

## 对生长情况的质量控制

如果需要，使用 BacT/ALERT® 3D 系统时，各实验室可以对不同批次的 BacT/ALERT® 血培养瓶实施常规质量控制检测。

### 血培养瓶 (SA、SN、FA、FN、PF、FA Plus、PF Plus 和 FN Plus)

每一盒 BacT/ALERT® 血培养瓶（包括 BacT/ALERT® SA、SN、FA、FN、PF、FA Plus、PF Plus 和 FN Plus）中都包装有一份符合性证明书。应当将此证明书归档以备检查。如果需要更多的质控，应该用 SPS 抗凝新鲜人血，以每类培养瓶符合性证明书上所列的一种或多种微生物接种培养瓶，大约 400 CFU/瓶。通用步骤描述如下：

1. 向培养瓶加入 1-2 mL 血液（临床使用）。
2. 用在固体培养基上培养 18-24 小时的样品，准备胰蛋白酶肉汤 (TSB) 的悬浮液，达到 660 nm 透光率为 85-90% 或 McFarland 0.5 密度 ( $10^8$ )。
3. 如下所述对此悬浮液进行连续稀释：
  - a. 稀释 1:100：从步骤 2 中吸取 0.1 mL 悬浮液，加入 9.9 mL TSB 中。
  - b. 稀释 1:100：从步骤 3a 中吸取 0.1 mL 悬浮液，加入 9.9 mL TSB 中。
  - c. 稀释 1:10：从步骤 3b 中吸取 1.0 mL 稀释液，加入 9.0 mL TSB 中（这样密度应该大约为  $10^3$ ）。
4. 用步骤 3c 得到的 0.4 mL 最终稀释液，接种加入需要的成人培养瓶中。使用 BacT/ALERT® PF 时，用步骤 3c 得到的 0.2 mL 最终稀释液接种。
5. 尽快加载培养瓶。所有需氧微生物应该在 48 小时内呈现阳性，所有的厌氧微生物应该在 72 小时内呈现阳性。

REF 259793 43-02546

## CERTIFICATE OF CONFORMANCE BacT/ALERT® FN

This is to certify that samples of this lot were tested by standard procedures which include the methods and control ATCC® cultures specified in "Quality Control for Commercially Prepared Microbiological Culture Media" (CLSI® Approved Standard)<sup>1</sup> and met the following specifications:

**pH**  
7.40 – 7.75

**Sterility**  
No evidence of contamination.

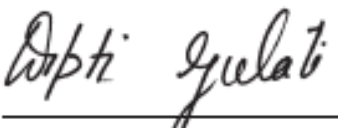
**Growth Performance**  
Satisfactory growth was exhibited with the following test microorganisms:

*Bacteroides fragilis* ATCC® 25285\*  
*Bacteroides vulgatus* ATCC 8482  
*Clostridium perfringens* ATCC 13124  
*Escherichia coli* ATCC 25922  
*Peptostreptococcus asaccharolyticus* ATCC 14963  
*Staphylococcus aureus* ATCC 25923  
*Streptococcus pneumoniae* ATCC 6305\*

\*CLSI recommended strain.

The manufacturing records for this lot have been reviewed and approved. The lot was formulated and processed within established requirements.

For technical assistance in the USA, contact bioMérieux Customer Service at 1-800-682-2666. Outside the USA, contact your local bioMérieux Representative.

  
Dipti Gulati  
Director, Quality Control

CLSI M22-A3

- Available Parameter Sets
  - Custom
    - Copy of Global+Natural Resistance
      - MIC Interpretation
        - Breakpoints
        - Forcing rules
      - Therapeutic Interpretation
        - Interpretations
        - Deduction rules
      - Disabled Phenotypes
      - Graphic
  - Pre-defined
    - CLSI
      - CLSI+Natural Resistance
        - MIC Interpretation
          - Breakpoints
          - Forcing rules
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          - Interpretations
          - Deduction rules
        - Disabled Phenotypes
        - Graphic
    - EUCAST+EUCAST-based
    - EUCAST+Phenotypic
    - Global CLSI-based+CLSI
    - Global CLSI-based+Natural Resistance
    - Global CLSI-based+Phenotypic
    - Global European-based+EUCAST-base
    - Global European-based+Phenotypic
    - Industry

