

remel

RapID™ CB Plus System

REF R8311008..... 20

1. INTENDED USE

The RapID™ CB Plus is a qualitative micromethod using enzyme reactions to identify clinical isolates of *Corynebacterium* species and other irregular Gram-positive bacilli. Used in a diagnostic workflow to aid clinicians in treatment options for patients suspected of having bacterial infections. The device is not automated, is for professional use only and is not a companion diagnostic.

A complete listing of the organisms addressed by the RapID CB Plus System is provided in the RapID CB Plus Differential Chart.

2. SUMMARY AND EXPLANATION

The RapID CB Plus System is comprised of (1) RapID CB Plus Panels and (2) RapID CB Plus Reagent. RapID CB Plus Panels are disposable plastic trays with 18 reaction cavities, which contain dehydrated reactants. The Panel allows the simultaneous inoculation of each cavity with a predetermined amount of inoculum. A suspension of the test organism in RapID Inoculation Fluid is used as the inoculum which rehydrates and initiates test reactions. After incubation of the panel, each test cavity is examined for reactivity by noting the development of a color. In some cases, reagents must be added to the test cavities to provide a color change. The resulting pattern of positive and negative test scores is used as the basis for identification of the test isolate by comparison with the probability values in the Differential Chart (Table 4), or by use of the RapID ERIC™ software.

3. PRINCIPLE

The tests used in the RapID CB Plus System are based on microbial degradation of specific substrates detected by various indicator systems. The reactions employed are a combination of conventional tests and single-substrate chromogenic tests, described in Table 1.

4. REAGENTS

RapID CB Plus Reagent (provided with kit)	(15 ml/Btl)
Reactive ingredient per liter:	
<i>p</i> -Dimethylaminocinnamaldehyde	0.06 g
RapID Inoculation Fluid (R8325106, supplied separately)	(2 ml/tube)
KCl	6.0 g
CaCl ₂	0.5 g
Deminerlized Water.....	1000.0 ml
RapID Nitrate A Reagent (R8309003, supplied separately)	(15 ml/Btl)
Sulfanilic Acid	8.0 g
Glacial Acetic Acid	280.0 ml
Deminerlized Water.....	720.0 ml
RapID Nitrate B Reagent (R8309004, supplied separately)	(15 ml/Btl)
N,N-Dimethyl-1-naphthylamine	6.0 g
Glacial Acetic Acid	280.0 ml
Deminerlized Water.....	720.0 ml

5. PRECAUTIONS

This product is for *in vitro* diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, media, and test panels after use. Directions should be read and followed carefully.

Non-disposable apparatus should be sterilised by any appropriate procedure after use, although the preferred method is to autoclave for 15 minutes at 121°C; disposables should be autoclaved or incinerated. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated area swabbed with a standard bacterial disinfectant or 70% alcohol. Do NOT use sodium hypochlorite. Materials used to clean spills, including gloves, should be disposed of as biohazardous waste.

Do not use reagents beyond the printed expiration dates.

Do not use if there is evidence of contamination or other signs of deterioration.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established. In the event of malfunction do not use device.

Caution!

- RapID CB Plus Reagent is toxic and may cause harm to the environment. Harmful by inhalation, contact with skin or eyes, or if swallowed. May impair fertility or cause harm to unborn child.
- RapID Nitrate A Reagent and RapID Nitrate B Reagent may cause irritation to skin, eyes, and respiratory system.

DANGER



US ONLY



US & EU

H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H360	May damage fertility. May damage the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
P201	Obtain special instructions before use
P202	Do not handle until all safety precautions have been read and understood
P281	Use personal protective equipment as required
P264	Wash face, hands and any exposed skin thoroughly after handling
P280	Wear eye/face protection
P260	Do not breathe dust/fume/gas/mist/ vapors/spray
P271	Use only outdoors or in a well-ventilated area
P308+313	IF exposed or concerned: Get medical attention/advice
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P302+P352	IF ON SKIN: Wash with plenty of soap and water
P332+P313	If skin irritation occurs: Get medical advice/attention
P362	Take off contaminated clothing and wash before reuse
P305+P351 +P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313	If eye irritation persists: Get medical advice/attention
P405	Store locked up
P403+P233	Store in a well-ventilated place. Keep container tightly closed
P501	Dispose of contents/container to an approved waste disposal plant

- Refer to Safety Data Sheet, available on company website, and product labeling for information on potentially hazardous components, for detailed information on reagent chemicals.

Composition / information on ingredients

2-Methoxyethanol 109-86-4

Acetic acid 64-19-7

Hydrochloric acid 7647-01-0

WARNING! This product contains a chemical known in the State of California to cause birth defects or other reproductive harm.

Emergency Telephone Number
INFOTRAC - 24 Hour Number: 1-800-535-5053
Outside of the United States, call 24 Hour Number:
001-352-323-3500 (Call Collect)

6. STORAGE

2°C-8°C

RapID CB Plus System, RapID Nitrate A Reagent, and RapID Nitrate B Reagent should be stored in their original containers at 2-8°C until used. Allow products to equilibrate to room temperature before use. DO NOT interchange reagents among different RapID systems. Remove only the number of panels necessary for testing. Reseal the plastic pouch and promptly return to 2-8°C. Panels must be used the same day they are removed from storage. RapID Inoculation Fluid should be stored in its original container at room temperature (20-25°C) until used.

7. PRODUCT DETERIORATION

This product should not be used if (1) the expiration date has passed, (2) the plastic tray is broken or the lid is compromised, or (3) there are other signs of deterioration.

8. SPECIMEN COLLECTION, STORAGE, AND TRANSPORT

Specimens should be collected and handled following recommended guidelines.⁹⁻¹¹

9. MATERIALS SUPPLIED

- 20 RapID CB Plus Panels
- 20 report forms
- RapID CB Plus Reagent (one plastic dropper-bottle containing reagent sufficient for 20 panels)
- 1 color guide
- 2 chipboard incubation trays
- Instructions for use (IFU).

10. CONTENTS SYMBOLS

CB Plus Panels	CB Plus Panels
Report Forms	RapID Report Forms
CB Plus Reagent	CB Plus Reagent
Incubation Trays	Incubation Trays

11. MATERIALS REQUIRED BUT NOT SUPPLIED

- Loop sterilization device
- Inoculating loop, swabs, collection containers
- Incubators, alternative environmental systems
- Supplemental media
- Quality control organisms
- Gram stain reagents
- Microscope slides
- Cotton swabs
- Catalase test reagent (3% hydrogen peroxide)
- RapID Inoculation Fluid - 2 ml (R8325106)
- McFarland #4 turbidity standard or equivalent (R20414)
- Pipettes
- RapID Nitrate A Reagent (R8309003)
- RapID Nitrate B Reagent (R8309004)
- ERIC (Electronic RapID Compendium, R8323600) (Optional)

12. PROCEDURE

Inoculum Preparation:

- Test organisms must be grown in pure culture and examined by Gram stain prior to use in the system.
Note: Spore-forming Gram-positive bacilli should NOT be tested on the RapID CB Plus System.
- Test organisms may be cultured on routine laboratory media commonly used for coryneforms. The following types of media are recommended: Non-selective media such as Trypticase Soy Agar with 5% sheep blood and Columbia blood agar.
Notes:
 - Plates used for inoculum preparation should be less than 72 hours old. Plates cultivated for 24 hours may be used if sufficient growth is available. Plates that are 72 hours old may be used for very slow-growing strains.
 - The use of media other than those recommended may compromise test performance.
- Perform a catalase test on the isolate. Record the result in the Catalase space on the panel lid.
- Observe the test isolate for the production of yellow pigment. Remove several colonies from the surface of the agar plate with a cotton or polyester-tipped swab and observe for pigment color on the swab. If the organism produces a yellow pigment, record a plus in the Yellow Pigment space on the panel lid.
Note: Only record yellow pigmentation. The production of any other color should be recorded as negative in the pigment space.
- Using a cotton swab or inoculating loop, suspend sufficient growth from the agar plate culture in RapID Inoculation Fluid (2 ml) to achieve a visual turbidity equal to a #4 McFarland turbidity standard or equivalent.

Notes:

- Suspensions significantly less turbid than a #4 McFarland may result in aberrant reactions.
- Bacterial suspensions that are slightly more turbid than a #4 McFarland standard will not affect test performance and are recommended for stock cultures and quality control strains. However, suspensions prepared with a turbidity far greater than a #4 McFarland standard may compromise test performance.
- Suspensions should be mixed thoroughly and vortexed if required.
- Suspensions should be used within 15 minutes of preparation.

- An agar plate may be inoculated for purity and any additional testing that may be required using a loopful of the test suspension from the inoculation fluid tube. Incubate the plate for at least 18-24 hours at 35-37°C.

Inoculation of RapID CB PLUS Panels:

- Peel back the lid of the panel over the inoculation port by pulling the tab marked "Peel to Inoculate" up and to the left.
- Using a pipette, gently transfer the entire contents of the Inoculation Fluid tube into the upper right-hand corner of the panel. Reseal the inoculation port of the panel by pressing the peel-back tab back in place.
- After adding the test suspension, and while keeping the panel on a level surface, tilt the panel back away from the test cavities at approximately 45° (see below).

