

DL-96II Microbial ID & AST system VS BioMerieux VITEK 2 Compact Comparison Report

*Dr. H Liang & Dr. XL Yang, Bacteriological Lab, The Armed Police General Hospital,
P.R. China, 24th Nov, 2011*

Preface:

DL-96II Microbial ID & AST system is manufactured by Zhuhai DL Biotech Corp, which has a strong research and development center in America. Based on advanced international technologies of bacteria identification combined with the actual situation of domestic clinical use of antibiotics, the company follows up the international CLSI standard requirements to develop completed microbial identification and drug sensitivity system.

1. Clinical Test Comparison

Objective: To deeply understand identification and drug sensitivity performance of DL-96II Microbial ID & AST system, comparison experiments between 96E, 96-NE, 96-STAPH, 96-STAEF, 96-FUNGUS identification and drug sensitivity compound strip of DL-96II Microbial ID & AST system and marketing approved identification card and drug sensitivity card of VITEK 2 COMPACT produced by BioMerieux are performed.

Material requirements: collect 125 pieces of isolated strain, standard stain and QC strain, and perform comparison experiment strictly according to operating procedures in User Manual.

1. Bacterial identification comparison results are as below list 1, 2 and 3

List 1. QC strain

QC Strain No.	Qty (strain)	Identification Results	DL-96II Microbial ID & AST system(DL)		VITEK 2 COMPACT (BioMerieux)	
			accordance quantity (strain)	coincidence rate (%)	accordance quantity (strain)	coincidence rate (%)
ATCC25922	1	Escherichia coli	1	100	1	100
ATCC27853	1	Pseudomonas aeruginosa	1	100	1	100
ATCC29213	1	Staphylococcus aureus	1	100	1	100
ATCC29212	1	Enterococcus faecalis	1	100	1	100

ATCC6258	1	Candida krusei	1	100	1	100
Total	5		5	100	5	100

List 2. Standard strain:

QC Strain No.	Qty (strain)	Bacteria Name	DL-96II Microbial ID & AST system(DL)		VITEK2 COMPACT (BioMerieux)	
			accordance quantity (strain)	coincidence rate (%)	accordance quantity (strain)	coincidence rate(%)
Escherichia	5	Escherichia coli	5	100	5	100
Salmonella	2	Salmonella typhi	2	100	2	100
Proteus	2	Proteus mirabilis	2	100	2	100
Klebsiella pneumoniae	3	Klebsiella pneumonia	3	100	3	100
Enterobacter spp.	2	Enterobacter cloacae	2	100	2	100
Pseudomonas sp.	8	Pseudomonas aeruginosa	6	100	6	100
		Pseudomonas fluorescens	2		2	
Aeromonas	2	Aeromonas sp.	2	100	2	100
Acinetobacter	4	Acinetobacter lwoffii	2	100	2	100
		Bauman Acinetobacter	2		2	
Narrow food Aeromonas	2	Stenotrophomonas maltophilia	2	100	2	100
Staphylococcus	3	Staphylococcus aureus	1	100	1	100
		Staphylococcus epidermidis	1		1	
		Staphylococcus haemolyticus	1		1	
Enterococcus	2	Enterococcus faecalis	1	100	1	100
		Enterococcus faecium	1		1	
Streptococcus	4	Streptococcus	4	100	4	100

pneumonia		pneumonia				
B-hemolytic streptococcus	2	No Streptococcus lactis	1	100	1	100
		Streptococcus equisimilis	1		1	
Grass green streptococcus	3	Streptococcus salivarius	2	100	2	100
		Streptococcus sanguis	1		1	
Candida	4	Candida albicans	1		1	100
		Nearly smooth dead yeast	1		1	
		Candida krusei	1		1	
		Candida glabrata	1		1	
Total	48		48	100%	48	100%

List 3. Isolated strain identification of clinic specimen

QC Strain No.	Qty (strain)	Bacteria Name	DL-96II Microbial ID & AST system(DL)		VITEK2 (BioMerieux) COMPACT	
			accordance quantity (strain)	Coincidence rate(%)	accordance quantity (strain)	Coincidence rate(%)
Enterobacter spp.	5	Enterobacter cloacae	3	100	3	100
		Enterobacter agglomerans	2		2	
Escherichia	5	Escherichia coli	5	100	5	100
Sarre sp.	1	Serratia marcescens	1	100	1	100
Salmonella	1	Proteus mirabilis	1	100	1	100
Klebsiella pneumonia	2	Klebsiella pneumonia	2	100	2	100
Providencia	1	Alcaligenes Providencia	1	100	1	100
Proteus	3	Enterobacter cloacae	3	100	3	100
Pseudomonas sp.	10	Pseudomonas aeruginosa	10	100	10	100
Comamonas spp.	2	Comamonas testosterone	2	100	2	100

Shortwave Aeromonas	2	Short wave capsule of Aeromonas	1	50	2	100
Vibrio	1	Vibrio cholera	1	100	1	100
Aeromonas	4	Aeromonas sp.	4	100	4	100
Acinetobacter	10	Acinetobacter lwoffii	5	90	6	100
		Bauman Acinetobacter	4		4	
Narrow food Aeromonas	5	Stenotrophomonas maltophilia	5	100	5	100
Staphylococcus	15	Staphylococcus aureus	10	100	10	100
		Staphylococcus epidemidis	3		3	
		Staphylococcus hemolyticus	2		2	
Enterococcus	20	Enterococcus faecalis	8	100	7	95
		Enterococcus faecium	7		7	
		Enterococcus avium	5		5	
Streptococcus anginosus group	2	Streptococcus anginosus	2	100	2	100
Streptococcus pneumonia	10	Streptococcus pneumoniae	9	90	10	100
B-hemolytic streptococcus	5	No Streptococcus lactis	3	100	3	100
		Streptococcus equisimilis	2		2	
Grass green Streptococcus	5	Streptococcus salivarius	3	100	3	80
		Streptococcus sanguis	2		2	

