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**Comparative study  
bioMérieux (Marcy-l'Etoile, Rhone, France)  
and DIAGNOSTICS (Galanta, Slovakia)**

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# 1. Introduction

The purpose of the study was comparison of two identification systems of companies bioMérieux (Marcy-l'Etoile, Rhone, FR) and DIAGNOSTICS (Galanta, Slovakia) in phenotypic bacterial identification segment of manual phenotype identification.

## 1.1 Used shortcuts

bioM	bioMérieux (Marcy-l'Etoile, Rhone, France)
CCM	Czech Collection of Microorganisms

# 2. Parameters of comparative study

Main diagnostic kits, having its equivalents in offer of both companies. We compared bioMérieux API kits. We selected diagnostic kits with the closest identification field to kits of company DIAGNOSTICS. These kits represents the best selling diagnostics.

Bacterial strains used in this study comes from Czech Collection of Microorganisms (CCM) and from routine traffic of bacteriological laboratories of company HPL i.n.c. (the biggest medical microbiology laboratories network in Slovakia), which were previously identified by diagnostics of company BIO-RAD, ERBA - Lachema i.n.c., or by MALDI-TOF method (Bruker Daltonics).

Each bacterial strain was tested simultaneously on products of DIAGNOSTICS and bioM. In case of misidentification, analysis was repeated and in case of satisfying output, result of identification was accepted as successful. In opposite case, the result was not accepted. Bacterial sample was excluded in some cases. Exclusion is commented and result was annulled in comparison of both manufacturers, even if the results was correct or incorrect in one of manufacturers tests. DIAGNOSTICS kits are designed to universal use, i.e. it was necessary to compare one kit of DIAGNOSTICS with two kits of bioM to get identic cover of bacterial species. Yeasts were tested externally in accredited laboratory IFCOR 99 (Brno, Czech Republic) and results of study were received from separate study.

Following products were selected for particular groups of microorganisms:

Group of microorganisms	DIAGNOSTICS	bioMérieux
Enterobacteriaceae	GN 24	api 20 E
G - nonfermenting rods	GN 24	api 20 NE
Staphylococcus	GP 24	api 20 STAPH
Streptococcus	GP 24	api 20 STREP
Neisseria	NEISS 8	api NH
Yeast	YST 8	api Candida

### Identification systems – short comparison

Manufacturer	DIAGNOSTICS	bioMérieux	bioMérieux	REMEL	REMEL	BD
ID kit	GN 24	API 20 E	API 20 NE	rapid NF PLUS	rapid ONE	BBL CRYSTAL E/NF System
Gram negative glucose fermenting rods	yes	yes	no	yes	yes	yes
Gram negative glucose nonfermenting rods	yes	no	yes	yes	no	yes
Number of tests	24-29	20	20	17	19	30
Number of genus/species	more than 150	94	60	70	70	105
suspending medium required	no	yes	yes	yes	yes	yes
actual taxonomy	yes (04/2013)	no	no	no	no	no
colorimetric tests	yes	yes	turbidity	yes	yes	yes
Evaluation in hours	18-24	18-24/48	24-48	4	4	18-20
possibility to work without reagents	yes	no	no	no	no	no
Reagents	optional	must be used	must be used	must be used	must be used	must be used
Pipetting	yes	yes	yes	no	no	no
Oil	yes	yes	yes	no	no	no
incubation temperature (°C)	35±2	36±1	29±2	-	-	34-36
Storage (°C)	2-25	2-8	2-8	2-8	2-8	2-25
Evaluation statistically / code book sw	statistically	electronic book	electronic code book	electronic code book	electronic code book	electronic code book
evaluation software availability	free	paid acces	paid acces	registration	registration	paid acces
Price in territory	-	-	-	-	-	-

## 3. Testing procedure

### A) GN 24 vs. Api 20 E

74 bacterial strains of gram-negative glucose fermenting bacteria were compared. Twelve of them were CCM bacterial strains and remaining 62 of them were clinical isolates.

**Results:**

Parameter	DIAGNOSTICS	bioM
Identification efficiency of CCM strains (%)	100 (12/12)	83,3 (10/12)
Identification efficiency of clinical isolates (%)	85,5 (53/62)	69,4 (43/62)
Overall id. efficiency (%)	87,8 (65/74)	71,6 (53/74)
Species / genus identification (%)	60,8 / 27 % from 87,8 %	33 / 39 % from 71,6 %
Unidentified - unacceptable profile (%)	8,1 (6/74)	9,4 (7/74)
misidentification (%)	4 (3/74)	18,9 (14/74)
ID matrix – No. of species		

Commentary on api 20E

Substitution of *Klebsiella pneumoniae* ssp. *pneumoniae* for *Klebsiella pneumoniae* ssp. *ozenae* (bioM 2x) was accepted. Substitution of *Klebsiella pneumoniae* ssp. *pneumoniae* for *Klebsiella oxytoca* (bioM 1x) was accepted. Substitution of *Klebsiella pneumoniae* ssp. *Pneumoniae* for *Raoultella terrigena* (bioM 2x) was not accepted. Significant genus substitution were by citrobacter / enterobacter in kit api 20 E. Relatively a large number of wrong identifications occurred.