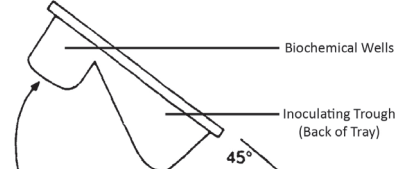
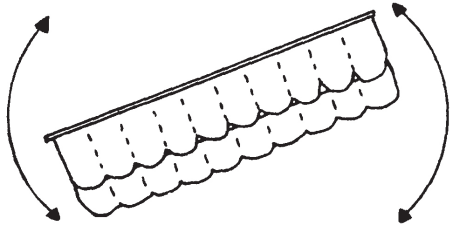


Table 1. Principles and Components of the RapID CB Plus System

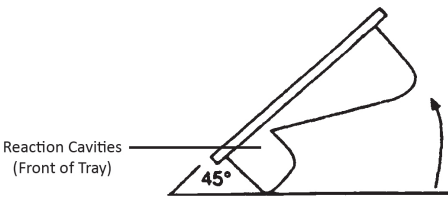
Cavity #	Test Code	Reactive Ingredient	Quantity	Principle	Bibliography #
1	GLU	Glucose	2%	Utilization of the carbohydrate substrate produces acidic products which lower the pH and change the indicator.	1-5
2	SUC	Sucrose	2%		
3	RIB	Ribose	2%		
4	MAL	Maltose	2%		
5	αGLU	<i>p</i> -Nitrophenyl-α,D-glucoside	0.1%	Enzymatic hydrolysis of the colorless aryl-substituted glycoside or phosphoester, releases yellow <i>o</i> - or <i>p</i> -nitrophenol which is detected by the formation of a yellow color.	1-3, 6, 7
6	βGLU	<i>p</i> -Nitrophenyl-β,D-glucoside	0.1%		
7	NAG	<i>p</i> -Nitrophenyl-n-acetyl-β,D-glucosaminide	0.1%		
8	GLY1	<i>p</i> -Nitrophenyl-glycoside	0.1%		
9	ONPG	<i>o</i> -Nitrophenyl-β,D-galactoside	0.1%		
10	PHS	<i>p</i> -Nitrophenyl phosphate	0.2%	Hydrolysis of the fatty acid ester releases acidic products which lower the pH and change the indicator.	5, 7
11	EST	Fatty acid ester	2%		
12	PRO	Proline-β-naphthylamide	0.05%	Enzymatic hydrolysis of the aryl-amide substrate releases free β-naphthylamine which is detected with the RapID CB Plus Reagent.	3, 6-8
13	TRY	Tryptophane-β-naphthylamide	0.05%		
14	PYR	Pyrrrolidine-β-naphthylamine	0.05%		
15	LGLY	Leucyl-glycine-β-naphthylamide	0.05%		
16	LEU	Leucine-β-naphthylamide	0.05%	Hydrolysis of urea produces basic products which change the pH indicator.	1-3, 5
17	URE	Urea	1.2%		
18	NIT	Potassium nitrate	0.6%	Utilization of nitrate results in the formation of nitrite which is detected by the addition of RapID Nitrate Reagents.	1, 3, 5, 9

- While tilted back, gently rock the panel from side to side to evenly distribute the inoculum along the rear baffles as illustrated below.



- While maintaining a level, horizontal position (best achieved by using the bench top against the reaction cavity bottoms), slowly tilt the panel forward toward the reaction cavities until the inoculum flows along the baffles into the reaction cavities (see below). This should evacuate all of the inoculum from the rear portion of the panel.

Note: If the panel is tilted too quickly, air may be trapped at the test cavity junction, restricting fluid movement.



- Return the panel to a level position. If necessary, gently tap the panel on the bench top to remove any air trapped in the cavities.

Notes:

- Examine the test cavities. Test cavities should appear bubble-free and uniformly filled. Slight irregularities in test cavity fills are acceptable and will not affect test performance. If the panel is grossly misfilled, a new panel should be inoculated and the misfilled panel discarded.
- Complete the inoculation of each panel receiving inoculation fluid before inoculating additional panels.
- Do not allow the inoculum to rest in the back portion of the panel for prolonged periods without completing the procedure.

Incubation of RapID CB Plus Panels:

Incubate inoculated panels at 35-37°C in a non-CO₂ incubator for at least 4 hours but not more than 6 hours. For ease of handling, panels may be incubated in the chipboard incubation trays provided with the kit.

Scoring of RapID CB Plus Panels:

CAT (catalase) and PIG (yellow pigment) are not performed in the RapID CB Plus panel. However, they are recorded as part of the microcode score.

- While firmly holding the RapID CB Plus panel on the bench top, peel off the label lid over the reaction cavities by pulling the

RapID CB Plus Panel Test Location

Cavity #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Test Code	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT
												RapID CB Plus Reagent						NIT A NIT B

Table 2. Interpretation of RapID CB Plus System Tests*

Cavity #	Test Code	Reagent	Reaction		Comments
			Positive	Negative	
Tests contained in the RapID CB Plus Panel:					
1	GLU	None	Yellow, gold, or light yellow-orange	Red or dark orange	Only the development of a distinct yellow, gold, or yellow-orange should be scored as positive. Any other shade is scored as negative.
2	SUC				
3	RIB				
4	MAL				
5	αGLU				
6	βGLU	None	Yellow	Clear, tan	Any development of a yellow color should be scored as positive. Shades of yellow color may be different from cavity to cavity. Do not compare the color of one cavity to another.
7	NAG				
8	GLY1				
9	ONPG				
10	PHS				
11	EST	None	Yellow or yellow-orange	Red or orange	Only the development of a distinct yellow or yellow-orange should be scored as positive.
12	PRO	RapID CB Plus Reagent	Purple, red, or dark pink	Yellow or orange	Only significant color development should be scored as positive. Very pale colors should be scored as negative.
13	TRY				
14	PYR				
15	LGLY				
16	LEU				
17	URE	None	Red or dark red-orange	Yellow or orange	Only the development of a distinct red or deep red-orange should be scored as positive.
18	NIT	RapID Nitrate A and B	Red or pink	Clear or very pale pink	Any red to medium pink color should be scored as positive.
Tests not contained in the RapID CB Plus Panel that are part of the microcode:					
19	CAT	3% Hydrogen Peroxide	Bubbles	No bubbles	Any significant bubbling should be scored as positive.
20	PIG	None	Yellow pigment	No pigment or any other color	Only yellow-pigmented isolates are scored as positive.

*NOTE: Panels should be read by looking down through the reaction cavities against a white background.

Table 3. Quality Control Chart for RapID CB Plus Panels

Organism	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT
<i>Paenibacillus polymyxa</i> ATCC® 842	+	+	+	+	+	+	+	V	+	+	+	–	–	–	–	–	–	+
<i>Corynebacterium pseudodiphtheriticum</i> ATCC® 10701	–	–	–	–	–	–	–	–	–	V	–	+	+	–	+	+	+	+
<i>Arcanobacterium pyogenes</i> ^a ATCC® 19411 (also known as <i>Trueperella pyogenes</i>)	+	–	V	V	+	–	V	+	+	–	V	+	V	+	V	+	–	–

+, positive; –, negative; V, variable

^a **Key indicator strains** demonstrate acceptable performance of the most labile substrate in the system and reactivity in a significant number of wells, according to Clinical and Laboratory Standards Institute recommendations for streamlined quality control.¹⁶

to batch. As a result, culture media may influence constitutive enzymatic activity of designated quality control strains. If quality control strain results differ from the patterns indicated, a subculture onto medium from a different batch or from another manufacturer will often resolve quality control discrepancies.

15. LIMITATIONS

- The use of RapID CB PLUS System and the interpretation of results requires the knowledge of a competent microbiologist, familiar with laboratory procedures, who is trained in general microbiological methods and who judiciously makes use of training, experience, specimen information, and other pertinent procedures before reporting the identification obtained using this system.
- The RapID CB Plus System must be used with pure cultures of test organisms. The use of mixed microbial populations or direct testing of clinical material without culture will result in aberrant results.
- The RapID CB Plus System is designed for use with the taxa listed in the RapID CB Plus Differential Chart. Gram-positive bacilli that form spores or Gram-negative bacilli should not be tested.
- Expected values listed for RapID CB Plus System tests may differ from conventional test results or previously reported information.
- The accuracy of the RapID CB Plus System is based on statistical use of a multiplicity of specially designed tests and an exclusive, proprietary database. The use of any single test found in the RapID CB Plus System to establish the identification of a test isolate is subject to the error inherent in that test alone.

16. PERFORMANCE CHARACTERISTICS

The RapID CB Plus System performance characteristics have been established by laboratory testing of clinical, reference, and stock cultures.¹²⁻¹⁵ Among 435 strains tested, 422 (97%) RapID CB Plus results agreed with the reference results. Among the 422 strains that agreed, 395 (91%) agreed without additional testing. Twenty-seven (6%) probability overlap microcodes were encountered which required additional testing for resolution of choices and complete identification. Seven (1.6%) strains provided questionable microcodes and six (1.4%) RapID CB Plus results did not agree with reference identifications.

