

CKG16

Calibration standard set

1. About the standard

- 1.1. The manual describes calibration procedure for **DEN-1** and **DEN-1B** using calibration standard set **CKG16**.
- 1.2. The McFarland Standards are made from different concentrations of latex beads mixed in a buffer liquid. The original BSS (Barium Sulphate Suspension) Standards were precipitated from barium chloride and sulfuric acid according to the original McFarland Standards, but resulted in a flocculate which is susceptible to instability. McFarland Standards correspond to the respective turbidity values of the McFarland BSS Standard. They have better durability. The suspension separates slowly. CLSI (Clinical and Laboratory Standards Institute) accepts the use of latex particle suspension turbidity standards (polymer) for the preparation of standardized bacterial suspensions (1).
- 1.3. **Principle.** Adjusting a bacterial suspension turbidity to these standards produces a bacterial suspension in expected density range.
- 1.4. **Reagents.** McFarland Standard tubes contain latex particles suspended in a special buffer that are adjusted to the equivalent absorbance range using a spectrophotometer with 10 mm cuvettes (light path) at 625 nm. The shelf life in original closed condition is indicated on the label. Each tube is marked with a traceable lot number. Do not freeze, overheat or open the tubes.
- 1.4.1. To download the certificate of analysis and quality for the used standard, follow the link or QR code to the right and enter the lot number from the sticker, see example to the right.
- 1.5. **Storage.** We recommend storing protected from direct light (UV) in the transparent but UV light resorbing special packaging, at +15 ... +30 °C. Avoid breakage by storing in the package.
- 1.6. **Product stability.** This product should not be used if any of the following points occurs:
- There is any evidence of dehydration or volume reduction.
 - Product is contaminated.
 - The color changed.
 - Expiry date has passed.
 - There are other signs of deterioration.
- 1.7. **Risks and Safety.** Please observe the necessary precautions for use of laboratory reagents and body fluids; as well as possibly also of microbiological samples. Applications should be performed by expert personnel only. Follow the national and laboratory internal guidelines for work safety and infection control. Wear suitable protective clothing and disposable gloves while handling. It is important to ensure effective protection against infection according to laboratory guidelines.
- 1.7.1. For additional safety information please refer to the information on the label and the corresponding Safety Data Sheet (SDS). Download by QR-Code or link:
- 1.8. **Contents / Main Components.** McFarland Equivalent Standard set, contains latex particles, equivalent to Abs. (625 nm; 10 mm) of McFarland BSS Standards. Tube size is Ø 15.8 × 101.8 mm and fits both DEN-1 and DEN-1B model densitometers.
- 1.8.1. Additionally required or recommended materials, depending from the use of method:
- Glass sample tubes w/o lid, Ø16x100x0.8 mm, 78 pcs..... BS-050102-LK
- 1.9. **Specimen.** Suspension of bacteria.

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Safety Data Sheet



2. Calibration procedure

2.1. **Before using the standards.** Invert the tubes carefully several times to assure uniformity of the suspension of the latex particles.

2.2. **About calibration of the DEN-1 / DEN-1B.** The device is pre-calibrated at the factory for operation with the glass tubes 16 mm in external diameter (see the label on the bottom side of the unit) at temperature range from +15°C to +25°C and saves calibration data when being switched off.

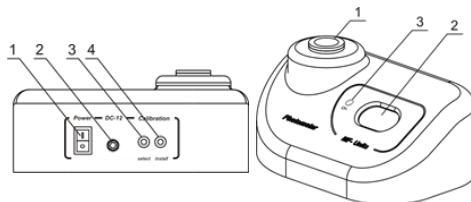


Figure 1. Rear panel of DEN-1/DEN-1B unit

Figure 2. Front view

Attention! Recalibrate the unit before using other type of tubes (e.g. with different outer diameter, bottom shape or material such as plastic).

2.2.1. Perform calibration from lower to higher calibration value. Use at least 2 points for calibration. Available calibration standards: 0.5, 1.0, 2.0, 3.0 and 4.0.

2.2.2. Connect the external power supply to electric circuit. Switch on the unit using the **Power** switch (fig. 1/1) on the rear panel.