### AES Parameter Set Definition

**Knowledge Base Version:** 05.03 - Dec 24, 2012 11:41:16 AM

**Name:**  **Parameter Set Status:** Active

**Description:**

**Based On:** Global CLSI-based+Natural Resistance

### Values

Enable Biological Validation      **Maximum MIC corrections:**

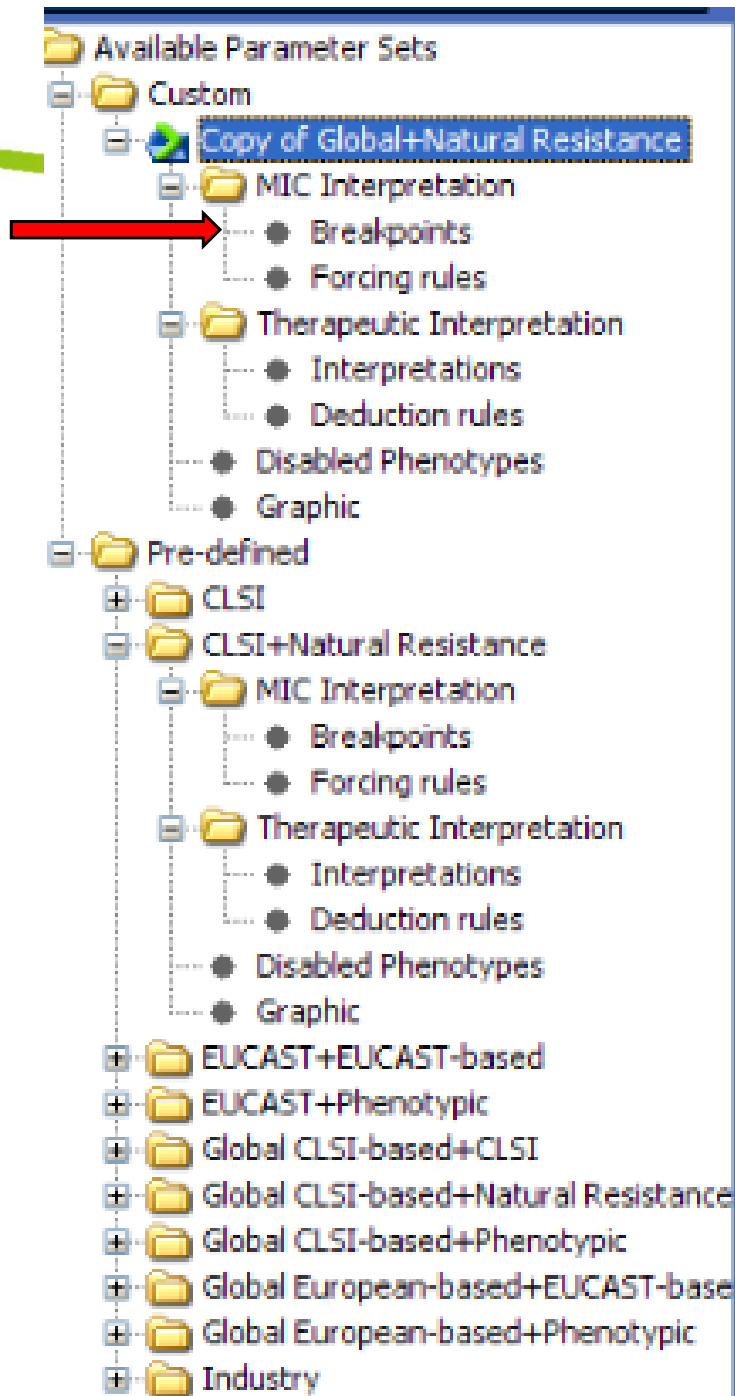
Enable Forcing Rules      **MIC Interpretation:**