17. BIBLIOGRAPHY

- Baron, E.J., L.R. Peterson, and S.M. Finegold. 1994. Bailey and Scott’s Diagnostic Microbiology. 9th ed. Mosby, St. Louis, MO.
- Coyle, M.B. and B.A. Lipsky. 1990. Clin. Microbiol. Rev. 3:224-

Table 4 - RapID CB Plus Differential Chart

Organism	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT	CAT	PIG
<i>Corynebacterium accolens</i>	95	11	29	0	0	0	0	0	0	0	0	99	1	1	0	0	7	51	99	0
<i>Corynebacterium afermentans subsp. afermentans</i>	0	0	0	0	0	0	0	0	0	88	38	86	26	0	3	47	1	1	98	0
<i>Corynebacterium afermentans subsp. lipophilum</i>	0	0	0	0	0	0	0	0	0	0	9	98	0	0	0	0	0	0	98	0
<i>Corynebacterium amycolatum</i>	97	41	70	80	4	0	0	0	0	97	88	99	93	0	9	11	18	76	98	0
<i>Corynebacterium argentoratense</i>	98	0	5	0	0	0	0	0	0	14	69	99	90	0	7	82	0	0	98	0
<i>Corynebacterium auris</i>	0	0	0	0	0	90	0	0	0	96	95	99	71	1	8	76	1	1	98	0
<i>Corynebacterium bovis</i>	28	8	3	13	0	0	0	2	99	19	9	90	9	0	9	71	8	0	98	0
<i>Corynebacterium cystitidis</i>	90	0	0	0	0	0	0	90	0	95	5	33	45	9	28	88	99	0	98	0
<i>Corynebacterium diphtheriae</i>	98	2	81	90	99	0	0	0	0	1	24	99	21	1	30	41	0	28	98	0
<i>Corynebacterium glucuronolyticum</i>	95	86	91	24	0	7	0	99	0	6	11	99	86	6	48	78	71	19	98	0
<i>Corynebacterium jeikeium</i> (JK)	88	2	78	9	1	1	0	0	0	85	92	0	58	1	41	69	1	2	98	0
<i>Corynebacterium kutscheri</i>	96	93	82	96	93	99	0	0	0	0	58	96	90	99	98	95	99	81	98	0
<i>Corynebacterium matruchotii</i>	70	62	74	65	2	80	2	2	20	8	15	90	82	93	91	0	0	98	98	0
<i>Corynebacterium minutissimum</i>	98	73	76	99	3	9	0	0	4	83	27	99	78	1	74	88	0	0	98	0
<i>Corynebacterium propinquum</i> (ANF3)	0	0	0	0	0	0	0	0	0	91	63	6	79	33	70	57	2	99	98	0
<i>Corynebacterium pseudodiphtheriticum</i>	0	0	0	0	1	0	0	0	0	22	9	96	66	31	72	82	99	86	98	0
<i>Corynebacterium pseudotuberculosis</i>	84	4	85	30	18	0	0	0	0	4	7	99	78	0	69	74	99	0	98	13
<i>Corynebacterium renale</i>	88	2	11	0	0	0	12	99	7	5	2	98	14	1	0	0	99	0	90	58
<i>Corynebacterium striatum</i>	97	96	49	0	0	2	0	0	1	81	37	99	90	6	70	82	1	98	98	0
<i>Corynebacterium ulcerans</i>	97	0	95	88	97	0	8	2	1	88	40	99	99	1	33	62	98	0	98	0
<i>Corynebacterium urealyticum</i> (D-2)	1	0	3	1	0	0	0	0	0	0	38	1	66	1	7	66	99	0	98	0
<i>Corynebacterium xerosis</i>	98	96	90	90	96	0	4	0	0	84	22	96	76	0	51	88	1	61	99	0
CDC Group F-1	98	1	96	88	0	0	0	0	0	1	1	98	79	0	2	39	99	24	96	0
CDC Group G (G/LD)	96	82	88	0	0	0	0	0	0	77	21	99	31	71	68	82	0	50	96	0
CDC Group 11	90	0	8	2	0	0	0	0	0	98	32	98	76	0	0	6	1	91	97	0
<i>Listeria grayi/murrayi</i>	95	4	95	90	98	99	99	56	0	1	92	1	47	3	8	12	1	58	98	0
<i>Listeria innocua</i>	96	2	0	92	98	99	99	31	0	1	96	0	92	0	12	8	0	0	98	0
<i>Listeria ivanovii</i>	96	12	33	95	76	95	99	0	0	2	88	1	37	0	8	21	1	0	98	0
<i>Listeria monocytogenes</i>	96	2	7	96	99	99	99	14	0	0	96	0	80	0	1	9	1	0	96	0
<i>Listeria seeligeri</i>	96	2	0	95	98	98	98	0	0	4	96	1	42	0	10	22	1	0	95	0
<i>Listeria welshimeri</i>	96	5	1	96	69	99	99	73	0	2	96	1	81	0	15	33	2	0	95	0
<i>Actinomyces israelii</i>	98	95	92	13	99	97	2	4	87	2	8	98	64	19	86	90	2	31	0	0
<i>Actinomyces naeslundii</i>	90	82	13	90	86	96	0	2	91	11	2	98	65	1	71	87	94	77	0	0
<i>Actinomyces viscosus</i>	96	98	62	96	92	90	0	7	91	5	6	92	1	0	76	88	82	96	98	0
<i>Arcanobacterium haemolyticum</i>	95	9	88	83	98	26	92	99	84	88	86	81	66	72	78	90	2	3	0	0
<i>Arcanobacterium pyogenes</i> (also known as <i>Trueperella pyogenes</i>)	92	24	82	77	98	0	69	89	90	53	18	90	3	2	83	90	1	0	0	0
<i>Bifidobacterium</i> spp. (Gp E)	91	90	39	90	95	74	15	0	43	2	44	83	16	5	11	3	1	0	0	0
<i>Brevibacterium casei</i>	0	0	5	1	93	0	35	0	0	49	16	99	88	28	78	86	1	7	99	9
<i>Brevibacterium</i> spp. (Gp B)	1	0	9	0	4	3	29	1	1	88	19	96	86	11	76	90	5	9	95	16
<i>Cellulomonas</i> spp. (Gp A3/A4)	98	98	66	98	98	99	90	7	88	96	81	89	80	96	75	80	1	84	96	76
<i>Corynebacterium otitidis</i> ^c	0	0	0	0	0	0	0	0	0	95	92	99	99	0	96	57	0	0	98	0
<i>Dermabacter hominis</i>	95	90	77	88	99	91	98	92	95	71	63	29	92	98	88	77	0	0	98	0
<i>Erysipelothrix rhusiopathiae</i>	88	0	9	0	0	12	99	2	93	80	2	85	73	93	30	19	0	0	3	0
<i>Exiguobacterium acetylicum</i>	98	98	78	98	99	98	1	0	91	20	1	0	2	0	0	0	1	0	99	92
<i>Leifsonia aquatica</i> ^b	28	0	8	9	99	94	96	88	16	4	2	98	88	2	91	87	1	8	98	95
<i>Microbacterium</i> spp.	98	98	87	92	99	90	98	1	96	66	36	8	77	5	80	29	1	5	98	86
<i>Oerskovia</i> spp.	98	97	41	90	96	98	90	33	81	11	7	98	92	28	79	90	1	45	98	94
<i>Rhodococcus equi</i>	18	2	12	2	80	82	0	2	18	94	96	91	88	4	35	87	61	55	95	0
<i>Rothia</i> spp.	92	90	0	77	99	55	0	0	0	3	1	98	90	88	91	96	0	81	98	0
<i>Schaalia odontolyticus</i> ^c	92	90	12	65	81	66	3	2	86	14	38	98	13	0	92	82	1	91	0	0
<i>Trueperella bernardiae</i> ^a	60	0	40	45	96	0	99	0	0	5	0	90	15	4	63	74	1	0	0	0
<i>Winkia neuii</i> ^d	74	59	62	54	99	2	2	74	92	1	57	99	13	1	40	98	1	18	96	0

^aPreviously designated as *Arcanobacterium bernardiae* and prior to that *Actinomyces bernardiae* (group 2)

^bPreviously designated as *Corynebacterium aquaticum*

^cPreviously designated as *Actinomyces odontolyticus*

^dPreviously designated as *Actinomyces neuii* (Gp 1)

^ePreviously designated as *Turicella otitidis*



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Version	Date of modifications introduced
IFU8311008	August 2023 Updated to meet IVDR requirements

Printed in the UK

18. SYMBOL LEGEND

	Catalogue Number
	In Vitro Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
	Contains sufficient for <N> tests
	Do not use if package is damaged
	Do not re-use
	Batch Code (Lot Number)
	Use By (Expiration Date)
	Importer
	Unique Device Identifier
	Authorized representative in the European Community
	UK Conformity Assessed
	European Conformity Assessment
	Manufacturer

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Tabla 3. Gráfico de control de calidad para los paneles Rapid CB Plus

Microrganismo	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT
<i>Paenibacillus polymyxa</i> ATCC™ 842	+	+	+	+	+	+	+	V	+	+	+	–	–	–	–	–	–	+
<i>Corynebacterium pseudodiphtheriticum</i> ATCC™ 10701	–	–	–	–	–	–	–	–	–	V	–	+	+	–	+	+	+	+
<i>Arcanobacterium pyogenes</i> ^a ATCC™ 19411 (también se conoce como Trueperella pyogenes)	+	–	V	V	+	–	V	+	+	–	V	+	V	+	V	+	–	–

+, positivo; –, negativo; V, variable

^a En las **cepas indicadoras clave** se observa un rendimiento aceptable del sustrato más lábil del sistema y reactividad en un número significativo de pocillos, de acuerdo con las recomendaciones del Clinical and Laboratory Standards Institute para optimizar el control de calidad.¹⁶

15. LIMITACIONES

- El uso del sistema RapID CB PLUS y la interpretación de los resultados precisa el conocimiento de un microbiólogo competente, familiarizado con los procedimientos de laboratorio, que esté formado en métodos microbiológicos generales y que haga un uso responsable de la formación, la experiencia, la información sobre la muestra y otros procedimientos pertinentes antes de informar sobre la identificación obtenida mediante este sistema.
- El sistema RapID CB Plus debe usarse con cultivos puros de microorganismos de prueba. El uso de poblaciones microbianas mezcladas o pruebas directas de material clínico sin cultivo ocasionará la generación de resultados anómalos.
- El sistema RapID CB Plus está diseñado para su uso con los taxones enumerados en el gráfico diferencial de RapID CB Plus. No se deben analizar ni los bacilos grampositivos que forman esporas ni los bacilos gramnegativos.
- Los valores esperados que se enumeran para las pruebas del sistema RapID CB Plus pueden ser diferentes a los de la prueba convencional o a la información previamente notificada.
- La precisión del sistema RapID CB Plus se basa en el uso estadístico de una multiplicidad de pruebas especialmente diseñadas y una base de datos exclusiva patentada. El uso de una sola prueba del sistema RapID CB Plus para establecer la identificación de un aislado de la prueba está sujeto al error inherente a esa prueba por sí sola.