Candida	10	Candida albicans	4	100	4	90
		Nearly smooth dead yeast	4		4	
		Candida krusei	1		0	
		Candida glabrata	1		1	
Total	119		116	97.4%	117	98.3%

Considering comparison data in List 1, 2 and 3, there are 3 inconsistent strains between DL-96II and VITEK2 COMPACT, see details in List 4

List 4 . Inconsistent Strains Analysis

Result from VITEK2 COMPACT	Result from DL-96II	Remark
Short wave capsule of Aeromonas	Brevumdimonas	Inconsistent
Comamonas testosterone	Comamonas acidovorans	Inconsistent
Streptococcus pneumoniae	Measle haemolysans	Inconsistent

2. Drug sensitivity result Analysis

119 clinic isolated strains has been measured on drug sensitivity, the test result is as below:

Strain type	No. of test cases	CA(%)	MIE(%)	ME(%)	VME(%)
Gram negative bacilli Gram positive cocci Fungus	119	99.5	0	0	0.5

Remark:

Drug sensitivity result remark:

Explain result of CA actual method and reference method by CLIS, its CA of explanation result (for instance Sensitivity, Intermediary and drug resistance person), See below calculating formula

$$CA = \frac{\text{Test quantity consistent with judged result of reference method}}{\text{Total test quantity}} * 100\%$$

Critical error referring to reference method result is R and result of two experiments result is sensitivity (S), calculating formula of MVE is as below

$$\text{VME} = \frac{\text{Result explanation belongs to critical test quantity error (reference method S, test method R)}}{\text{Reference method is test quantity of drug sensitivity}} * 100\%$$

Critical error referring to result of reference system is S and two experiments result is R. Calculating formula of ME is as below

$$\text{ME} = \frac{\text{Result explanation belong to critical test quantity error (reference method S, drug resistance of test method R)}}{\text{Reference method is test quantity of drug resistance}} * 100\%$$

General error stands for

- 1) Reference system result is R or S, whereas the experiment result is I
or
- 2) Reference system result is I, experiment result is S or R.

Calculating formula of MIE is as below:

$$\text{MIE} = \frac{\text{Result explanation belongs to general test quantity error (S/I or R/I)}}{\text{Total test quantity}} * 100$$

2. Clinical Trial Analysis

- 1) As for QC strains like ATCC25922、ATCC27853、ATCC29213、ATCC29212、ATCC6258, the coincidence rate at the bacterial strain identification of DL-96II Microbial ID & AST system with its matched ID/AST cards (Colorimetry & Turbidimetry method) made by ZHUHAI DL BIOTECH . CO., LTD, and VITEK 2 COMPACT with its test cards made by BioMerieux, both are 100%. The coincidence rate at susceptibility testing of both is also 100%.
- 2) As for standard strains, the identification compliance rates of both are 100%.
- 3) As for 119 clinical strains specimens, the coincidence rate of DL-96II Microbial ID & AST system with its matched test cards (Colorimetry & Turbidimetry method) made by ZHUHAI DL BIOTECH . CO., LTD is 97.4%.
As for 119 clinical strains specimens, the coincidence rate of VITEK 2 COMPACT with its cards made by BioMerieux is 98.3%.
Comparing DL-96II Microbial ID & AST system and its matched test cards (Colorimetry & Turbidimetry method) made by ZHUHAI DL BIOTECH . CO., LTD with VITEK 2 COMPACT and its cards made by BioMerieux, the comparison and identification rate is 99.1%.
- 4) Susceptibility testing analysis of 119 clinical strains specimens

The testing sample contains 119 clinical strains specimens and 2,618 antimicrobials, such as SMZ-TMP, Imipenem, Aztreonam, Penicillin, Oxacillin, Erythromycin and so on, the comparison coincidence rate is 99.5%.

3.Evaluation

This comparative test indicates that the average compliance rate of DL-96II auto microbial ID/AST system and its ID/AST Cards (Colorimetry & Turbidimetry method) is very close to that of VITEK 2 COMPACT from Biomerieux.

According to the above result of comparative test of bacteria and fungus, it generalizes the features of DL-96II as below:

- Bacterial identification test and antimicrobial susceptibility test work at the same time, and then give the ID/AST result simultaneously.
- Antimicrobial susceptibility analysis function: its database completely complies with the latest annual CLSI (Clinical and Laboratory Standards Institute) to set the MIC values.
- The types of antibiotics include Cephalosporins, Penicillins, Aminoglycosides, Quinolones, Phosphonomycin, Glycopeptides, Tetracyclines, Carbapenems, β -lactams, β -lactam / β -lactamase compound inhibitor.
- Advanced antimicrobial susceptibility analysis “expert system”: according to CLSI and other authorized publications, it shows abnormal phenotype, drug selection and anomaly reports, tips on correct operation, and other regular problems in clinicians medication, in susceptibility results.
- According to CLSI standards, it provides with the scientific notes of antimicrobial susceptibility results to give standard medication guide to clinicians.
- According to CLSI standards, it divides the antimicrobial drugs into 4 groups (group A/B/C/U) and reports the MIC results to provide clinical medication guide.

4. Comparative Test Conclusion

DL-96II auto microbial identification and antimicrobial susceptibility testing system and its ID/AST cards (Colorimetry & Turbidimetry method) from Zhuhai DL Biotech Cor., Ltd., has very similar accuracy rate of bacterial and fungus' identification and antimicrobial susceptibility test, compared with VITEK2 COMPACT and its reagent cards. So DL-96II is able to meet the needs of clinical use in clinical labs.