

INTENDED USE

The McFarland Standards are for use as part of a quality control program for adjusting densities of bacterial suspensions that are used for identification and susceptibility testing.

SUMMARY AND EXPLANATION

The McFarland Standard tubes contain latex particles suspended in a buffer solution that are adjusted to an acceptable transmission range using a spectrophotometer at a wavelength of either 600 or 625 nm. A bacterial suspension, once adjusted to the same turbidity of a McFarland Standard, produces expected bacterial plate counts and can be used in a variety of identification or susceptibility kits and methods.

PRINCIPLE OF THE TEST

The McFarland Standards are used for adjusting densities of bacterial suspensions. Each standard is made from different concentrations of latex beads mixed in a buffer liquid. The original McFarland Standards were made from the combination of barium chloride and sulfuric acid that result in a flocculate. Problems were encountered with this technique which included instability, storage, and reproducibility of the resulting suspension. These problems have been overcome by using latex particles in a buffer solution, resulting in the McFarland Standards used today.

MATERIALS PROVIDED

- SD2350 McFarland Standard Set (0.5, 1.0, 2.0, 3.0, 4.0)
- SD2300 McFarland Standard 0.5
- SD2301 McFarland Standard 1.0
- SD2302 McFarland Standard 2.0
- SD2303 McFarland Standard 3.0
- SD2304 McFarland Standard 4.0
- Density card
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Densitometer

STABILITY AND STORAGE

All components should be stored 15°C-30°C. Do not freeze. Components stored under these conditions will be stable until the expiration date shown on the label.

PRECAUTIONS

- Do not use product beyond the expiration date.
- Directions should be carefully read prior to use.
- The same size tube should be used in comparing bacterial suspensions to the McFarland Standards.

SAMPLE STORAGE AND COLLECTION

n/a

TEST PROCEDURE

Manual Use:

1. Prior to use, gently invert the McFarland Standard tube several times to assure uniformity of the suspension of latex particles.
2. Adjust the turbidity of the log growth of the bacterial suspension to that of a known McFarland Standard.
3. Compare the turbidity by holding bacterial sample and McFarland Standard tubes up against the black and white bars printed on the enclosed density card.

Densitometer Use:

1. Ensure the densitometer is being used with tubes equivalent to those of the McFarland standards. If the routine use tubes are different the McFarland standards must be decanted into these tubes for calibration.
2. Prior to use, gently invert the McFarland Standard tube several times to assure uniformity of the suspension of latex particles.
3. Ensure the outsides of the tubes are clear of fingerprints, dust or debris.
4. Use the McFarland Standards to calibrate the densitometer.
5. The densitometer may now be used to adjust the turbidity of the log growth of the bacterial suspension to that of a known McFarland Standard.

QUALITY CONTROL PROCEDURE

Each lot of McFarland Standards is tested, and results fall into a tight range of acceptability.

McFarland Standard	Expected range for run % T	
	Lowest	Highest
0.5	78.5	84
1.0	54	61
2.0	35	42
3.0	22	28
4.0	14	20

INTERPRETATION OF RESULTS

Equal disappearance or distortion of the black bar indicates a similar turbidity.

McFarland Standard	Approximate Cell Count Density (x10 ⁸ cells)
0.5	1.5
1.0	3.0
2.0	6.0
3.0	9.0
4.0	12.0

LIMITATIONS OF THE PROCEDURE

- Coloured media may not provide the proper contrast with McFarland Equivalence Standards. Incorrect results will occur.
- Bacterial suspensions of older cultures may not compare to expected bacterial counts.
- These standards have been adjusted by a spectrophotometer. Use of any other instrumentation may not give reliable results.










PERFORMANCE CHARACTERISTICS

Tolerance:

McFarland Standard	Acceptable Ranges			
	Low % T	Low Density	High % T	High Density
0.5	78.5	0.4	84	0.6
1.0	54	0.9	61	1.1
2.0	35	1.8	42	2.2
3.0	22	2.8	28	3.4
4.0	14	3.6	20	4.4

REFERENCES

- Zapata, A. & Ramirez-Arcos, S. *Curr. Microbiol.* 2015;Jun:70(6):907-9
- Tille, P. et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.
- CLSI. 2009. 10th Ed. M02-A10. *CLSI*, Wayne, PA.
- McFarland, J. *J.Amer.Med.Assoc.* 14:1176, 1907.
- NCCLS Document. *Performance Standards for Antimicrobial Disk Susceptibility Tests.* 4th ed. 10:7, p 10, 1990.

	= Use by
	= Lot number
	= Catalogue number
	= Manufacturer
	= Authorized Representative in the European Community
	= Contains sufficient for <n> tests
	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use