Outdated taxonomy in the identification matrix:

Outdated taxonomy	Actual taxonomy
Enterobacter sakazakii	Cronobacter sakazakii
<i>Salmonella choleraesuis</i>	<i>Salmonella enterica</i>
<i>Salmonella gallinarum</i>	-
<i>Salmonella arizonae</i>	<i>Salmonella enterica</i> ssp. <i>arizonae</i>
<i>Salmonella paratyphi</i>	<i>Salmonella enterica</i> ssp. <i>enterica</i>
<i>Salmonella pullorum</i>	<i>Salmonella enterica</i> ssp. <i>enterica</i> serovar <i>pullorum</i> – this type of test can not detect serovar!
<i>Salmonella typhi</i>	<i>Salmonella enterica</i> ssp. <i>enterica</i>
<i>Photobacterium damsela</i>	<i>Photobacterium damselae</i>

Commentary on GN 24

Identification of *Proteus vulgaris* CCM 1799 as *Proteus* sp. was accepted. *Vibrio parahaemolyticus* was not identified. Substitution of *Shigella boydii* for *Shigella dysenteriae* was accepted as genus identification. Substitution of genus citrobacter / enterobacter has not occurred. Results of unidentified samples were comparable. Occurrence of wrongly identified samples was significantly lower

**B) GN 24 vs. Api 20 NE**

37 bacterial strains of gram-negative glucose nonfermenting bacteria were compared. Four of them were CCM and 33 were clinical isolates. Results of API 20 NE kit were readed / evaluated after 24 hours, and also after 48 hours. Results are marked in separate columns. Results of GN 24 kit were evaluated only once - after 24 hours.

**Results:**

Parameter	DIAGNOSTICS	bioM (24 hours)	bioM (48 hours)
Identification efficiency of CCM strains (%)	100 (4/4)	50 (2/4)	75 (3/4)
Identification efficiency of clinic isolates (%)	69,7 (23/33)	27,3 (9/33)	39,4 (13/33)
Overall id. efficiency (%)	73 (27/37)	29,7 (11/37)	43,2 (16/37)
Species / genus identification (%)	40,5 % / 32,4 % from 73 %	21,6 % / 8,1 % from 29,7 %	29,7% / 13,5 % from 43,2 %
Unidentified (%) (unacceptable profile)	18,9 (7/37)	56,8 (21/37)	43,2 (16/37)
misidentification (%)	8,1 % (3/37)	13,5 (5/37)	13,5 (5/37)

Commentary on api 20NE

Results of identification were evaluated after 24 hours. In case, that results were satisfactory, they were closed and they were not evaluated more. Results, that were not satisfactory after 24 hours, were incubated for next 24 hours. Then, the results were finally closed and evaluated. Trend was captured in some cases, when the right result was evaluated as unsatisfactory after 24 hours. This fact was not evaluated. There was captured relatively high percentage of results evaluated as „unacceptable profile“, which were marked as „unidentified“.

Commentary on GN 24

Identification of acinetobacters was without problems. Right identification of most common occurring species *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia* and *Burkholderia cepacia*. Occurrence of wrong identifications was much lower.

**C) GP 24 vs. Api 20 STAPH**

45 bacterial species of gram-positive catalase positive coccus were compared. Ten of them were CCM and 35 were clinical isolates.

**Results:**

Parameter	DIAGNOSTICS	bioM
Identification efficiency of CCM strains (%)	100 (10/10)	60 (6/10)
Identification efficiency of clinic isolates (%)	85,7 (30/35)	54,3 (19/35)
Overall id. efficiency (%)	88,9 (40/45)	55,6 (25/45)
Species / genus identification (%)	77,8 % / 11,1 % from 88,9 %	37,8 % / 17,7 % from 55,6 %
Unidentified (%) (unacceptable profile)	8,9 (4/45)	33,3 (15/45)
Misidentification (%)	2,2 % (1/45)	11,1 (5/45)

Commentary on api 20 STAPH

Relatively low identification efficiency of diagnostic kit with high part of unidentified samples was observed. Number of wrong identifications was average. Database of microorganisms is not completely actual.

Commentary on GP 24

Between API 20 STAPH and GP 24 was the most significant difference in identification efficiency from all tested kits.

