

chromID™ MRSA agar (MRSA)

IVD

Chromogenic medium for the screening of methicillin-resistant *Staphylococcus aureus* (MRSA)

SUMMARY AND EXPLANATION

chromID™ MRSA agar is a chromogenic medium for the screening of methicillin-resistant *S. aureus* (MRSA) in chronic carriers or patients who are at risk for MRSA. This medium does not replace conventional antimicrobial susceptibility tests.

MRSA are multi-resistant bacteria which may cause nosocomial infections (1, 2). The detection of MRSA carriers is particularly important for the epidemiological prevention and monitoring of these infections. In this context, the use of chromID™ MRSA agar contributes towards the active surveillance of MRSA.

PRINCIPLE

chromID™ MRSA agar consists of a rich nutritive base combining different peptones. It also contains chromogenic α-glucosidase substrates and a combination of several antibiotics (patent registered), which favor:

- the growth of methicillin-resistant staphylococci (MRSA) including hetero-resistant strains.
- the direct detection of MRSA strains by revealing α-glucosidase activity (patent registered): blue-green colonies.

The selective mixture inhibits most Gram-negative and Gram-positive bacteria not belonging to the genus *Staphylococcus*, as well as yeasts and molds.

CONTENT OF THE KIT

Ready-to-use media:	
REF 43 472	Pack of 2x10 plates (90 mm)
REF 43 479	Pack of 10x10 plates (90 mm) MRSA *

* printed on each plate

COMPOSITION

Theoretical formula:

This medium can be adjusted and/or supplemented according to the performance criteria required.

Plant and animal peptones (porcine or bovine).....	20.1 g
Tris	0.65 g
Chromogenic mixture.....	0.125 g
Selective mixture	20 ml
Agar.....	13 g
Purified water.....	1 l

pH 7.3

MATERIAL REQUIRED BUT NOT PROVIDED

- Bacteriology incubator.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only.

- 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).
- All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. Refer to "CLSI® M29-A, Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Current Revision". For additional information on handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories – CDC/NIH – Latest edition", or the current regulations in the country of use.
- Culture media should not be used as manufacturing material or components.
- Do not use reagents after the expiry date.
- Do not use reagents if the packaging is damaged.
- Do not use contaminated plates or plates that exude moisture.
- The use of this medium may be difficult for people who have problems recognizing colors.
- The performance data were obtained using the procedure and the 35-37°C incubation temperature indicated in this package insert. Any change or modification in the procedure may affect the results and should be validated beforehand by the user.
- Interpretation of test results should be made taking into consideration colonial and microscopic morphology and, if necessary, the results of any other tests performed.

STORAGE CONDITIONS

- Store the plates in their box at 2-8°C until the expiry date.
- If not in the box, plates can be stored in the cellophane sachet for 2 weeks at 2-8°C in the dark.

SPECIMENS

Different types of specimens may be used: nose, throat, skin (perineum, wound, groin).

Notes: It is recommended to use swabs (preferably flocked) with liquid transport medium to optimize rapidity of response time and sensitivity for MRSA detection.

If dry swabs are used (preferably flocked), inoculation must be performed as rapidly as possible (within 18 hours).

Good laboratory practices for collection and transport should be respected and adapted to each type of specimen.

INSTRUCTIONS FOR USE

The medium must not be exposed to light other than during the inoculation and reading steps.

1. Allow the plates to come to room temperature.
2. Inoculate the specimens directly onto the chromID™ MRSA agar.
3. Incubate the plates inverted at 35-37°C in aerobic conditions. The cultures are generally examined after 18 and/or 24 hours of incubation.
A positive result may be obtained after 18 hours of incubation, however if a negative result is obtained (no growth or coloration) incubation must be extended to 24 hours.

READING AND INTERPRETATION

After incubation, observe the bacterial growth and the appearance of colonies. Methicillin-resistant α -glucosidase-producing *Staphylococcus aureus* strains produce the following characteristic colors:

Incubation time	Characteristic color
18 ± 1 h	Small white colonies with green sheen * Pale blue-green * Blue-green Dark blue-green
24 ± 1h	Blue-green Dark blue-green

* After 24h ± 1h, these colors are not characteristic of MRSA.

The presence of at least one colony with a characteristic color identified as MRSA gives the sample a positive status.

After 18-24 hours of incubation, microbiological, biochemical or immunological tests can be performed to confirm the identification of *S. aureus* and thus improve the specificity of the medium.