16. CARACTERÍSTICAS DE RENDIMIENTO

Se han establecido las características de rendimiento del sistema RapID CB Plus mediante pruebas de laboratorio de cultivos clínicos, de referencia y madre.¹²⁻¹⁵ De las 435 cepas analizadas, 422 resultados (97 %) de RapID CB Plus coincidieron con los resultados de referencia. Entre las 422 cepas que coincidieron, 395 (91 %) coincidieron sin pruebas adicionales. Se encontraron 27 (6 %) microcódigos de probabilidad de solapamiento que requirieron pruebas adicionales para resolver las opciones y completar la identificación. Siete (1,6 %) cepas proporcionaron microcódigos dudosos y seis (1,4 %) resultados de RapID CB Plus no coincidieron con las identificaciones de referencia.

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Tabla 4. Gráfico diferencial de RapID CB Plus

Microrganismo	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT	CAT	PIG
<i>Corynebacterium accolens</i>	95	11	29	0	0	0	0	0	0	0	0	99	1	1	0	0	7	51	99	0
<i>Corynebacterium afermentans subsp. afermentans</i>	0	0	0	0	0	0	0	0	0	88	38	86	26	0	3	47	1	1	98	0
<i>Corynebacterium afermentans subsp. lipophilum</i>	0	0	0	0	0	0	0	0	0	0	9	98	0	0	0	0	0	0	98	0
<i>Corynebacterium amycolatium</i>	97	41	70	80	4	0	0	0	0	97	88	99	93	0	9	11	18	76	98	0
<i>Corynebacterium argentoratense</i>	98	0	5	0	0	0	0	0	0	14	69	99	90	0	7	82	0	0	98	0
<i>Corynebacterium auris</i>	0	0	0	0	0	90	0	0	0	96	95	99	71	1	8	76	1	1	98	0
<i>Corynebacterium bovis</i>	28	8	3	13	0	0	0	2	99	19	9	90	9	0	9	71	8	0	98	0
<i>Corynebacterium cystitidis</i>	90	0	0	0	0	0	0	90	0	95	5	33	45	9	28	88	99	0	98	0
<i>Corynebacterium diphtheriae</i>	98	2	81	90	99	0	0	0	0	1	24	99	21	1	30	41	0	28	98	0
<i>Corynebacterium glucuronolyticum</i>	95	86	91	24	0	7	0	99	0	6	11	99	86	6	48	78	71	19	98	0
<i>Corynebacterium jeikeium</i> (JK)	88	2	78	9	1	1	0	0	0	85	92	0	58	1	41	69	1	2	98	0
<i>Corynebacterium kutscheri</i>	96	93	82	96	93	99	0	0	0	0	58	96	90	99	98	95	99	81	98	0
<i>Corynebacterium matruchotii</i>	70	62	74	65	2	80	2	2	20	8	15	90	82	93	91	0	0	98	98	0
<i>Corynebacterium minutissimum</i>	98	73	76	99	3	9	0	0	4	83	27	99	78	1	74	88	0	0	98	0
<i>Corynebacterium propinquum</i> (ANF3)	0	0	0	0	0	0	0	0	0	91	63	6	79	33	70	57	2	99	98	0
<i>Corynebacterium pseudodiphtheriticum</i>	0	0	0	0	1	0	0	0	0	22	9	96	66	31	72	82	99	86	98	0
<i>Corynebacterium pseudotuberculosis</i>	84	4	85	30	18	0	0	0	0	4	7	99	78	0	69	74	99	0	98	13
<i>Corynebacterium renale</i>	88	2	11	0	0	0	12	99	7	5	2	98	14	1	0	0	99	0	90	58
<i>Corynebacterium striatum</i>	97	96	49	0	0	2	0	0	1	81	37	99	90	6	70	82	1	98	98	0
<i>Corynebacterium ulcerans</i>	97	0	95	88	97	0	8	2	1	88	40	99	99	1	33	62	98	0	98	0
<i>Corynebacterium urealyticum</i> (D-2)	1	0	3	1	0	0	0	0	0	0	38	1	66	1	7	66	99	0	98	0
<i>Corynebacterium xerosis</i>	98	96	90	90	96	0	4	0	0	84	22	96	76	0	51	88	1	61	99	0
CDC Grupo F-1	98	1	96	88	0	0	0	0	0	1	1	98	79	0	2	39	99	24	96	0
CDC Grupo G (G/LD)	96	82	88	0	0	0	0	0	0	77	21	99	31	71	68	82	0	50	96	0
CDC Grupo I1	90	0	8	2	0	0	0	0	0	98	32	98	76	0	0	6	1	91	97	0
<i>Listeria grayi/murrayi</i>	95	4	95	90	98	99	99	56	0	1	92	1	47	3	8	12	1	58	98	0
<i>Listeria innocua</i>	96	2	0	92	98	99	99	31	0	1	96	0	92	0	12	8	0	0	98	0
<i>Listeria ivanovii</i>	96	12	33	95	76	95	99	0	0	2	88	1	37	0	8	21	1	0	98	0
<i>Listeria monocytogenes</i>	96	2	7	96	99	99	99	14	0	0	96	0	80	0	1	9	1	0	96	0
<i>Listeria seeligeri</i>	96	2	0	95	98	98	98	0	0	4	96	1	42	0	10	22	1	0	95	0
<i>Listeria welshimeri</i>	96	5	1	96	69	99	99	73	0	2	96	1	81	0	15	33	2	0	95	0
<i>Actinomyces israelii</i>	98	95	92	13	99	97	2	4	87	2	8	98	64	19	86	90	2	31	0	0
<i>Actinomyces naeslundii</i>	90	82	13	90	86	96	0	2	91	11	2	98	65	1	71	87	94	77	0	0
<i>Actinomyces viscosus</i>	96	98	62	96	92	90	0	7	91	5	6	92	1	0	76	88	82	96	98	0
<i>Arcanobacterium haemolyticum</i>	95	9	88	83	98	26	92	99	84	88	86	81	66	72	78	90	2	3	0	0
<i>Arcanobacterium pyogenes</i> (también se conoce como Trueperella pyogenes)	92	24	82	77	98	0	69	89	90	53	18	90	3	2	83	90	1	0	0	0
<i>Bifidobacterium</i> spp. (Gp E)	91	90	39	90	95	74	15	0	43	2	44	83	16	5	11	3	1	0	0	0
<i>Brevibacterium casei</i>	0	0	5	1	93	0	35	0	0	49	16	99	88	28	78	86	1	7	99	9
<i>Brevibacterium</i> spp. (Gp B)	1	0	9	0	4	3	29	1	1	88	19	96	86	11	76	90	5	9	95	16
<i>Cellulomonas</i> spp. (Gp A3/A4)	98	98	66	98	98	99	90	7	88	96	81	89	80	96	75	80	1	84	96	76
<i>Corynebacterium otitidis</i> ^a	0	0	0	0	0	0	0	0	0	95	92	99	99	0	96	57	0	0	98	0
<i>Dermabacter hominis</i>	95	90	77	88	99	91	98	92	95	71	63	29	92	98	88	77	0	0	98	0
<i>Erysipelothrix rhusiopathiae</i>	88	0	9	0	0	12	99	2	93	80	2	85	73	93	30	19	0	0	3	0
<i>Exiguobacterium acetylicum</i>	98	98	78	98	99	98	1	0	91	20	1	0	2	0	0	0	1	0	99	92
<i>Leifsonia aquatica</i> ^b	28	0	8	9	99	94	96	88	16	4	2	98	88	2	91	87	1	8	98	95
<i>Microbacterium</i> spp.	98	98	87	92	99	90	98	1	96	66	36	8	77	5	80	29	1	5	98	86
<i>Oerskovia</i> spp.	98	97	41	90	96	98	90	33	81	11	7	98	92	28	79	90	1	45	98	94
<i>Rhodococcus equi</i>	18	2	12	2	80	82	0	2	18	94	96	91	88	4	35	87	61	55	95	0
<i>Rothia</i> spp.	92	90	0	77	99	55	0	0	0	3	1	98	90	88	91	96	0	81	98	0
<i>Schaalia odontolyticus</i> ^c	92	90	12	65	81	66	3	2	86	14	38	98	13	0	92	82	1	91	0	0
<i>Trueperella bernardiae</i> ^d	60	0	40	45	96	0	99	0	0	5	0	90	15	4	63	74	1	0	0	0
<i>Winkia neuvi</i> ^d	74	59	62	54	99	2	74	92	1	57	99	13	1	40	98	1	18	96	0	0

^a Designado previamente como *Arcanobacterium bernardiae* y antes como *Actinomyces bernardiae* (grupo 2).