**D) GP 24 vs. Api 20 STREP**

55 bacterial strains of gram-positive catalase negative coccus were compared. 9 of them were CCM and other 46 were clinical isolates, 12 of clinical isolates were enterococcus.

**Results:**

Parameter	DIAGNOSTICS	bioM
Identification efficiency of CCM strains in %	77,8 (7/9)	88,9 (8/9)
Identification efficiency of clinic isolates in %	65,2 (30/46)	60,9 (28/46)
Overall id. efficiency in %	67,3 (37/55)	65,5 (36/55)
Species / genus identification in %	49,1 % / 18,2 % from 67,3 %	45,5 % / 20 % from 65,5 %
Unidentified in % (unacceptable profile)	23,6 (13/55)	27,3 (15/55)
Identified wrongly in %	9,1 % (5/55)	7,3 (4/55)

Diagnostics of streptococcus by phenotype is not very suitable for this group of microorganisms and always gives only average results.

Commentary on api 20 STREP

Considering method possibilities, Kit gives above average results. *Streptococcus pneumoniae* identification is very good (better than BBL Crystal kit BD).

Commentary on GP 24

Diagnostic kit gives a little bit better identification efficiency than api 20 STREP. 6-7 from 10 samples were identified in average. Kit ENC 8 can be used for enterococcus identification, it has eight tests. Price is only about the third of the 24 tests kit then.

**E) NEISS 8 vs. Api NH**

20 bacterial strains of genus *Neisseria* and *Moraxella catarrhalis* were compared. 3 of them were CCM strains and 17 were clinical isolates.

**Results:**

Parameter	DIAGNOSTICS	bioM
Identification efficiency of CCM strains (%)	100 (3/3)	100 (3/3)
Identification efficiency of clinic isolates (%)	82,4 (14/17)	76,5 (13/17)
Overall id. efficiency (%)	85 (17/20)	80 (16/20)
Species / genus identification (%)	80 % / 5 % from 85 %	75 % / 5 % from 80 %
Unidentified (%) (unacceptable profile)	0 (0/20)	0 (0/20)
Misidentification (%)	15 % (3/20)	35 % (7/20)

Commentary on api NH

Kit gives very good results. Substitution of *Neisseria cinnarea* for *Neisseria elongate* was accepted, since their phenotypes are identical and they can be differentiated only by microscopy. Kit allows identification of *haemophilus* also (advantage of kit).

Commentary on NEISS 8

Diagnostic kit identification efficiency is above standard. Identification of *Neisseria gonorrhoeae* and *Neisseria meningitidis* is reliable. Both kits give results to 4 hours from beginning of incubation. No expensive inoculation fluid needed.

**F) YST 8 vs. Api Candida**

50 yeast strains were compared. 30 of them were CCM and 20 were clinical isolates. Testing was done externally at accredited laboratory IFCOR 99 (Brno, Czech republic).

**Results:**

Parameter	DIAGNOSTICS	bioM
Identification efficiency of CCM strains (%)	100 (30/30)	100 (30/30)
Identification efficiency of clinic isolates (%)	85 (17/20)	85 (17/20)
Overall id. efficiency (%)	94 (17/20)	94 (17/20)
Species / genus identification (%)	94 % / 0 % from 94 %	94 % / 0 % from 94 %
Unidentified (%) (unacceptable profile)	0 (0/50)	0 (0/50)
Misidentification (%)	0 (0/50)	0 (0/50)

Commentary on api Candida

Testing laboratory marked high percentage of false positive results of test URE. 9 of 10 samples were identified in average.

Commentary on YST 8

Testing laboratory appreciate absence of false positive and negative results by all tests. Identification efficiency was identical with api Candida product.

Both kits are highly above standard by screening of clinical significant species of yeasts. Benefit of YST 8 is higher working comfort and several times lower price for determination.

## 4. Conclusion

Comparative study confirmed high identification efficiency of DIAGNOSTICS i.n.c. kits. This fact confirms results of previous independent comparative study with products of ERBA Lachema i.n.c. (earlier PLIVA Lachema Diagnostics i.n.c.), which are most represented in regions of CZ and SK. Diagnostic kits identification efficiency shown that is fully comparable with bioMérieux kits which are considered as „gold standard“ in segment of manual phenotype identification. Identification efficiency is by half higher in some cases (GP 24 vs. Api STAPH). Products of DIAGNOSTICS i.n.c. offers some significant benefits to users - whether by its universality causing the reduction of microorganisms substitution and testing on inappropriate type of kit and time and finance loses connected with it, or with higher working comfort without use of suspensional medium or without necessity of use of additional reagents in some cases. In region of middle Europe is very significant factor the price of diagnostics, which is in case of DIAGNOSTICS i.n.c. products significantly lower than in case of bioMérieux company products.