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Colorimeter Standard Set

REF R20343 contains 1 of each standard: 0.5, 1.0, 2.0, and 3.0.

1. INTENDED USE

Remel Colorimeter Standard Set is used to verify the correct standardization of the VITEK® Colorimeter. It has been specifically manufactured for use with the VITEK® Colorimeter in conjunction with VITEK® cards to provide optimum card performance.

2. SUMMARY AND EXPLANATION

Original McFarland standards were prepared by adding $BaCl_2$ to H_2SO_4, resulting in $BaSO_4$ precipitation.[1] Colorimeter Standards are prepared from suspensions of uniform polystyrene microparticles with absorbance values similar to the original $BaSO_4$ standards.[2] Stability of suspensions, shelf life, and ease of use have been improved with the Colorimeter Standards.

3. PRINCIPLE

Polystyrene microparticles are suspended in a special buffer and adjusted to an acceptable transmission range using the VITEK® Colorimeter. Adjusting the turbidity of a bacterial suspension to Colorimeter Standards produces bacterial counts in an expected range.

4. REAGENTS*

Electrically charged polystyrene microparticles suspended in a special buffer.

*Adjusted as required to meet performance standards.

5. PRECAUTIONS

This product is for Laboratory Use only and should be used by properly trained individuals. Directions should be read and followed carefully. Since Colorimeter Standard Set has been specifically manufactured for use in the VITEK® Colorimeter, the expected values may not correspond to other McFarland standards.

6. STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original container at room temperature (20-25°C) until used. Do not freeze or overheat.

7. PRODUCT DETERIORATION

This product should not be used if (1) there is evidence of dehydration, (2) the product is contaminated, (3) tubes are scratched or discolored, (4) the color has changed, (5) the expiration date has passed, or (6) there are other signs of deterioration.

8. MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, swabs, transfer pipettes, (3) Saline, broth, or crystal violet, (4) VITEK® Colorimeter, procedure manual, expendables.

9. PROCEDURE

9.1. Gently invert appropriate Colorimeter Standard several times to fully suspend the polystyrene microparticles.

9.2. Refer to VITEK® Colorimeter Manual for standardization procedure. NOTE: Colorimeter standardization (functional test) must be performed using glass tubes to obtain correct readings with Colorimeter Standards. The crystal violet and saline tubes should be inspected routinely and replaced with new tubes as necessary if there are signs of deterioration or problems obtaining accurate readings.

9.3. Clean all tubes with an absorbent cloth or tissue prior to each use.

10. QUALITY CONTROL

All lot numbers of Colorimeter Standards have been tested and found to be acceptable.

11. LIMITATIONS

11.1. Visually comparing Colorimeter Standards and bacterial suspensions by use of backlight illumination could result in bacterial suspensions of incorrect densities.

11.2. Bacterial densities prepared from *Haemophilus* influenzae ≤ 24 hours old may be too heavy.[3]

11.3. Colorimeter Standards are recommended when performing procedures described in the VITEK® Colorimeter Manual. Performance with instruments using alternative light sources has not been established.

12. EXPECTED VALUES

Tube No.	0.5	1.0	2.0	3.0
Colorimeter Color Range	Red	Blue	Green	Yellow
Colorimeter % Transmittance Range	80-88	67-77	46-56	27-37
Approximate Density (X 10^8/ml)	1.5	3.0	6.0	9.0

13. PERFORMANCE CHARACTERISTICS

In a comparative study, bacterial suspensions prepared using Colorimeter Standards were in agreement with suspensions prepared using barium sulfate standards.

14. BIBLIOGRAPHY

1. McFarland, J. 1907. JAMA. 14:1176-1178.
2. Lorian, V. 1985. Antibiotics in Laboratory Medicine. Lippincott Williams and Wilkins, Philadelphia, PA.
3. Doern, G.V. and R.N. Jones. 1988. Antimicrob. Agents Chemother. 32:1747-1753.

15. PACKAGING

REF R20343 contains 1 of each standard: 0.5, 1.0, 2.0, and 3.0.

16. SYMBOL LEGEND

REF	Catalogue Number
IVD	*In Vitro* Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
LAB	For Laboratory Use Only
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

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