 plates 120X120 mm)
41864	Mueller Hinton 2 (6X200 ml bottles)
51075	Mueller Hinton 2 (Dehydrated medium)

DATE.....

SIGNATURE :.....

Table 2:

Product name	Reference	Lot number	Expiry date	Manufacturing date	Distribution Beginning Date	Distribution End Date
Mueller Hinton 2 (120X120 mm)	43511	1002907630	09-APR-2014	29-JAN-2014	03-FEB-2014	07-MAR-2014
		1002912150	11-APR-2014	31-JAN-2014	03-MAR-2014	10-MAR-2014
		1002941530	24-APR-2014	13-FEB-2014	04-MAR-2014	11-MAR-2014
		1002955540	01-MAY-2014	20-FEB-2014	28-FEB-2014	28-FEB-2014
		1002965240	05-MAY-2014	24-FEB-2014	13-MAR-2014	13-MAR-2014
Mueller Hinton 2 (2X10 plates 90 mm)	43301	22881	12-APR-2014	21-DEC-2013	13-JAN-2014	30-JAN-2014
		22970	24-APR-2014	02-JAN-2014	22-JAN-2014	04-FEB-2014
		22995	25-APR-2014	03-JAN-2014	07-FEB-2014	18-FEB-2014
		23099	07-MAY-2014	15-JAN-2014	31-JAN-2014	10-FEB-2014
		23228	16-MAY-2014	24-JAN-2014	06-FEB-2014	18-FEB-2014
		23305	23-MAY-2014	31-JAN-2014	06-FEB-2014	28-FEB-2014
		23374	29-MAY-2014	06-FEB-2014	21-FEB-2014	07-MAR-2014
		23385	30-MAY-2014	07-FEB-2014	19-FEB-2014	05-MAR-2014
		23448	05-JUN-2014	13-FEB-2014	20-FEB-2014	12-MAR-2014
		23460	06-JUN-2014	14-FEB-2014	07-MAR-2014	12-MAR-2014
		23540	13-JUN-2014	21-FEB-2014	07-MAR-2014	12-MAR-2014
		23576	17-JUN-2014	25-FEB-2014	05-MAR-2014	05-MAR-2014
Mueller Hinton 2 (10X10 plates 90 mm)	43309	22818	09-APR-2014	182-DEC-2013	03-JAN-2014	13-FEB-2014
		22872	11-APR-2014	20-DEC-2013	15-JAN-2014	15-JAN-2014
		22879	12-APR-2014	21-DEC-2013	10-JAN-2014	17-JAN-2014
		22892	14-APR-2014	23-DEC-2013	17-JAN-2014	24-JAN-2014
		22941	21-APR-2014	30-DEC-2013	23-JAN-2014	05-FEB-2014
		22996	29-APR-2014	07-JAN-2014	03-FEB-2014	12-MAR-2014
		23154	12-MAY-2014	20-JAN-2014	31-JAN-2014	07-MAR-2014
		23302	23-MAY-2014	31-JAN-2014	19-FEB-2014	21-FEB-2014
		23314	26-MAY-2014	03-FEB-2014	14-FEB-2014	28-FEB-2014
		23473	09-JUN-2014	17-FEB-2014	05-MAR-2014	12-MAR-2014
Mueller Hinton 2 (4X5 plates 145 mm)	43302	1002901840	08-APR-2014	28-JAN-2014	13-FEB-2014	28-FEB-2014
		1002919110	15-APR-2014	04-FEB-2014	26-FEB-2014	12-MAR-2014
		1002942910	24-APR-2014	13-FEB-2014	26-FEB-2014	12-MAR-2014
		1002947480	01-MAY-2014	20-FEB-2014	13-MAR-2014	13-MAR-2014
Mueller Hinton 2 (6X200 ml bottles)	41864	1001763360	12-MAY-2014	21-NOV-2012	30-NOV-2012	08-APR-2013
		1002104500	31-AUG-2014	08-MAR-2013	03-APR-2013	19-JUL-2013
		1002309490	17-NOV-2014	27-MAY-2013	15-JUL-2013	13-FEB-2014
		1002555220	25-FEB-2015	04-SEPT-2013	26-SEPT-2013	27-NOV-2013
		1002555230	25-FEB-2015	04-SEPT-2013	26-SEPT-2013	26-SEPT-2013
		1002680470	19-APR-2015	22-OCT-2013	21-NOV-2013	13-MAR-2014
Mueller Hinton 2 Dehydrated medium	51075	1000094440	22-NOV-2014	21-JAN-2011	28-JAN-2011	15-JUL-2011
		1000171100	22-NOV-2014	16-FEB-2011	24-FEB-2011	16-AUG-2011
		1000280580	22-NOV-2014	30-MAR-2011	05-APR-2011	25-JUL-2011
		1000475240	09-AUG-2014	13-JUN-2011	23-JUN-2011	30-JUN-2011
		1000487960	30-MAR-2015	23-JUN-2011	09-AUG-2011	7-NOV-2011

Product name	Reference	Lot number	Expiry date	Manufacturing date	Distribution Beginning Date	Distribution End Date
		1000645000	03-MAR-2015	30-AUG-2011	05-SEPT-2011	29-NOV-2011
		1000824280	30-MAR-2015	09-NOV-2011	24-NOV-2011	21-DEC-2011
		1000887970	26-OCT-2015	02-DEC-2011	12-DEC-2011	13-APR-20 12
		1000942800	26-OCT-2015	29-DEC-2011	12-JAN-2012	5-APR-2012
		1001138550	10-FEB-2016	20-MAR-2012	29-MAR-2012	29-JUN-2012
		1001263950	10-FEB-2016	18-APR-2012	25-APR-2012	23-JUL-2012
		1001304110	26-OCT-2015	31-MAY-2012	11-JUN-2012	02-JUL-2012
		1001304120	10-FEB-2016	01-JUN-2012	16-JUL-2012	16-JUL-2012
		1001432680	16-APR-2016	09-JUL-2012	18-JUL-2012	03-JAN-2013
		1001536130	16-APR-2016	02-AUG-2012	20-AUG-2012	17-DEC-2012
		1001686430	16-APR-2016	01-OCT-2012	10-OCT-2012	28-DEC-2012
		1001778240	12-OCT-2016	06-NOV-2012	17-DEC-2012	13-MAY-2013
		1001922580	12-OCT-2016	08-JAN-2013	28-FEB-2013	26-APR- 2013
		1002059400	18-DEC-2016	18-FEB-2013	15-APR-2013	29-NOV-2013
		1002201900	18-DEC-2016	18-APR-2013	10-JUL-2013	31-OCT- 2013
		1002416600	26-MAY-2017	23-JUL-2013	01-OCT-2013	13-MAR-2014
		867188701	09-AUG-2014	08-DEC-2010	07-JAN-2011	10-FEB-2011