Enable Therapeutic Interpretation Changes      **Based On:** Global CLSI-based

Enable Deduction by Phenotype      **Therapeutic Interpretation:**

Enable Deduction by Equivalent Antibiotic      **Based On:** NATURAL RESISTANCE

Enable Deduction without Expertise      **Geographic Context:**







Available Parameter Sets

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      - Deduction rules
      - Disabled Phenotypes
      - Graphic
  - EUCAST+EUCAST-based
  - EUCAST+Phenotypic
  - Global CLSI-based+CLSI
  - Global CLSI-based+Natural Resistance
    - MIC Interpretation
      - Breakpoints
      - Forcing rules
    - Therapeutic Interpretation

### MIC Interpretation Guideline

**Knowledge Base Version:** 05.03 - Dec 24, 2012 11:41:16 AM

**Name:** Copy of GLOBAL, 2009

**Parameter Set Status:** Active

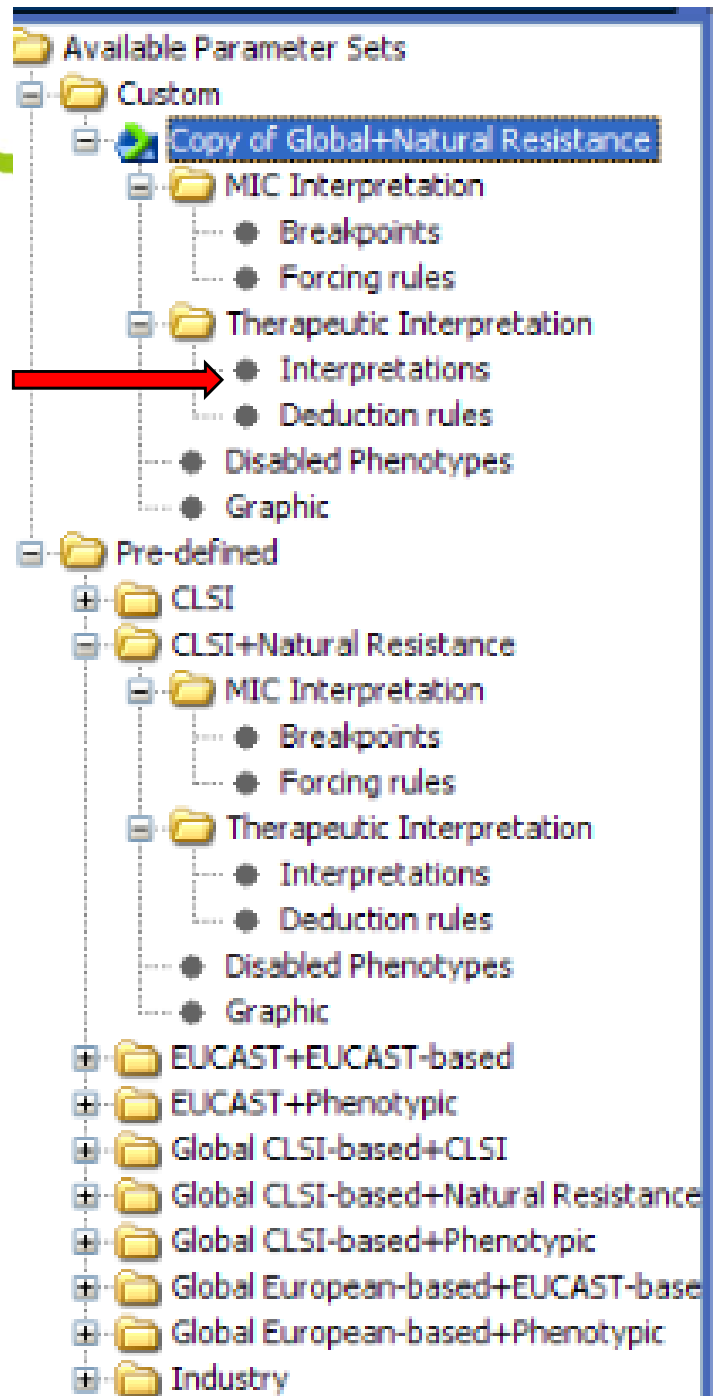