^b Designado previamente como *Corynebacterium aquaticum*.

^c Designado previamente como *Actinomyces odontolyticus*.

^d Designado previamente como *Actinomyces neuvi* (Gp 1).

^e Designado previamente como *Turicella otitidis*.



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Versión	Fecha de la introducción de modificaciones
IFU8311008	Agosto de 2023 Se ha actualizado para cumplir los requisitos del IVDR

Impreso en el Reino Unido

18. LEYENDA DE LOS SÍMBOLOS

	Número de catálogo
	Producto sanitario de diagnóstico in vitro
	Consultar las instrucciones de uso (IFU)
	Limitaciones de temperatura (temperatura de conservación)
	Contenido suficiente para <N> pruebas
	No usar si el paquete está dañado
	No reutilizar
	Código de lote (número de lote)
	Usar antes de (fecha de caducidad)
	Importador
	Identificador único del producto
	Representante autorizado en la Comunidad Europea
	Evaluación del cumplimiento normativo de Reino Unido
	Evaluación de conformidad europea
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Tabella 3. Grafico del controllo di qualità dei pannelli RapID CB Plus

Microrganismo	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT
<i>Paenibacillus polymyxa</i> ATCC™ 842	+	+	+	+	+	+	+	V	+	+	+	–	–	–	–	–	–	+
<i>Corynebacterium pseudodiphtheriticum</i> ATCC™ 10701	–	–	–	–	–	–	–	–	–	V	–	+	+	–	+	+	+	+
<i>Arcanobacterium pyogenes</i> ^a ATCC™ 19411 (n ^o to anche come <i>Trueperella pyogenes</i>)	+	–	V	V	+	–	V	+	+	–	V	+	V	+	V	+	–	–

+, positivo; –, negativo; V, variabile

^a I **ceppi indicatori principali** dimostrano prestazioni accettabili del substrato più labile nel sistema e una reattività in un numero significativo dei pozzetti, in conformità alle raccomandazioni del Clinical and Laboratory Standards Institute per la semplificazione del controllo di qualità.¹⁶

14. CONTROLLO DI QUALITÀ

Tutti i numeri di lotto del sistema RapID CB Plus sono stati sottoposti a test utilizzando i seguenti microrganismi di controllo di qualità e si sono dimostrati accettabili. I test dei microrganismi di controllo di qualità dovrebbero essere eseguiti in conformità alle procedure di controllo di qualità in laboratorio prescritte. Se dovesse risultare che la qualità è scadente, non procedere alla registrazione dei risultati relativi al paziente. La Tabella 3 elenca i risultati previsti per la batteria selezionata di microrganismi in esame.

Il test di controllo di qualità deve essere eseguito a ogni spedizione e nuovo lotto ricevuto.

È responsabilità dell’utente eseguire il test di controllo di qualità in conformità ai requisiti e alle norme locali applicabili.

Note:

- Il controllo di qualità dei reagenti RapID si effettua ottenendo reazioni attese per i test che richiedono l’aggiunta di reagenti (pozzetti da 12 a 16 e 18).
- I microrganismi che siano stati trasferiti ripetutamente su terreni agar per periodi prolungati possono produrre risultati aberranti.
- Congelare o liofilizzare i ceppi per il controllo di qualità. Prima dell’uso, trasferire 2-3 volte i ceppi per il controllo di qualità dal mezzo di conservazione al terreno di coltura agar raccomandato per l’uso con il sistema RapID CB Plus.
- Formulazioni, additivi e ingredienti dei terreni di coltura variano da produttore a produttore e possono variare da lotto a lotto. Di conseguenza, i terreni di coltura possono influenzare l’attività enzimatica costitutiva dei ceppi designati per il controllo di qualità. Se i risultati del ceppo per il controllo di qualità differiscono dai modelli indicati, spesso le discrepanze riscontrate possono essere risolte con una sottocoltura effettuata su terreno di un lotto diverso o proveniente da un altro produttore.

15. LIMITAZIONI

- Per l’uso del sistema RapID CB Plus e l’interpretazione dei risultati sono necessarie le conoscenze di microbiologi competenti, che abbiano familiarità con le procedure di laboratorio, che siano formati sui metodi generali di microbiologia e che si avvalgano, con criterio, della formazione, dell’esperienza, delle informazioni sul campione e di altre procedure adeguate, prima di refertare l’identificazione ottenuta tramite l’utilizzo di questo sistema.
- I microrganismi in esame con il sistema RapID CB Plus devono provenire da colture pure. L’utilizzo di popolazioni batteriche miste o l’analisi diretta di materiale clinico non proveniente da coltura può fornire risultati aberranti.

Tabella 4 - Tabella differenziale RapID CB Plus

Microrganismo	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT	CAT	PIG	
<i>Corynebacterium accolens</i>	95	11	29	0	0	0	0	0	0	0	0	0	0	1	1	0	0	7	51	99	0
<i>Corynebacterium afermentans subsp. afermentans</i>	0	0	0	0	0	0	0	0	0	88	38	86	26	0	3	47	1	1	98	0	
<i>Corynebacterium afermentans subsp. lipophilum</i>	0	0	0	0	0	0	0	0	0	0	9	98	0	0	0	0	0	0	98	0	
<i>Corynebacterium amycolatum</i>	97	41	70	80	4	0	0	0	0	97	88	99	93	0	9	11	18	76	98	0	
<i>Corynebacterium argentoratense</i>	98	0	5	0	0	0	0	0	0	14	69	99	90	0	7	82	0	0	98	0	
<i>Corynebacterium auris</i>	0	0	0	0	0	90	0	0	0	96	95	99	71	1	8	76	1	1	98	0	
<i>Corynebacterium bovis</i>	28	8	3	13	0	0	0	2	99	19	9	90	9	0	9	71	8	0	98	0	
<i>Corynebacterium cystitidis</i>	90	0	0	0	0	0	0	90	0	95	5	33	45	9	28	88	99	0	98	0	
<i>Corynebacterium diphtheriae</i>	98	2	81	90	99	0	0	0	0	1	24	99	21	1	30	41	0	28	98	0	
<i>Corynebacterium glucuronolyticum</i>	95	86	91	24	0	7	0	99	0	6	11	99	86	6	48	78	71	19	98	0	
<i>Corynebacterium jeikeium</i> (JK)	88	2	78	9	1	1	0	0	0	85	92	0	58	1	41	69	1	2	98	0	
<i>Corynebacterium kutscheri</i>	96	93	82	96	93	99	0	0	0	0	58	96	90	99	98	95	99	81	98	0	
<i>Corynebacterium matruchotii</i>	70	62	74	65	2	80	2	2	20	8	15	90	82	93	91	0	0	98	98	0	
<i>Corynebacterium minutissimum</i>	98	73	76	99	3	9	0	0	4	83	27	99	78	1	74	88	0	0	98	0	
<i>Corynebacterium propinquum</i> (ANF3)	0	0	0	0	0	0	0	0	0	91	63	6	79	33	70	57	2	99	98	0	
<i>Corynebacterium pseudodiphtheriticum</i>	0	0	0	0	1	0	0	0	0	22	9	96	66	31	72	82	99	86	98	0	
<i>Corynebacterium pseudotuberculosis</i>	84	4	85	30	18	0	0	0	0	4	7	99	78	0	69	74	99	0	98	13	
<i>Corynebacterium renale</i>	88	2	11	0	0	0	12	99	7	5	2	98	14	1	0	0	99	0	90	58	
<i>Corynebacterium striatum</i>	97	96	49	0	0	2	0	0	1	81	37	99	90	6	70	82	1	98	98	0	
<i>Corynebacterium ulcerans</i>	97	0	95	88	97	0	8	2	1	88	40	99	99	1	33	62	98	0	98	0	
<i>Corynebacterium urealyticum</i> (D-2)	1	0	3	1	0	0	0	0	0	0	38	1	66	1	7	66	99	0	98	0	
<i>Corynebacterium xerosis</i>	98	96	90	90	96	0	4	0	0	84	22	96	76	0	51	88	1	61	99	0	
Gruppo CDC F-1	98	1	96	88	0	0	0	0	0	1	1	98	79	0	2	39	99	24	96	0	
Gruppo CDC G (G/LD)	96	82	88	0	0	0	0	0	0	77	21	99	31	71	68	82	0	50	96	0	
Gruppo CDC I1	90	0	8	2	0	0	0	0	0	98	32	98	76	0	0	6	1	91	97	0	
<i>Listeria grayi/murrayi</i>	95	4	95	90	98	99	99	56	0	1	92	1	47	3	8	12	1	58	98	0	
<i>Listeria innocua</i>	96	2	0	92	98	99	99	31	0	1	96	0	92	0	12	8	0	0	98	0	
<i>Listeria ivanovii</i>	96	12	33	95	76	95	99	0	0	2	88	1	37	0	8	21	1	0	98	0	
<i>Listeria monocytogenes</i>	96	2	7	96	99	99	99	14	0	0	96	0	80	0	1	9	1	0	96	0	
<i>Listeria seeligeri</i>	96	2	0	95	98	98	98	0	0	4	96	1	42	0	10	22	1	0	95	0	
<i>Listeria welshimeri</i>	96	5	1	96	69	99	99	73	0	2	96	1	81	0	15	33	2	0	95	0	
<i>Actinomyces israelii</i>	98	95	92	13	99	97	2	4	87	2	8	98	64	19	86	90	2	31	0	0	
<i>Actinomyces naeslundii</i>	90	82	13	90	86	96	0	2	91	11	2	98	65	1	71	87	94	77	0	0	
<i>Actinomyces viscosus</i>	96	98	62	96	92	90	0	7	91	5	6	92	1	0	76	88	82	96	98	0	
<i>Arcanobacterium haemolyticum</i>	95	9	88	83	98	26	92	99	84	88	86	81	66	72	78	90	2	3	0	0	
<i>Arcanobacterium pyogenes</i> (nota anche come <i>Trueperella pyogenes</i>)	92	24	82	77	98	0	69	89	90	53	18	90	3	2	83	90	1	0	0	0	
<i>Bifidobacterium</i> spp. (Gp E)	91	90	39	90	95	74	15	0	43	2	44	83	16	5	11	3	1	0	0	0	
<i>Brevibacterium casei</i>	0	0	5	1	93	0	35	0	0	49	16	99	88	28	78	86	1	7	99	9	
<i>Brevibacterium</i> spp. (Gp B)	1	0	9	0	4	3	29	1	1	88	19	96	86	11	76	90	5	9	95	16	
<i>Cellulomonas</i> spp. (Gp A3/A4)	98	98	66	98	98	99	90	7	88	96	81	89	80	96	75	80	1	84	96	76	
<i>Corynebacterium otitidis</i> ^c	0	0	0	0	0	0	0	0	0	95	92	99	99	0	96	57	0	0	98	0	
<i>Dermabacter hominis</i>	95	90	77	88	99	91	98	92	95	71	63	29	92	98	88	77	0	0	98	0	
<i>Erysipelothrix rhusiopathiae</i>	88	0	9	0	0	12	99	2	93	80	2	85	73	93	30	19	0	0	3	0	
<i>Exiguobacterium acetylicum</i>	98	98	78	98	99	98	1	0	91	20	1	0	2	0	0	0	1	0	99	92	
<i>Leifsonia aquatica</i> ^b	28	0	8	9	99	94	96	88	16	4	2	98	88	2	91	87	1	8	98	95	
<i>Microbacterium</i> spp.	98	98	87	92	99	90	98	1	96	66	36	8	77	5	80	29	1	5	98	86	
<i>Oerskovia</i> spp.	98	97	41	90	96	98	90	33	81	11	7	98	92	28	79	90	1	45	98	94	
<i>Rhodococcus equi</i>	18	2	12	2	80	82	0	2	18	94	96	91	88	4	35	87	61	55	95	0	
<i>Rothia</i> spp.	92	90	0	77	99	55	0	0	0	3	1	98	90	88	91	96	0	81	98	0	
<i>Schaalia odontolyticus</i> ^c	92	90	12	65	81	66	3	2	86	14	38	98	13	0	92	82	1	91	0	0	
<i>Trueperella bernardiae</i> ^a	60	0	40	45	96	0	99	0	0	5	0	90	15	4	63	74	1	0	0	0	
<i>Winkia neuII</i> ^d	74	59	62	54	99	2	2	74	92	1	57	99	13	1	40	98	1	18	96	0	

