

IVD

chromID[®] MRSA SMART Agar (MRSM)

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

SUMMARY AND EXPLANATION

REF 413050 / 413051

chromID[®] MRSA SMART agar is a chromogenic medium for the screening of methicillin-resistant *S. aureus* (MRSA) in chronic carriers or patients at risk of carriage (1, 2, 3).

This medium does not replace conventional antimicrobial susceptibility tests for the diagnosis of methicillin resistance.

MRSA are multi-resistant bacteria which may cause nosocomial infections. The detection of MRSA carriers is particularly important for the epidemiological prevention and monitoring of these infections (4, 5, 6). In this context, the use of chromID MRSA SMART agar contributes towards the active surveillance of MRSA.

PRINCIPLE

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

- the growth of methicillin-resistant staphylococci (MRSA) including hetero-resistant strains and *mecC* variants.
- the direct detection of MRSA strains by revealing enzyme activity: pink to red colonies.

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

CONTENT OF THE KIT

	Ready-to-use medium:
REF 413050	Pack of 2x10 plates (90 mm)
REF 413051	Pack of 10x10 plates (90 mm)
	MRSA *

* printed on the plate

COMPOSITION

Theoretical formula:	
This medium can be adjusted and/or supplemented performance criteria required:	according to the
Plant and animal peptones (porcine or bovine) Opacifying agent Tris Agar Chromogenic mixture Selective mixture Purified water	
pH 7.5	

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.
- 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 indicated in this package insert. Any change or modification in the procedure may affect the results and must be validated beforehand by the user.
- Interpretation of the test results should be made taking into consideration the macro 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 for 2 weeks at 2-8°C in the cellophane sachet, **in the dark**.

SPECIMENS

The medium can be used for the following specimens: nose, throat, skin and soft tissues (perineum, wound, groin, axilla).

Notes:

- It is recommended to use swabs with liquid transport medium to optimize rapidity of response time and sensitivity for MRSA.

If dry swabs are used, inoculation must be performed as rapidly as possible.

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

INSTRUCTIONS FOR USE

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

- 1. Allow the plates to come to room temperature.
- Inoculate the specimens directly onto the chromID[®] MRSA SMART agar.
- 3. Incubate the plates inverted at $35 \pm 2^{\circ}$ C in aerobic conditions. The cultures must be examined between 18 and 24 hours of incubation.

READING AND INTERPRETATION

After incubation, observe the bacterial growth and the appearance of isolated colonies.

Methicillin-resistant *Staphylococcus aureus* strains produce characteristic pink to red colored colonies.

A characteristic color that spreads over the bacterial lawn, must not be taken into account.

QUALITY CONTROL

Protocol:

Performance of the medium can be tested using strains including *Staphylococcus aureus* $ATCC^{\ensuremath{\mathbb{B}}}$ 43300TM and *Staphylococcus aureus* $ATCC^{\ensuremath{\mathbb{R}}}$ 29213TM.

For this, prepare a suspension calibrated to 0.5 McF, and then dilute in sterile saline solution in order to obtain an inoculum, after isolation on an agar plate:

- of 10⁴ CFU:
- with *Staphylococcus aureus* ATCC[®] 43300TM (MRSA). • of 10^5 CFU:
- with Staphylococcus aureus ATCC[®] 29213™ (MSSA).

Range of expected results:

Strain	Results at 33-37°C	
Staphylococcus aureus ATCC [®] 43300™	Growth within 18-24 hours	Pink to red colonies
Staphylococcus aureus ATCC [®] 29213™	No growth within 18-24 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, temperature and incubation time etc.).

LIMITATIONS OF THE METHOD

- Some coagulase-negative staphylococci may produce characteristic colors.
- Some *S. aureus* strains that do not have the *mecA* gene may produce typical colonies.
- Some strains of *Enterobacteriaceae* may produce colonies with a characteristic color. The difference in appearance of these colonies enables them to be differentiated from MRSA.

PERFORMANCE

Performance of chromID MRSA SMART agar was evaluated at 2 sites according to the same protocol, using human clinical specimens, within the context of MRSA carrier screening.

chromID MRSA SMART agar was compared to another commercially available chromogenic screening medium.

The evaluations (England and Germany) were performed using 5,084 fresh clinical specimens, including 2,665 nasal, 626 throat and 1,793 skin and soft tissue swabs.

Readings were performed after 18-24 hours of incubation at 33-37°C in aerobic conditions.

All the typical colonies were confirmed.

108 specimens (including 55 nasal, 10 throat and 43 soft tissue swabs) were found to be positive on at least one of the 2 media.

Sensitivity (95% Confidence Interval)

chromID MRSA SMART	Other medium
94.4%	85.2%
[88.4-97.4]	[77.3-90.7]
102/108	92/108

Specificity (95% Confidence Interval)

Without Gram stain		After Gr	am stain
chromID MRSA SMART	Other medium	chromID MRSA SMART	Other medium
98.9%	99.4%	99.7%	99.6%
[98.5-99.1]	[99.2-99.6]	[99.6-99.9]	[99.4-99.7]
4919/4976	4947/4976	4963/4976	4955/4976

WASTE DISPOSAL

Unused reagents may be considered as non hazardous waste and disposed of accordingly.

Dispose of used 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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- 3. PAN A., LEE A., COOPER B. et al. Risk factors for previously unknown meticillin-resistant *Staphylococcus aureus* carriage on admission to 13 surgical wards in Europe *J. Hosp Infect*, 2013, 83, p. 107-113.
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- 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.
- 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

Symbole	Signification	
REF	Catalogue number	
IVD	In Vitro Diagnostic Medical Device	
	Manufacturer	
	Temperature limitation	
2	Use by	
LOT	Batch code	
Ĩ	Consult Instructions for Use	
Σ	Contains sufficient for <n> tests</n>	
	Protect from light	

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