



IVD

## SUMMARY AND EXPLANATION

### Summary and Explanation

DensiCHEK™ Plus Standards are used to verify the DensiCHEK™ Plus instrument measurement performance. Use of these standards enables the accuracy of the instrument to be monitored and therefore confirms accuracy of the organism suspension.

## PRINCIPLE

The true value expressed in McFarland standards (McF), is printed on the label of the Standard tube. Place the Standard Tube into the DensiCHEK™ Plus. The value displayed on the instrument can be compared to the value printed on the label.

## CONTENTS OF THE KIT

- Set of four standards: 0.0 (blank), 0.5, 2.0 and 3.0
- Package insert

## COMPOSITION OF THE STANDARDS

- Demineralized Water 90.0 to 100.0%
- Hexamethylenetetramine 1.0 to 10.0%
- Formazin Polymer <1.0%
- Other components <1.0%
- Formaldehyde <0.1%

## MATERIALS REQUIRED (NOT PROVIDED)

- Lint-free cloth

## WARNINGS AND PRECAUTIONS

- Do not open tubes.
- Do not shake the Standard. Air bubbles will affect readings.

## STORAGE CONDITIONS

- The kit can be used until the expiration date indicated on the packaging
- Do not freeze or overheat

### Temperature:

- Storage: 5 °C to 30 °C (41 °F to 86°F)
- Operating: 15 °C to 30 °C (59 °F to 86°F)

### Relative Humidity:

- Storage: 20% to 85% non-condensing
- Operating: 20% to 80% non-condensing.

## TEST FREQUENCY

It is recommended to use one or more of the McF Standards (0.5, 2.0, 3.0) to test the accuracy of the DensiCHEK™ Plus prior to first use, on a monthly basis, or more frequently if required by your local regulatory guidelines.

## INSTRUMENT VERIFICATION

**IMPORTANT:** Confirm the DensiCHEK™ Plus instrument is set to GLASS tube setting to perform calibration. Refer to *Changing Tube Type Settings* in the Instrument User Manual.

1. Select the 0.0 McF Standard and clean the outside surface with a lens tissue.
2. Gently invert the 0.0 McF Standard five to six times to ensure it is homogeneous.
3. Ensure the instrument is on and insert the 0.0 McF Standard into the instrument and press the Zero/Scroll key. Slowly rotate the standard one full rotation. The instrument will display a series of dashes followed by 0.00.
4. Select the desired Standard (0.5, 2.0 or 3.0) and clean the outside surface with a lens tissue.
5. Gently invert the standard five to six times to ensure it is homogeneous.
6. Insert the Standard into the instrument and rotate slowly one full rotation until a numerical value is displayed.
7. Check that the displayed McFarland value is within the acceptable range:

Standard	Acceptable Range	
0.5 McF	0.44	0.56
2.0 McF	1.85	2.15
3.0 McF	2.79	3.21

8. If any Standards are outside of the acceptable range, repeat steps 1 - 7. If your standard is still out of range, contact bioMérieux Technical Support.






## WASTE DISPOSAL

It is the responsibility of each laboratory to handle waste and effluents produced according to their type and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

## WARRANTY

The Warranty of Seller set forth above and the obligations and liabilities of Seller thereunder are exclusive and in lieu of all other remedies or warranties, express or implied, arising by law or otherwise, with respect to the system delivered hereunder (including without limitation any obligation of Seller with respect to merchantability, fitness for particular purpose, and consequential damages, and whether or not occasioned by Seller's negligence).

## INDEX OF SYMBOLS

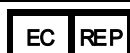
Symbol	Meaning
	CE-Marking of Conformity
	Consult Instructions for Use
	Use By
	Manufacturer
	Caution, consult accompanying documents
	Biological risks
	In Vitro Diagnostic Medical Device
	Batch code
	Authorized Representative in the European Community
	Catalogue number
	Serial Number
	Temperature limitation

## TRADEMARKS

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