

# GenoType Mycobacterium AS

VER 1.0

**P**

**IFU-298-17**

**CE**

**IVD**

in vitro

# GenoType Mycobacterium AS VER 1.0

## Mycobacteria

GenoType Mycobacterium AS - in vitro  
 : *M. simiae*, *M. mucogenicum*, *M. goodii*, *M. celatum*, *M. smegmatis*, *M. genavense*, *M. lentiflavum*, *M. heckeshornense*,  
*M. szulgai*, *M. intermedium*, *M. phlei*, *M. haemophilum*, *M. kansasii*, *M. ulcerans*, *M. gastri*, *M. asiaticum* *M. shimoidei*.

(NTM)

[1].

NTM  
[1].

- NTM

GenoType Mycobacterium AS

DNA•STRIP

(i)

(ii)

AM-B)

(iii)

C A B (AM-A

( ).

1/2

1 2

2/2

2 2

1

2°C 8°C.

2

20°C 18°C

(C+) (IC) 20°C 18°C 20°C 18°C

AM-A, AM-B, IC C+

AM-A, AM-B, IC C+;

AM-A, AM-B, IC C+.

C

(HYB)

(SUB-C)

- EUH210:



H315:  
P280:

(DEN)

<2%

H319:

/ /

P305+351+338:

P313:

www.hain-lifescience.com/products/msds.html

(CON-C)

(CON-D)

( [2] [3]).

(CC)  
(IC),  
(GC),

*Mycobacterium*

GenoType Mycobacterium CM VER 2.0

GenoType Mycobacterium AS.

(IC),

( . . )

CC IC.

P

(C+).  
(IC).  
)

*M. kansasii*  
IC C+,

19

*M. kansasii*  
( . . )

( . [2] [3]).

( )

II

2-

Level III Laboratory+ [4], the Clinical Microbiology Procedures Handbook+ [5],

CDC Public Health Mycobacteriology: A Guide for the

2°C 8°C.  
1-2 [6,7].

4-

for the Level III Laboratory+[4].  
Diagnostics, Franklin Lakes, USA)).

NALC/NaOH

CDC Public Health Mycobacteriology: A Guide

( , Loewenstein-Jensen, Middlebrook),

1-1,5

( , MGIT (BD

II

M  
USA))

(Loewenstein-Jensen, Middlebrook),

( , MGIT (BD Diagnostics, Franklin Lakes,

GenoLyse® ( . . )

C.

GenoType Mycobacterium AS.

AM-B)

AM-A AM-B

AM-A AM-B

C A B (AM-A

. 10 AM-A ( . . 2)  
. 35 AM-B ( . . 2)  
. 5

: 50

( AM-A -

+

( . . )

12

AM-A

( 12 )

4x 24

AM-B.

( 45 96 )

AM-B C+

5

( C+

)

AM-A,

15 95°C 1  
 30 95°C } 10  
 2 65°C }  
 25 95°C } 20  
 40 50°C }  
 40 70°C }  
 8 70°C 1  
 H n2,2°C/

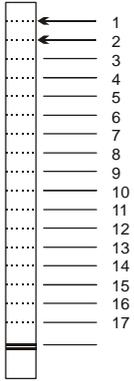
. 20°C +8°C.

www.hain-lifescience.com, Hain Lifescience, Overview equipment programs+  
 TwinCubator.

45°C ( ±1°C)  
 TwinCubator. HYB STR CON-D 37-45°C. (CON-C SUB-C,  
 (SUB-C ) 1:100 (CON-C SUB-D)  
 CON-C SUB-C 10 1  
 SUB-C 4  
 1 20 (DEN, ) 5  
 2. 20  
 3. 1 (HYB, ).  
 4. ( )  
 5. /TwinCubator 30 45°C.  
 6. 1/3  
 7. 1 /TwinCubator. (STR, ) 15 45°C  
 8.  
 9. 1 (RIN) 1 /TwinCubator ( RIN  
 ).  
 10. 1 ( ) 30 /TwinCubator. 1  
 11. ( ) 1 1 (RIN) 1 /TwinCubator ( ).  
 12. 1 ( ) ( )  
 ( 3, 20 )  
 13.  
 14.