**Based On:** Global CLSI-based

### Breakpoints

**Sort By:** Organism, Antibiotic, Category



Organism/Group	Antibiotic	Category	S	I	R	Source	Comment
Coagulase positiv...	Oxacillin		<= 2		>= 4	CLSI	
Cryptococcus ne...	Fluconazole		<= 4	8	>= 16		
Enterobacteriaceae	Aztreonam		<= 4	8	>= 16		
Enterobacteriaceae	Cefazolin		<= 4		>= 8		
Enterobacteriaceae	Cefotaxime		<= 1	2	>= 4		
Enterobacteriaceae	Ceftaroline		<= 1	2 - 4	>= 8	Manufacturer	
Enterobacteriaceae	Ceftazidime		<= 4	8	>= 16		
Enterobacteriaceae	Ceftizoxime		<= 1	2	>= 4		
Enterobacteriaceae	Ceftriaxone		<= 1	2	>= 4		
Enterobacteriaceae	Doripenem		<= 1	2	>= 4	FDA	
Enterobacteriaceae	Ertapenem		<= 0.5	1	>= 2	CLSI	
Enterobacteriaceae	Imipenem		<= 1	2	>= 4		
Enterobacteriaceae	Meropenem		<= 1	2	>= 4		
Enterococcus	Amoxicillin/Clavul...		<= 8	16	>= 32		
Enterococcus	Ampicillin		<= 8		>= 16	CLSI	
Enterococcus	Ampicillin/Sulbactam		<= 4	8 - 16	>= 32		