Note. For **DEN-1B**, external power supply is optional when the batteries are in use.

Attention! Make sure that the tube socket is empty.

2.2.3. Press the **Select** button (fig. 1/3) on the rear of the unit.

Note. Use a thin pin of maximum diameter of 2 mm for pressing the **Select** and **Install** buttons.

2.2.4. To calibrate **DEN-1B** model, it is necessary to set values for an empty socket **--** and transparent standard **0.00**.

2.2.4.1 **Empty socket.** Display shows **--** indication. Press **Install** button (fig. 1/4) to save empty socket value. Display shows next required calibration value.

2.2.4.2 **Transparent standard.** Display shows **0.00** indication. Insert standard for **0.00** value into the socket (fig. 2/1) of the unit. If the standard for 0.00 value is not available, fill the tube (of the kind that is used for operations) with distilled water. Use the tube as the **0.00** value standard. Press **Install** button to save empty socket value. Display shows next required calibration value.

Note! Calibrate the unit using as many points as possible to obtain precise results. Minimum requirement are 2 points closest to the working range limits (e.g. 0.00 and 4.00 for operation in 0.00 - 4.00 McF range).

2.2.5. **Common calibration rules.** Display shows indication of necessary calibration value. Insert the necessary standard into the socket (fig. 2/1) of the unit and press the **Install** button to save the value for current standard.

Note. If pressing the **Install** button does not switch to the next standard value, it means that the current standard in the socket has lower turbidity value than the previous standard. Shake or replace the standard.

2.2.6. If a standard is not available, press the **Select** button to skip to the next calibration value without recording the value.

2.2.7. Repeat steps **2.2.5-2.2.6** until the calibration is complete. After recording or skipping the last value, unit automatically exits calibration mode and is ready for operation.

2.3. **Reset to factory calibration.** To reset the calibration of the unit to factory settings, ensure that you are in the working mode and the socket of the unit is empty. Press and hold **Install** key for 5 seconds. The unit displays a dot . , then changes it to **0.0** or **0.00**. The values are now reset.

2.4. Switch off the unit using the **Power** switch (position **O**). If an external power supply is used, disconnect it from electric circuit.

3. Analysis

3.1. **McFarland Latex Standards.** The table below refers to McFarland latex standards.

- Wavelength 625 nm
- Optical path length..... 10 mm

McFarland units (MFU)	Approximate cell density
0.5 MFU	1.5×10^8 cells/ml
1.0 MFU	3.0×10^8 cells/ml
2.0 MFU	6.0×10^8 cells/ml
3.0 MFU	9.0×10^8 cells/ml
4.0 MFU	12.0×10^8 cells/ml

3.2. **Quality controls and proficiency test.** Each LOT number of McFarland Standard has been tested spectrophotometrically and passed our quality control.

3.3. **Capability characteristics.**

3.3.1. **Limitations.** For all McFarland Standards there are generally typically limitations known. Please note the literature of your method, normative documents or further available information. When comparing with bacterial suspensions intrinsic color and in particular turbidity of the medium must be considered.



Note. This product information exclusively relates to the reagent described in this leaflet. In particular, this product information cannot be applied to similar reagents from other manufacturers.



Note. Periodically check for updates of information on this product on our website.

3.4. **Instruction for use.**

- For professional use only.
- To avoid errors, the use of qualified personnel is carried out. National guidelines for work safety and quality assurance must be followed.
- The used equipment must comply with the state of technology and the laboratory requirements.
- All samples and used tubes/vials must be marked clearly identifiable to exclude any confusion.

3.5. **Support and information service.** For methodological and technical support, please contact us by email at service@biosan.lv. Periodically check for updates of this product information on our website.

3.6. **Waste Management.** Please observe your national laws and regulations.

4. References

1. **CLSI / Clinical and Laboratory Standards Institute.** *Performance Standards for Antimicrobial Disk Susceptibility Tests; vol32. M02-A11.* Wayne, PA. : s.n., 2012.

Biosan SIA

Ratsupites 7, build.2, Riga, LV-1067, Latvia
Phone: +371 67426137 Fax: +371 67428101

<http://www.biosan.lv>