^aPrecedentemente designato come *Arcanobacterium bernardiae* e prima ancora come *Actinomyces bernardiae* (gruppo 2)

^bPrecedentemente designato come *Corynebacterium aquaticum*

^cPrecedentemente designato come *Actinomyces odontolyticus*

^dPrecedentemente designato come *Actinomyces neuII* (Gp 1)

^aPrecedentemente designato come *Turicella otitidis*

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Versione	Data delle modifiche introdotte
IFU8311008	Agosto 2023 Aggiornato per soddisfare i requisiti IVDR

Stampato nel Regno Unito

Tabela 3. Karta kontroli jakości dla paneli RapID CB Plus

Mikroorganizm	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT
<i>Paenibacillus polymyxa</i> ATCC™ 842	+	+	+	+	+	+	+	V	+	+	+	–	–	–	–	–	–	+
<i>Corynebacterium pseudodiphtheriticum</i> ATCC™ 10701	–	–	–	–	–	–	–	–	–	V	–	+	+	–	+	+	+	+
<i>Arcanobacterium pyogenes</i> ^a ATCC™ 19411 (gatunek znany również jako <i>Trueperella pyogenes</i>)	+	–	V	V	+	–	V	+	+	–	V	+	V	+	V	+	–	–

+, wynik dodatni; –, wynik ujemny; V, wynik zmienny

^a **Kluczowe szczepy wskaźnikowe** wykazują akceptowalne działanie w przypadku najbardziej nietrwałego substratu w systemie i reaktywność w znaczącej liczbie dołków, zgodnie z zaleceniami instytutu Clinical and Laboratory Standards Institute dotyczącymi usprawnionej kontroli jakości¹⁶.

Uwagi:

- Kontrola jakości odczynników RapID polega na uzyskaniu reakcji oczekiwanych dla testów wymagających dodania danych odczynników (komory 12–16 i 18).
- Mikroorganizmy, które były wielokrotnie przenoszone na pożywki agarowe przez dłuższy czas, mogą dawać nieprawidłowe wyniki.
- Szczepy do kontroli jakości należy przechowywać w postaci zamrożonej lub liofilizowanej. Przed użyciem przechowywane szczepy do kontroli jakości należy posiać 2–3 razy na agar zalecany do stosowania z systemem RapID CB Plus.
- Receptury, dodatki i składniki pożywek hodowlanych różnią się w zależności od producenta i mogą różnić się między partiami. W rezultacie podłoże hodowlane może wpływać na konstytutywną aktywność enzymatyczną szczepów wybranych do kontroli jakości. Jeśli wyniki uzyskane dla szczepów do kontroli jakości różnią się od wskazanych wzorów, często możliwe jest wyeliminowanie rozbieżnych wyników uzyskiwanych podczas kontroli jakości poprzez przeprowadzenie hodowli podrzędnej na pożywce z innej partii lub od innego producenta.

15. OGRANICZENIA

- Do korzystania z systemu RapID CB PLUS i interpretacji uzyskanych wyników niezbędna jest wiedza wykwalifikowanego mikrobiologa zaznajomionego z procedurami laboratoryjnymi, przeszkolonego w zakresie ogólnych metod mikrobiologicznych i umiejętnie korzystającego z wiedzy przekazanej podczas szkolenia, zdobytego doświadczenia, informacji o próbkach i innych stosownych procedur przed zgłoszeniem wyników identyfikacji uzyskanych przy użyciu tego systemu.
- Systemu RapID CB Plus należy używać z czystymi kulturami badanych mikroorganizmów. Wykorzystanie mieszanych populacji mikroorganizmów lub bezpośrednie badanie materiału klinicznego bez prowadzenia hodowli spowoduje uzyskanie nieprawidłowych wyników.
- System RapID CB Plus jest przeznaczony do użytku z taksonami wymienionymi na kartach różnicowania mikroorganizmów za pomocą systemu RapID CB Plus. Nie należy badać Gram-dodatnich pałeczek wytwarzających przetrwalniki ani pałeczek Gram-ujemnych.
- Wartości oczekiwane określone dla testów zawartych w systemie RapID CB Plus mogą różnić się od wyników testów konwencjonalnych lub poprzednio zgłoszonych informacji.
- Dokładność systemu RapID CB Plus bazuje na statystycznym wykorzystaniu wielu specjalnie zaprojektowanych testów i dedykowanej, zastrzeżonej bazy danych. Wykorzystanie jakiegokolwiek pojedynczego testu zawartego w systemie RapID CB Plus w celu identyfikacji badanego izolatu jest obarczone błędem właściwym tylko dla tego testu.