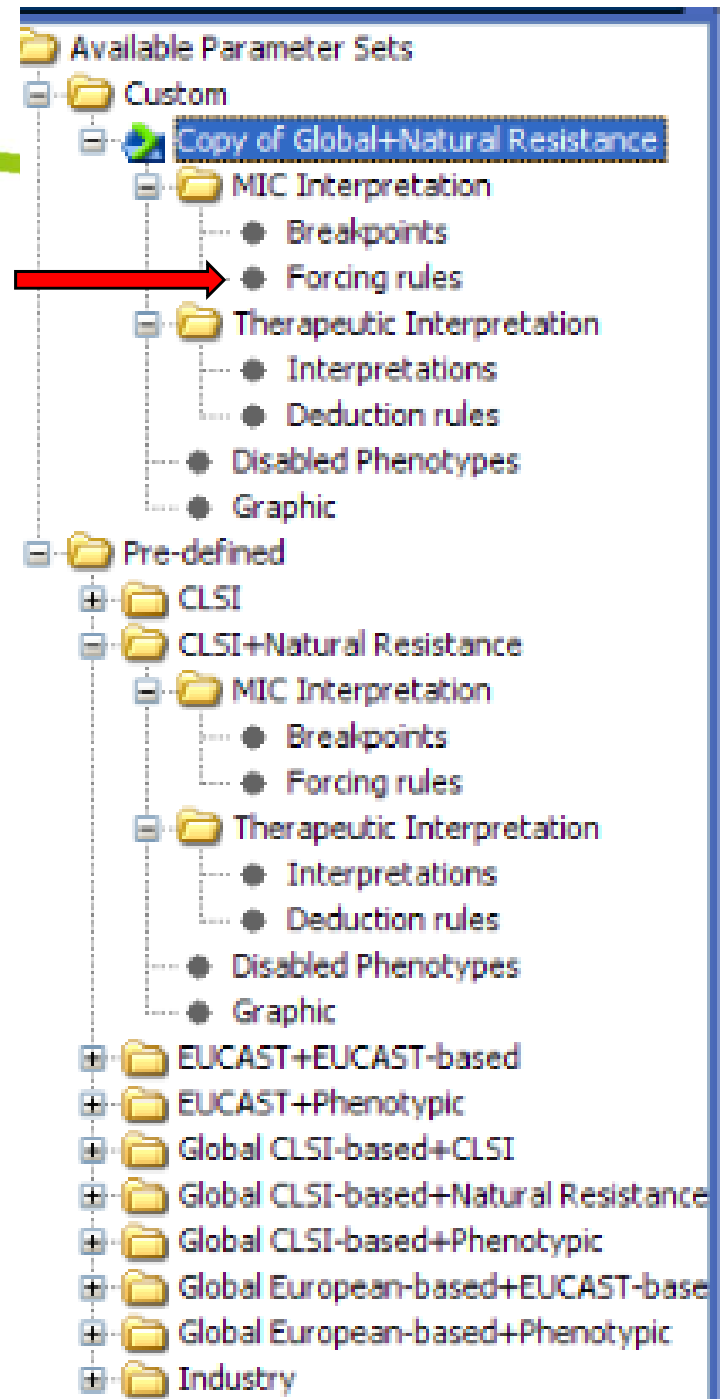


应慎重观察“敏感”结果。保证抗菌药物敏感试验结果和菌株鉴定是准确和可重复的。见附录 A 脚注“a”。

菌种 \ 抗菌药物	氨苄西林	阿莫西林-克拉维酸	氨苄西林-舒巴坦	哌拉西林	替卡西林	I 代头孢菌素: 头孢唑啉、头孢噻吩	头霉素: 头孢西丁、头孢替坦	II 代头孢菌素: 头孢呋辛	四环素类	呋喃妥因	多黏菌素 B 黏菌素
弗劳地枸橼酸杆菌	R	R	R			R	R	R			
克氏枸橼酸杆菌	R	R	R	R	R						
产气肠杆菌	R	R	R			R	R	R			
阴沟肠杆菌	R	R	R			R	R	R			
大肠埃希菌	此微生物对 β-内酰胺类不存在固有耐药										
赫氏埃希菌	R				R						
蜂房哈夫尼亚菌	R	R	R			R	R				
肺炎克雷伯菌	R				R						
摩根摩根菌	R	R				R		R	R	R	R
奇异变形杆菌	此微生物对 β-内酰胺类不存在固有耐药										
潘氏变形杆菌	R					R		R	R	R	R
普通变形杆菌	R					R		R	R	R	R
雷氏普罗威登斯菌	R	R				R			R	R	R
斯氏普罗威登斯菌	R	R				R			R	R	R
沙门菌和志贺菌	此微生物对 β-内酰胺类不存在固有耐药；报告结果时参见 2A 注释 (5)										
粘质沙雷菌	R	R	R			R	R	R		R	R
小肠结肠炎耶尔森菌	R	R			R	R					

注：III 代头孢菌素、头孢吡肟、氨曲南、替卡西林-克拉维酸、哌拉西林-他唑巴坦和碳青霉烯类药物在肠杆菌科细菌中不存在固有耐药，因此，这些药物未列在表中。

Klebsiella pneumoniae ssp pneumo...	SHV1 HYPERPRODUCTION	Ampicillin	R	R
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## 查看,激活,禁用以及打印强制性规则