QUALITY CONTROL

Protocol:

The nutrient capacity of the medium can be tested using the following strains:

- *Staphylococcus aureus* ATCC® 43300
- *Staphylococcus aureus* ATCC® 29213

Range of expected results:

Strain	Results at 33-37°C	
<i>Staphylococcus aureus</i> ATCC® 43300	Growth within 18 hours	Pale blue-green colonies with possibility of isolated white colonies
	Growth within 24 hours	Blue-green colonies
<i>Staphylococcus aureus</i> ATCC® 29213	No growth within 24 hours	

Note:

It is the responsibility of the user to perform Quality Control taking into consideration the intended use of the medium, and in accordance with any local applicable regulations (frequency, number of strains, incubation temperature, etc.).

LIMITATIONS OF THE METHOD

- Certain strains of *S. aureus* that possess the *mec A* gene but have a low MIC in relation to the antibiotics in the medium, may not develop on this type of medium.
- Rare strains of *S. aureus* that do not possess the *mec A* gene may develop characteristic colonies.
- Certain coagulase-negative staphylococci may produce characteristic colors.
- Some organisms other than staphylococci may produce colonies with a characteristic color. The difference in appearance of these colonies enables them to be differentiated from MRSA.
- If an antimicrobial susceptibility test is to be performed, it is recommended to use a subculture on a suitable non-selective medium.

PERFORMANCE

Performance was evaluated at 3 sites, France, Belgium and the United Kingdom, using 1 470 human specimens. Three different types of swabs were used: dry flocked swab, flocked swab with transport medium and cotton swab with transport medium.

The media were incubated at 35-37°C.

The sensitivity and specificity were evaluated after 18 ± 1h and 24 ± 1h of incubation for chromID™ MRSA agar (ref. 43472) in comparison with chromID™ MRSA agar (ref. 43451) incubated at 24 ± 1h and 48 ± 2h.

	No. of samples tested per specimen type			TOTAL
	Nose	Throat	Skin	
Positive	56	41	44 *	141
Negative	672	330	327	1329
TOTAL	728	371	371 **	1470

* 20 perineum, 17 groin, 6 wound, 1 axilla

** 114 perineum, 246 groin, 9 wound, 2 axilla

Sensitivity of detection (all specimen types taken into account - 95% confidence interval)

	chromID MRSA – Ref. 43472	chromID MRSA Ref. 43451
18 h	113/141 80.1% [72.6 – 86.4]	
24 h	125/141 88.7% [82.2 – 93.4]	114/141 80.9% [73.4 – 87]
48 h		127/141 90.1% [83.9 – 94.5]

Specificity of color (all specimen types taken into account - 95% confidence interval)

	chromID MRSA – Ref. 43472	chromID MRSA Ref. 43451
18 h	1290/1329 97.1% [96.01 – 97.91]	
24 h	1290/1329 97.1% [96 – 97.9]	1292/1329 97.2% [96.2 – 98]
48 h		1282/1329 96.5% [95.3 – 97.4]

Note: Performance may fluctuate according to local epidemiology.

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

1. LELIEVRE H., LINA G., JONES M. E. et al. - Emergence and spread in French hospitals of methicillin-resistant *Staphylococcus aureus* with increasing susceptibility to gentamicin and other antibiotics. – *J. Clin. Microbiol.*, Nov. 1999, vol. 37, n°11, p. 3452-3457
2. MUTO C.A., JERNIGAN J.A., OSTROWSKY B.E. et al. – Guideline for preventing nosocomial transmission of multidrug-resistant strains of *Staphylococcus aureus* and *Enterococcus*. *Infect. Control. Hosp. Epidemiol.*, May 2003, Vol. 24, p. 362-386.
3. PETERSON L., DIEKEMA D. – Point - Counterpoint : To screen or not to screen for MRSA – *J. Clin. Microbiol.*, Mar. 2010, vol. 48, n°3, p. 683-689.
4. CREAMER E. et al. – The effect of rapid screening for MRSA on the identification and earlier isolation of MRSA positive patients – *Infect. Control. Hosp. Epidemiol.*, Apr. 2010, vol. 31, n°4, p. 374-381.

INDEX OF SYMBOLS

Symbol	Meaning
	Catalogue number
	In Vitro Diagnostic Medical Device
	Manufacturer
	Temperature limitation
	Use by
	Batch code
	Protect from light
	Consult Instructions for Use
	Contains sufficient for <n> tests

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