Tabela 4 — Karta różnicowania mikroorganizmów za pomocą systemu RapID CB Plus

Mikroorganizm	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT	CAT	PIG
<i>Corynebacterium accolens</i>	95	11	29	0	0	0	0	0	0	0	0	99	1	1	0	0	7	51	99	0
<i>Corynebacterium afermentans subsp. afermentans</i>	0	0	0	0	0	0	0	0	0	88	38	86	26	0	3	47	1	1	98	0
<i>Corynebacterium afermentans subsp. lipophilum</i>	0	0	0	0	0	0	0	0	0	0	9	98	0	0	0	0	0	0	98	0
<i>Corynebacterium amycolatum</i>	97	41	70	80	4	0	0	0	0	97	88	99	93	0	9	11	18	76	98	0
<i>Corynebacterium argentoratense</i>	98	0	5	0	0	0	0	0	0	14	69	99	90	0	7	82	0	0	98	0
<i>Corynebacterium auris</i>	0	0	0	0	0	90	0	0	0	96	95	99	71	1	8	76	1	1	98	0
<i>Corynebacterium bovis</i>	28	8	3	13	0	0	0	2	99	19	9	90	9	0	9	71	8	0	98	0
<i>Corynebacterium cystitidis</i>	90	0	0	0	0	0	0	90	0	95	5	33	45	9	28	88	99	0	98	0
<i>Corynebacterium diphtheriae</i>	98	2	81	90	99	0	0	0	0	1	24	99	21	1	30	41	0	28	98	0
<i>Corynebacterium glucuronolyticum</i>	95	86	91	24	0	7	0	99	0	6	11	99	86	6	48	78	71	19	98	0
<i>Corynebacterium jeikeium</i> (JK)	88	2	78	9	1	1	0	0	0	85	92	0	58	1	41	69	1	2	98	0
<i>Corynebacterium kutscheri</i>	96	93	82	96	93	99	0	0	0	0	58	96	90	99	98	95	99	81	98	0
<i>Corynebacterium matruchotii</i>	70	62	74	65	2	80	2	2	20	8	15	90	82	93	91	0	0	98	98	0
<i>Corynebacterium minutissimum</i>	98	73	76	99	3	9	0	0	4	83	27	99	78	1	74	88	0	0	98	0
<i>Corynebacterium propinquum</i> (ANF3)	0	0	0	0	0	0	0	0	0	91	63	6	79	33	70	57	2	99	98	0
<i>Corynebacterium pseudodiphtheriticum</i>	0	0	0	0	1	0	0	0	0	22	9	96	66	31	72	82	99	86	98	0
<i>Corynebacterium pseudotuberculosis</i>	84	4	85	30	18	0	0	0	0	4	7	99	78	0	69	74	99	0	98	13
<i>Corynebacterium renale</i>	88	2	11	0	0	0	12	99	7	5	2	98	14	1	0	0	99	0	90	58
<i>Corynebacterium striatum</i>	97	96	49	0	0	2	0	0	1	81	37	99	90	6	70	82	1	98	98	0
<i>Corynebacterium ulcerans</i>	97	0	95	88	97	0	8	2	1	88	40	99	99	1	33	62	98	0	98	0
<i>Corynebacterium urealyticum</i> (D-2)	1	0	3	1	0	0	0	0	0	0	38	1	66	1	7	66	99	0	98	0
<i>Corynebacterium xerosis</i>	98	96	90	90	96	0	4	0	0	84	22	96	76	0	51	88	1	61	99	0
CDC, grupa F-1	98	1	96	88	0	0	0	0	0	1	1	98	79	0	2	39	99	24	96	0
CDC, grupa G (G/LD)	96	82	88	0	0	0	0	0	0	77	21	99	31	71	68	82	0	50	96	0
CDC, grupa 11	90	0	8	2	0	0	0	0	0	98	32	98	76	0	0	6	1	91	97	0
<i>Listeria grayi/murrayi</i>	95	4	95	90	98	99	99	56	0	1	92	1	47	3	8	12	1	58	98	0
<i>Listeria innocua</i>	96	2	0	92	98	99	99	31	0	1	96	0	92	0	12	8	0	0	98	0
<i>Listeria ivanovii</i>	96	12	33	95	76	95	99	0	0	2	88	1	37	0	8	21	1	0	98	0
<i>Listeria monocytogenes</i>	96	2	7	96	99	99	99	14	0	0	96	0	80	0	1	9	1	0	96	0
<i>Listeria seeligeri</i>	96	2	0	95	98	98	98	0	0	4	96	1	42	0	10	22	1	0	95	0
<i>Listeria welshimeri</i>	96	5	1	96	69	99	99	73	0	2	96	1	81	0	15	33	2	0	95	0
<i>Actinomyces israelii</i>	98	95	92	13	99	97	2	4	87	2	8	98	64	19	86	90	2	31	0	0
<i>Actinomyces naeslundii</i>	90	82	13	90	86	96	0	2	91	11	2	98	65	1	71	87	94	77	0	0
<i>Actinomyces viscosus</i>	96	98	62	96	92	90	0	7	91	5	6	92	1	0	76	88	82	96	98	0
<i>Arcanobacterium haemolyticum</i>	95	9	88	83	98	26	92	99	84	88	86	81	66	72	78	90	2	3	0	0
<i>Arcanobacterium pyogenes</i> (gatunek znany również jako <i>Trueperella pyogenes</i>)	92	24	82	77	98	0	69	89	90	53	18	90	3	2	83	90	1	0	0	0
<i>Bifidobacterium</i> spp. (Gp E)	91	90	39	90	95	74	15	0	43	2	44	83	16	5	11	3	1	0	0	0
<i>Brevibacterium casei</i>	0	0	5	1	93	0	35	0	0	49	16	99	88	28	78	86	1	7	99	9
<i>Brevibacterium</i> spp. (Gp B)	1	0	9	0	4	3	29	1	1	88	19	96	86	11	76	90	5	9	95	16
<i>Cellulomonas</i> spp. (Gp A3/A4)	98	98	66	98	98	99	90	7	88	96	81	89	80	96	75	80	1	84	96	76
<i>Corynebacterium otitidis</i> ^a	0	0	0	0	0	0	0	0	0	95	92	99	99	0	96	57	0	0	98	0
<i>Dermabacter hominis</i>	95	90	77	88	99	91	98	92	95	71	63	29	92	98	88	77	0	0	98	0
<i>Erysipelothrix rhusiopathiae</i>	88	0	9	0	0	12	99	2	93	80	2	85	73	93	30	19	0	0	3	0
<i>Exiguobacterium acetylicum</i>	98	98	78	98	99	98	1	0	91	20	1	0	2	0	0	0	1	0	99	92
<i>Leifsonia aquatica</i> ^a	28	0	8	9	99	94	96	88	16	4	2	98	88	2	91	87	1	8	98	95
<i>Microbacterium</i> spp.	98	98	87	92	99	90	98	1	96	66	36	8	77	5	80	29	1	5	98	86
<i>Oerskovia</i> spp.	98	97	41	90	96	98	90	33	81	11	7	98	92	28	79	90	1	45	98	94
<i>Rhodococcus equi</i>	18	2	12	2	80	82	0	2	18	94	96	91	88	4	35	87	61	55	95	0
<i>Rothia</i> spp.	92	90	0	77	99	55	0	0	0	3	1	98	90	88	91	96	0	81	98	0
<i>Schaalia odontolyticus</i> ^c	92	90	12	65	81	66	3	2	86	14	38	98	13	0	92	82	1	91	0	0
<i>Trueperella bernardiae</i> ^a	60	0	40	45	96	0	99	0	0	5	0	90	15	4	63	74	1	0	0	0
<i>Winkia neuII</i> ^d	74	59	62	54	99	2	2	74	92	1	57	99	13	1	40	98	1	18	96	0

^a Mikroorganizm poprzednio identyfikowany jako *Arcanobacterium bernardiae*, a jeszcze wcześniej jako *Actinomyces bernardiae* (grupa 2)

^b Mikroorganizm poprzednio identyfikowany jako *Corynebacterium aquaticum*

^c Mikroorganizm poprzednio identyfikowany jako *Actinomyces odontolyticus*

^d Mikroorganizm poprzednio identyfikowany jako *Actinomyces neuII* (Gp 1)

^e Mikroorganizm poprzednio identyfikowany jako *Turicella otitidis*

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Wersja	Data wprowadzenia zmian
IFU8311008	Sierpień 2023 r. Zaktualizowano w celu spełnienia wymogów rozporządzenia IVDR

Wydrukowano w Wielkiej Brytanii

Tabelul 3. Diagrama controlului de calitate pentru panelurile Rapid CB Plus

Organism (Microorganism)	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT
<i>Paenibacillus polymyxa</i> ATCC™ 842	+	+	+	+	+	+	+	V	+	+	+	–	–	–	–	–	–	+
<i>Corynebacterium pseudodiphtheriticum</i> ATCC™ 10701	–	–	–	–	–	–	–	–	–	V	–	+	+	–	+	+	+	+
<i>Arcanobacterium pyogenes</i> ^a ATCC™ 19411 (cunoscut și drept <i>Trueperella pyogenes</i>)	+	–	V	V	+	–	V	+	+	–	V	+	V	+	V	+	–	–

+, pozitiv; –, negativ; V, variabil

^a **Tulpinile indicatoare cheie** demonstrează performanța acceptabilă a celui mai labil substrat din sistem și reactivitatea într-un număr semnificativ de godeuri, conform recomandărilor Clinical and Laboratory Standards Institute pentru un control eficient al calității.¹⁶

Testarea pentru controlul de calitate trebuie efectuată cu fiecare livrare și număr de lot nou primite.

Este responsabilitatea utilizatorului să efectueze teste de control al calității în conformitate cu orice reglementări și cerințe locale aplicabile.

Note:

- Controlul de calitate al reactivilor Rapid se realizează prin obținerea reacțiilor preconizate pentru testele care necesită adăugarea reactivilor (cavitățile 12-16 și 18).
- Organismele care au fost transferate în mod repetat pe medii cu agar pentru perioade prelungite pot furniza rezultate aberante.
- Tulpinile pentru controlul de calitate trebuie depozitate înghețate sau liofilizate. Înainte de utilizare, tulpinile de control al calității trebuie transferate de 2-3 ori din locul de depozitare pe un mediu cu agar care este recomandat pentru utilizarea cu sistemul Rapid CB Plus.
- Formulele, aditivii și ingredientele mediului de cultură variază de la producător la producător și pot varia de la lot la lot. Ca rezultat, mediile de cultură pot influența activitatea enzimatică constitutivă a tulpinilor de control al calității desemnate. Dacă rezultatele tulpinilor de control al calității diferă de modelele indicate, o subcultură pe mediu dintr-un lot diferit sau de la alt producător va rezolva adesea discrepanțele privind controlul calității.