**MIC Interpretation Guideline**

**Knowledge Base Version:** 3.01 - Jul 1, 2008 11:47:30 AM

**Name:** Copy of GLOBAL, 2006 **Parameter Set Status:** Active

**Based On:** GLOBAL, 2006

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**Forcing Rules**

**Rule:** 86, Cefoxitin Screen, Oxacillin, Staphylococcus auricularis, Staphylococcus ...

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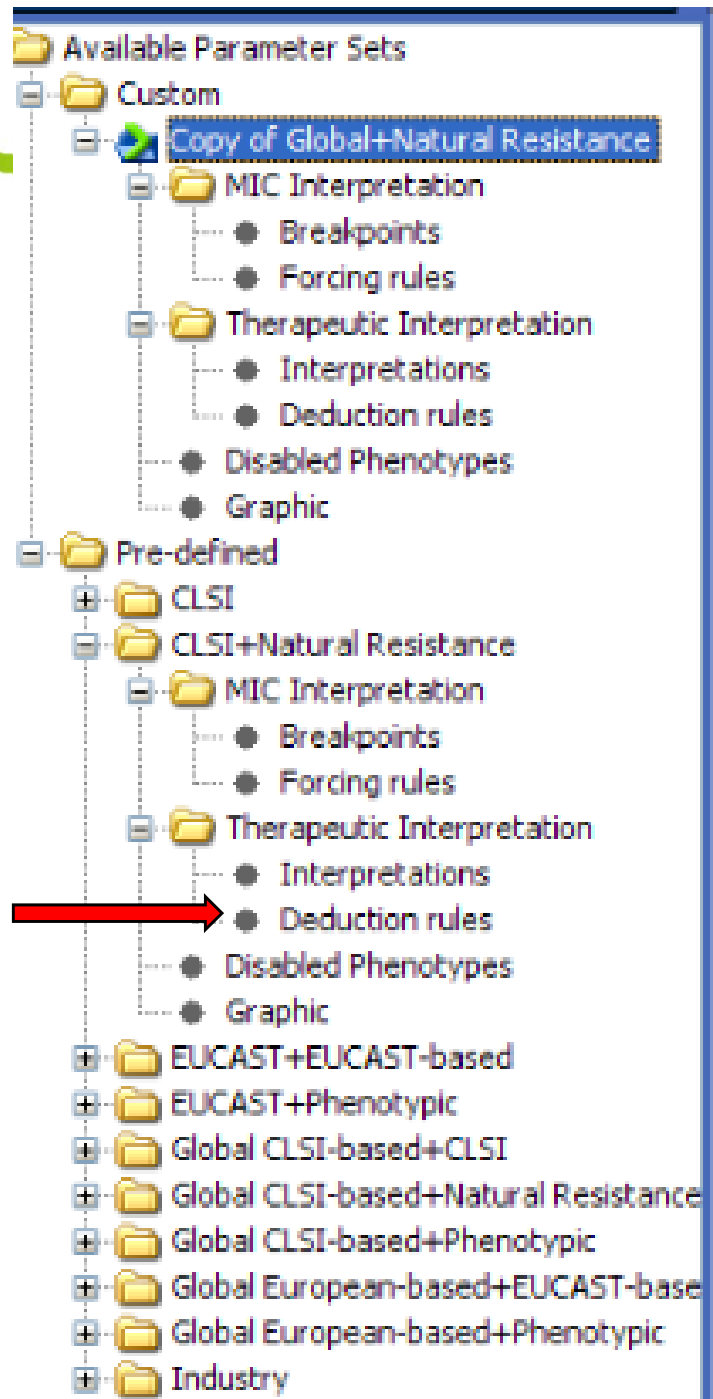
**Forcing Rule detail**

Enabled

**If the following conditions are true:**

	Organism is	Staphylococcus auricularis, Staphylococcus capitis, Staphylococcus chromogenes, Staphylococcus cohnii, Staphylococcus cohnii ssp cohnii, Staphylococcus cohnii ssp urealyticus, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus hominis ssp hominis, Staphylococcus hyicus, Staphylococcus intermedius, Staphylococcus kloosii, Staphylococcus lentus, Staphylococcus saprophyticus, Staphylococcus schleiferi, Staphylococcus sciuri, Staphylococcus simulans, Staphylococcus warneri, Staphylococcus xylosum
and	Test result is	Cefoxitin Screen: -
and	Result is	Oxacillin: 0.5 - 2