IC

17 ( . . ).



(CC)  
(IC)

(CC)

(IC)

C+

IC.

(GC)

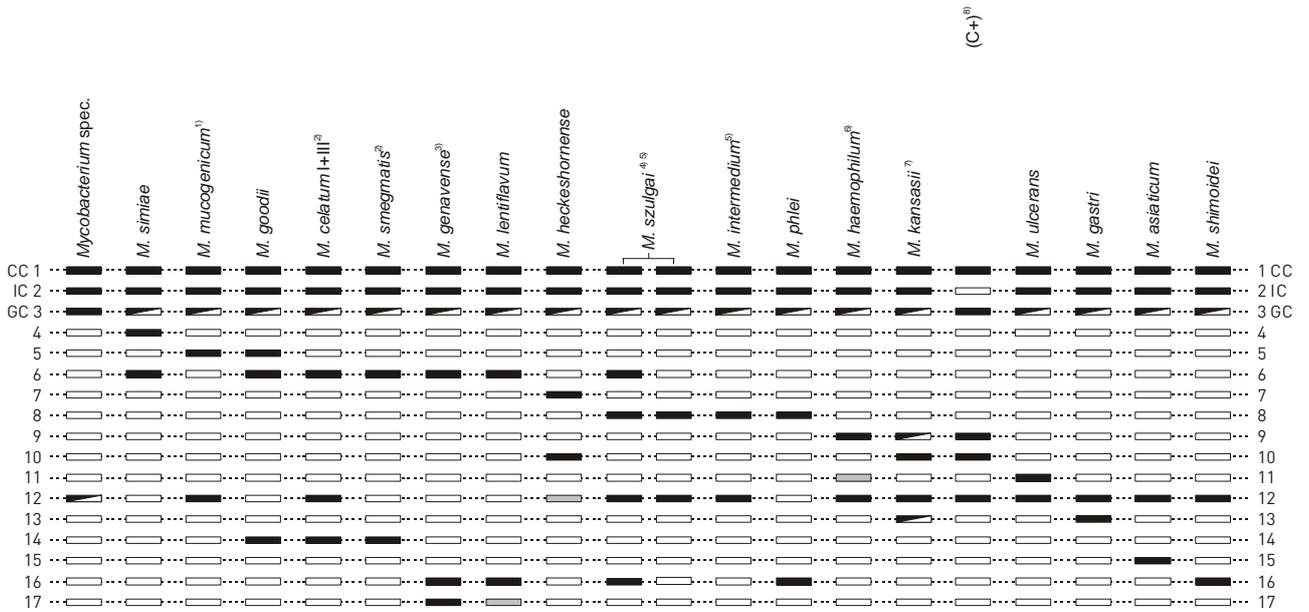
*Mycobacterium.*

GC

(I ), ( :  
 GenoType Mycobacterium CM VER 2.0 \_\_\_\_\_  
 GenoType Mycobacterium CM VER 1.0 \_\_\_\_\_

).  
 GenoType Mycobacterium AS.  
 GenoType

**Mycobacterium AS.**



1 ( ):  
 2 (I ):  
 3 (G ):

- 1) *M. mucogenicum*
  - 2) *M. smegmatis* ( . )
  - 3) *M. triplex*
  - 4) *M. genavense*
  - 5) *M. szulgai* *M. intermedium*  
 1, 2, 3, 10 11, . *Intermedium* .
  - 6) *M. nebraskense*
  - 7) *M. haemophilum*
  - 8) ( + )  
 10 12. *M. kansasii*
- IC. *M. celatum*
- GenoType Mycobacterium CM. *M. szulgai***
- M. kansasii*. 9

Hain Lifescience.

**GenoType Mycobacterium AS,**

**GenoLyse®,**

( )  
CON-C / SUB-C.