15. LIMITE

- Utilizarea sistemului Rapid CB PLUS și interpretarea rezultatelor necesită cunoștințele unui microbiolog competent, familiarizat cu procedurile de laborator, care este instruit în metode microbiologice generale și care utilizează în mod judicios instruirea, experiența, informațiile despre probe și alte proceduri pertinente înainte de raportarea identificării obținute cu ajutorul acestui sistem.
- Sistemul Rapid CB Plus trebuie utilizat cu culturi pure ale organismelor de test. Utilizarea populațiilor microbiene mixte sau testarea directă a materialului clinic fără cultură va genera rezultate aberante.
- Sistemul Rapid CB Plus este conceput pentru a fi utilizat cu taxonii enumerați în diagrama diferențială Rapid CB Plus. Bacilii gram-pozitivi care formează spori sau bacilii gram-negativi nu trebuie testați.
- Valorile așteptate enumerate pentru testele sistemului Rapid CB Plus pot diferi de rezultatele testelor convenționale sau de informațiile raportate anterior.

Tabelul 4 - diagrama diferențială Rapid CB Plus

Organism (Microorganism)	GLU	SUC	RIB	MAL	αGLU	βGLU	NAG	GLY1	ONPG	PHS	EST	PRO	TRY	PYR	LGLY	LEU	URE	NIT	CAT	PIG
<i>Corynebacterium accolens</i>	95	11	29	0	0	0	0	0	0	0	0	99	1	1	0	0	7	51	99	0
<i>Corynebacterium afermentans subsp. afermentans</i>	0	0	0	0	0	0	0	0	0	88	38	86	26	0	3	47	1	1	98	0
<i>Corynebacterium afermentans subsp. lipophilum</i>	0	0	0	0	0	0	0	0	0	0	9	98	0	0	0	0	0	0	98	0
<i>Corynebacterium amycolatum</i>	97	41	70	80	4	0	0	0	0	97	88	99	93	0	9	11	18	76	98	0
<i>Corynebacterium argentoratense</i>	98	0	5	0	0	0	0	0	0	14	69	99	90	0	7	82	0	0	98	0
<i>Corynebacterium auris</i>	0	0	0	0	0	90	0	0	0	96	95	99	71	1	8	76	1	1	98	0
<i>Corynebacterium bovis</i>	28	8	3	13	0	0	0	2	99	19	9	90	9	0	9	71	8	0	98	0
<i>Corynebacterium cystitidis</i>	90	0	0	0	0	0	0	90	0	95	5	33	45	9	28	88	99	0	98	0
<i>Corynebacterium diphtheriae</i>	98	2	81	90	99	0	0	0	0	1	24	99	21	1	30	41	0	28	98	0
<i>Corynebacterium glucuronolyticum</i>	95	86	91	24	0	7	0	99	0	6	11	99	86	6	48	78	71	19	98	0
<i>Corynebacterium jeikeium</i> (JK)	88	2	78	9	1	1	0	0	0	85	92	0	58	1	41	69	1	2	98	0
<i>Corynebacterium kutscheri</i>	96	93	82	96	93	99	0	0	0	0	58	96	90	99	98	95	99	81	98	0
<i>Corynebacterium matruchotii</i>	70	62	74	65	2	80	2	2	20	8	15	90	82	93	91	0	0	98	98	0
<i>Corynebacterium minutissimum</i>	98	73	76	99	3	9	0	0	4	83	27	99	78	1	74	88	0	0	98	0
<i>Corynebacterium propinquum</i> (ANF3)	0	0	0	0	0	0	0	0	0	91	63	6	79	33	70	57	2	99	98	0
<i>Corynebacterium pseudodiphtheriticum</i>	0	0	0	0	1	0	0	0	0	22	9	96	66	31	72	82	99	86	98	0
<i>Corynebacterium pseudotuberculosis</i>	84	4	85	30	18	0	0	0	0	4	7	99	78	0	69	74	99	0	98	13
<i>Corynebacterium renale</i>	88	2	11	0	0	0	12	99	7	5	2	98	14	1	0	0	99	0	90	58
<i>Corynebacterium striatum</i>	97	96	49	0	0	2	0	0	1	81	37	99	90	6	70	82	1	98	98	0
<i>Corynebacterium ulcerans</i>	97	0	95	88	97	0	8	2	1	88	40	99	99	1	33	62	98	0	98	0
<i>Corynebacterium urealyticum</i> (D-2)	1	0	3	1	0	0	0	0	0	0	38	1	66	1	7	66	99	0	98	0
<i>Corynebacterium xerosis</i>	98	96	90	90	96	0	4	0	0	84	22	96	76	0	51	88	1	61	99	0
Grupul CDC F-1	98	1	96	88	0	0	0	0	0	1	1	98	79	0	2	39	99	24	96	0
Grupul CDC G (G/LD)	96	82	88	0	0	0	0	0	0	77	21	99	31	71	68	82	0	50	96	0
Grupul CDC I1	90	0	8	2	0	0	0	0	0	98	32	98	76	0	0	6	1	91	97	0
<i>Listeria grayi/murrayi</i>	95	4	95	90	98	99	99	56	0	1	92	1	47	3	8	12	1	58	98	0
<i>Listeria innocua</i>	96	2	0	92	98	99	99	31	0	1	96	0	92	0	12	8	0	0	98	0
<i>Listeria ivanovii</i>	96	12	33	95	76	95	99	0	0	2	88	1	37	0	8	21	1	0	98	0
<i>Listeria monocytogenes</i>	96	2	7	96	99	99	99	14	0	0	96	0	80	0	1	9	1	0	96	0
<i>Listeria seeligeri</i>	96	2	0	95	98	98	98	0	0	4	96	1	42	0	10	22	1	0	95	0
<i>Listeria welshimeri</i>	96	5	1	96	69	99	99	73	0	2	96	1	81	0	15	33	2	0	95	0
<i>Actinomyces israelii</i>	98	95	92	13	99	97	2	4	87	2	8	98	64	19	86	90	2	31	0	0
<i>Actinomyces naeslundii</i>	90	82	13	90	86	96	0	2	91	11	2	98	65	1	71	87	94	77	0	0
<i>Actinomyces viscosus</i>	96	98	62	96	92	90	0	7	91	5	6	92	1	0	76	88	82	96	98	0
<i>Arcanobacterium haemolyticum</i>	95	9	88	83	98	26	92	99	84	88	86	81	66	72	78	90	2	3	0	0
<i>Arcanobacterium pyogenes</i> (cunoscut și drept <i>Trueperella pyogenes</i>)	92	24	82	77	98	0	69	89	90	53	18	90	3	2	83	90	1	0	0	0
<i>Bifidobacterium</i> spp. (gr. E)	91	90	39	90	95	74	15	0	43	2	44	83	16	5	11	3	1	0	0	0
<i>Brevibacterium casei</i>	0	0	5	1	93	0	35	0	0	49	16	99	88	28	78	86	1	7	99	9
<i>Brevibacterium</i> spp. (Gr. B)	1	0	9	0	4	3	29	1	1	88	19	96	86	11	76	90	5	9	95	16
<i>Cellulomonas</i> spp. (gr. A3/A4)	98	98	66	98	98	99	90	7	88	96	81	89	80	96	75	80	1	84	96	76
<i>Corynebacterium otitidis</i> ^a	0	0	0	0	0	0	0	0	0	95	92	99	99	0	96	57	0	0	98	0
<i>Dermabacter hominis</i>	95	90	77	88	99	91	98	92	95	71	63	29	92	98	88	77	0	0	98	0
<i>Erysipelothrix rhusiopathiae</i>	88	0	9	0	0	12	99	2	93	80	2	85	73	93	30	19	0	0	3	0
<i>Exiguobacterium acetylicum</i>	98	98	78	98	99	98	1	0	91	20	1	0	2	0	0	0	1	0	99	92
<i>Leifsonia aquatica</i> ^b	28	0	8	9	99	94	96	88	16	4	2	98	88	2	91	87	1	8	98	95
<i>Microbacterium</i> spp.	98	98	87	92	99	90	98	1	96	66	36	8	77	5	80	29	1	5	98	86
<i>Oerskovia</i> spp.	98	97	41	90	96	98	90	33	81	11	7	98	92	28	79	90	1	45	98	94
<i>Rhodococcus equi</i>	18	2	12	2	80	82	0	2	18	94	96	91	88	4	35	87	61	55	95	0
<i>Rothia</i> spp.	92	90	0	77	99	55	0	0	0	3	1	98	90	88	91	96	0	81	98	0
<i>Schaalia odontolyticus</i> ^c	92	90	12	65	81	66	3	2	86	14	38	98	13	0	92	82	1	91	0	0
<i>Trueperella bernardiae</i> ^a	60	0	40	45	96	0	99	0	0	5	0	90	15	4	63	74	1	0	0	0
<i>Winkia neuji</i> ^d	74	59	62	54	99	2	2	74	92	1	57	99	13	1	40	98	1	18	96	0

^a Desemnat anterior drept *Arcanobacterium bernardiae* și înainte *Actinomyces bernardiae* (grup 2)

^b Desemnat anterior drept *Corynebacterium aquaticum*

^c Desemnat anterior drept *Actinomyces odontolyticus*

^d Desemnat anterior drept *Actinomyces neuji* (Gp 1)

^e Desemnat anterior drept *Turicella otitidis*

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