**Then perform the following action:**



**AES Configuration**

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    - Industry

**Therapeutic Interpretation Guideline**

Knowledge Base Version: 3.01 - Jul 1, 2008 11:47:30 AM

Name: Copy of NATURAL RESISTANCE      Parameter Set Status: Active

Based On: NATURAL RESISTANCE

**Deduction Rules**

Rule: 21, BETA-LACTAMS, Enterobacteriaceae

**Deduction Rule detail**  Enabled

**If the following conditions are true:**

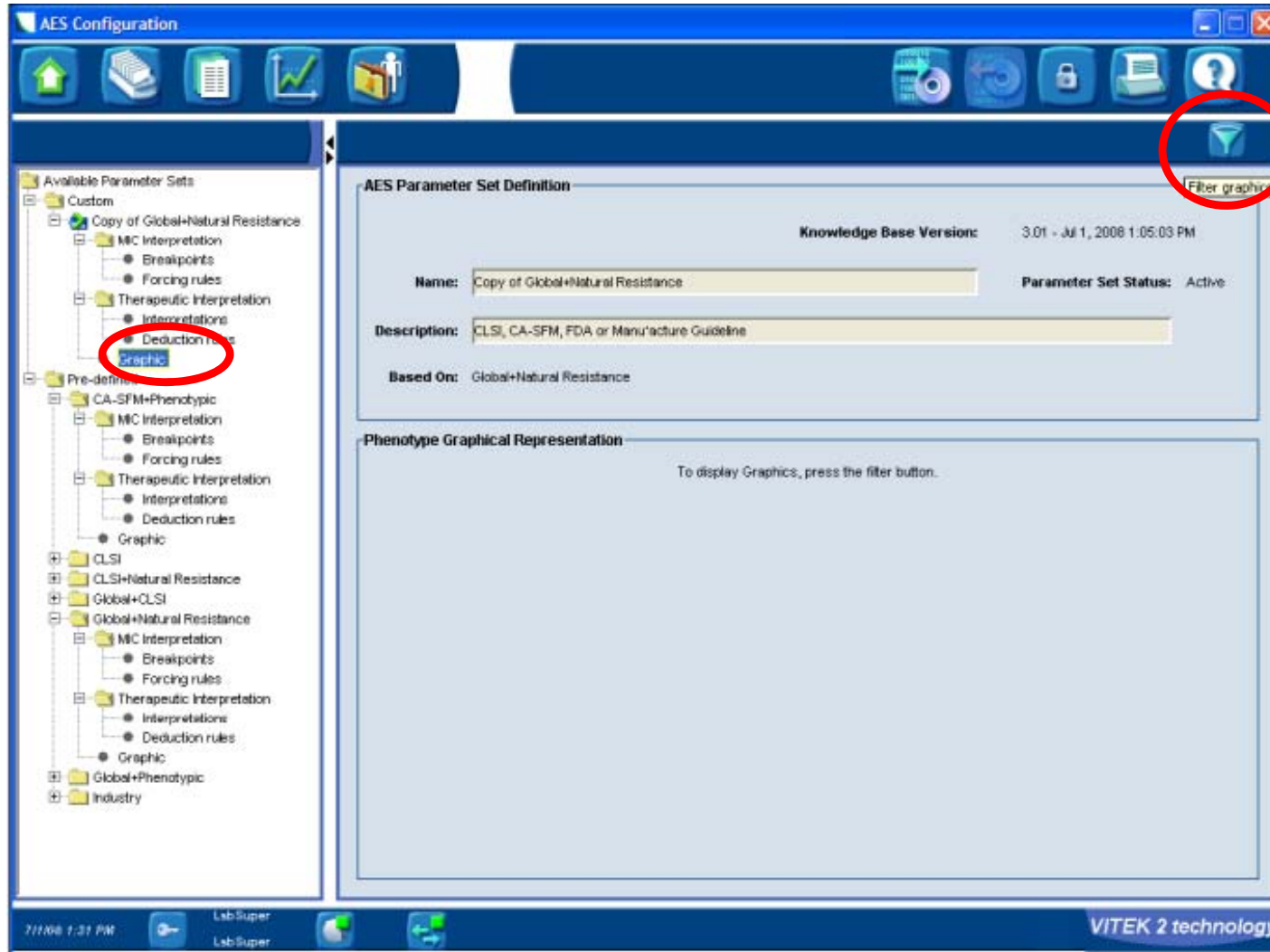
	Organism is	Enterobacteriaceae
and	Tested antibiotic is	Mezlocillin, Piperacillin
and	Interpretation is	S/R

**Then perform the following action:**

Deduce interpretation for	Mezlocillin, Piperacillin
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7/1/08 11:50 AM      Lab Super      Lab Super      VITEK 2 technology

查看AES的MIC分布击漏斗图标





## Phenotype Graphical Representation

Organism: Staphylococcus aureus

Species with phenotypes: Staphylococcus aureus

Antibiotic families: BETA-LACTAMS