(AM-A AM-B)

CON-C / SUB-C.

IC C+

( )

*M. kansasii*,

CC IC.

*M. kansasii*

IC,

10, 20, 200 1000  
2-

(GenoLyse®, )

+

TwinCubator ( )

( )

		298	29896
		12	96
1	2 (	2°C	8°C)
(Mycobacterium AS STRIPS)		12	2x 48
	(DEN)		
<2% NaOH,		240	2x 960
	(HYB)		
<10%		12	96
	(STR)		
>25%			
<1%		12	96
	(RIN)		
, <1% NaCl, <1%		36	3x 96
	(CON-C)		
-		120	960
	(CON-D)		
, 1%	, <1% NaCl	12	96
	(SUB-C)		
<10% 5-	<70% -4- -3- , <10% 4-	120	960
	(SUB-D)		
, <1% MgCl <sub>2</sub> , <1% NaCl		12	96
		1	4
		1	4
P		1	1
		1	1
		3	3
2	2 (	. 20°C	. 18°C)
C	( - GT Mycobacterium AS)	120	4x 240
C	( - GT Mycobacterium AS)	420	4x 840
	(IC GT Mycobacterium AS)	192	192
	(C+ GT Mycobacterium AS)	95	95
<b>GenoType Mycobacterium AS</b> (	12 )		298
<b>GenoType Mycobacterium AS</b> (	96 )		29896
<b>GenoLyse®</b> (	, 12 )		51612
<b>GenoLyse®</b> (	, 96 )		51610

**GenoType Mycobacterium AS**

GenoType Mycobacterium AS ( / ) [8,9]  
 319  
 16S rRNA 500 bp 5q , INNO-LIPA Rif.TB  
 (Innogenetics, Gent, Belgium), AccuProbe Hybridization Protection Assays: Mycobacterium Tuberculosis Complex / Avium / Avium Complex /  
 Intracellulare / Gordonae / Kansasii ( - Gen-Probe, San Diego, USA).  
 - , 304 319 76 Mycobacterium, GenoType Mycobacterium AS ( , 11 -  
 76  
 232 - 217 73 GenoType Mycobacterium AS.  
 232 217 ( CC, UC, GC). 1 GenoType Mycobacterium AS.  
 G+C, GC . 14 Mycobacterium spec.,  
 11 6 G+C.  
 1: - 1)) GenoType Mycobacterium AS ( / )

GenoType Mycobacterium AS	76	1	77	: 100%
	0	242	242	: 99,6%
	76	243	319	

2: - 1)) (GC) GenoType Mycobacterium AS ( / )

GenoType Mycobacterium AS	292	0	292	: 94,8%
	16	11	27	: 100%
	308	11	319	

**GenoLyse®**

52 , Mycobacterium ( Loewenstein-Jensen  
 MGIT (BD Diagnostics, Franklin Lakes, USA), GenoLyse® GenoType Mycobacterium AS  
 ( / ). 1) GenoType  
 Mycobacterium AS ( / ). 3).  
 3: 1) GenoType Mycobacterium AS ( / )  
 GenoLyse®

	<i>Mycobacterium spec.</i>	37	37	<i>Mycobacterium spec.</i>	
	<i>M. celatum</i>	2	2	<i>M. celatum</i>	
	GC	13	13	-	GC
		52	52		

AM-B). / (PNM) , - A B (AM-A  
 39  
 GenoType Mycobacterium AS %MDR CUL+ GenoLyse®,  
 GenoType Mycobacterium AS ( / ).  
 GenoType Mycobacterium CM VER 2.0. ( . 4).  
 4: - GenoType Mycobacterium AS ( / )  
 GenoLyse®  
 GenoType Mycobacterium AS (c  
 PNM)  
 +

GenoType Mycobacterium AS	38	0	38	: 100%
( )	0	1	1	: 100%
	38	1	39	: 100%

1) GenoType Mycobacterium AS /  
 GenoLyse®, GenoLyse®  
 GenoType Mycobacterium AS

**GenoType Mycobacterium AS**

**GenoType Mycobacterium AS** ( / )  
*Mycobacterium* 73

190 : *Actinomyces, Campylobacter, Capnocytophaga, Corynebacterium, Gordonia, Legionella, Nocardia, Nocardioioides, Nocardioopsis, Rhodococcus, Saccharomonospora, Streptomyces, Tsukamurella, Yersinia.*

**GenoType Mycobacterium AS,**

**GenoType Mycobacterium AS,**

*M. celatum M. smegmatis.*

*M. celatum M. smegmatis*

**GenoType Mycobacterium AS** ( / )

(GC).

99,8 %.

100%-

(PNM)

(AM-A AM-

B).

**GenoType Mycobacterium AS** ( )

*Mycobacterium, M.*

*asiaticum, M. celatum I+III, M. gastri, M. genavense, M. goodii, M. haemophilum, M. heckeshornense, M. intermedium, M. kansasii, M. lentiflavum, M. mucogenicum, M. nebraskense, M. phlei, M. shimoidae, M. simiae, M. smegmatis, M. szulgai, M. triplex M. ulcerans.*

<i>M. abscessus</i>	<i>M. canettii</i>	<i>M. intracellulare</i>	<i>M. peregrinum</i>
<i>M. africanum</i>	<i>M. chelonae</i>	<i>M. mageritense</i>	<i>M. pinnipedii</i>
<i>M. alvei</i>	<i>M. chimaera</i>	<i>M. malmoense</i>	<i>M. scrofulaceum</i>
<i>M. avium</i>	<i>M. fortuitum</i>	<i>M. marinum</i>	<i>M. tuberculosis</i>
<i>M. bovis BCG</i>	<i>M. gordonae</i>	<i>M. microti</i>	<i>M. xenopi</i>
<i>M. bovis subsp. bovis</i>	<i>M. immunogenum</i>	<i>M. palustre</i>	
<i>M. bovis subsp. caprae</i>	<i>M. interjectum</i>	<i>sM. paraffinicum%</i>	

*Bordetella pertussis, Corynebacterium ulcerans, C. xerosis, Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Nocardia amarae, N. asteroides, N. farcinica, N. otidiscaviarum, Pseudomonas aeruginosa, Rhodococcus erythropolis, R. rhodochrous, R. ruber, Staphylococcus aureus, S. pneumoniae, Streptomyces somaliensis, Tsukamurella inchoensis, T. paurometabola, T. pulmonis.*

**GenoType Mycobacterium AS** ( )

100%.

P - (GC).

**GenoType Mycobacterium AS,**

GC.  
98,5%.

( , LOD)

**GenoType Mycobacterium AS** ( )

( $1,65 \times 10^6$ ,  $1,65 \times 10^5$ ,  $1,65 \times 10^4$  and  $1,65 \times 10^3$  / ).

**GenoLyse®,**

**GenoType Mycobacterium AS**

%MDR CUL+

$1,65 \times 10^5$  / .

(intra-assay precision)

**GenoType Mycobacterium AS** ( )

*B. Pertussis*

%MDR CUL+

**GenoLyse®,**

(*Mycobacterium spec.*),

**GenoType Mycobacterium AS**

100%.

(inter-assay precision)

**GenoType Mycobacterium AS** ( )

(intra-assay precision),

**GenoLyse®,**

**GenoType Mycobacterium AS**

%MDR CUL+

(*Mycobacterium spec.*),

100%.

GenoType Mycobacterium AS ( ), 6 *M. tuberculosis*  
 4 ( : Loewenstein-Jensen, Stonebrink Middlebrook-7H10, : MGIT (BD  
 Diagnostics, Franklin Lakes, USA)).  
 GenoType Mycobacterium AS.

DIN EN ISO 23640.

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### IFU-298-17

	: %	(CON-C)	(CON-D)
c	%		
	: %		GenoType GenoType Mycobacterium AS).
	Myco bacterium CM VER 2.0		
	: %	19	%

