

Information sheet 1

CALIBRATION LEVELS, pipettes, dispensers etc.

Dandiag A/S offers both DANAK accredited and standard calibration in pipetting mode P, rP and D-mode. If DANAK accredited calibration is desired; please fill out order- and decontamination-form, **Formular 11**. If standard calibration is desired (page 2); please fill out order- and decontamination-form, **Formular 12**. Both forms contain options of calibration levels, which are described in the following. It is possible to choose other volume points than specified. It is also possible to draw up a service agreement where all details of service and calibration specifications are described. Pipettes are calibrated as a volume determination based on gravimetric weighing with grade 3 water. The method follows the guidelines described in DS/EN ISO/IEC 8655 Part 6: Piston operated volumetric apparatus – Part 6: Gravimetric methods for the determination of measurement errors.



Dandiag A/S is approved by DANAK under reg. no. 490 to perform accredited calibrations of pipettes, dispensers, piston burettes and bottle-top dispensers. Dandiag A/S hereby fulfills the requirements in the quality standard DS/EN ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories".

Accredited calibration of equipment is suitable for accredited laboratories, which work according to DS/EN ISO/IEC 17025 or DS/EN ISO/IEC 15189.

The issued DANAK calibration certificate states the measurement errors for the pipette in the calibrated volume point(s), together with the related calculation of expanded calibration uncertainty, U with a 95% confidence interval.

DANAK pre-calibration (as found) – calibration before service/adjustment

According to DS/EN ISO/IEC 17025, it is a requirement that calibration results (if possible) performed before service, reparation or adjustment must be reported. Dandiag will always perform a pre-calibration if the customer must be able to document the functionality of the pipette in the intervening period. Pre-calibration is offered in following calibration levels as described below. Pre-calibration can be selected on **Formular 11**.

Level 5.3 – DANAK accredited calibration

The pipette performance is tested for accuracy and precision with 5 measurements in 3 volume points (10%, 50% and 100% of max volume). Calibration level 5.3 is recommended for pipettes, which are used throughout the volume range.

Level 6.3 – DANAK accredited calibration

The pipette performance is tested for accuracy and precision with 6 measurements in 3 volume points (10%, 50% and 100% of max volume). Calibration level 6.3 is recommended for pipettes, which are used throughout the volume range and is suitable for the pharmaceutical industry.

Level 10.1 – DANAK fixed volume pipette

The pipette performance is tested for accuracy and precision with 10 measurements in the fixed nominal volume.

Level 10.1 – DANAK D-mode (multi-dispensing, only electronic piston operated pipettes)

The pipette performance is tested in the D-mode function for accuracy and precision with 10 measurements in volume point 10% of the pipette max volume, whereby the entire piston movement is tested. The pipette aspirates liquid in max volume, which is dispensed in 10 steps (10 equivalent volumes). The result describes the pipettes functionality in D-mode.

Level 10.1 – DANAK D-mode (Dispensers e.g., Multipettes)

D-mode in level 10.1 with 10 measurements in volume point 10% of the pipette max volume is the optimal way to test a dispenser. It is considered sufficient to test only one tip size (5ml tip) since the piston movement is the same regardless the tip size. The dispenser aspirates liquid in max volume, which is dispensed in 10 steps (10 measurements of 500µl with a 5ml tip). The dispenser can be tested in level 10.3 (10 measurements in 3 volume points 10%, 50% and 100% of the tip size) to verify that the dispenser tips comply with the manufacturer's specifications. The calibration is recommended for work in GMP laboratories.

Level 10.3 – DANAK accredited calibration

The pipette performance is tested for accuracy and precision with 10 measurements in 3 volume points (10%, 50% and 100% of max volume). Calibration level 10.3 is recommended for pipettes, which are used throughout the volume range.

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Standard (traceable) calibration

All equipment used is accredited calibrated and traceable to national and international standards.

The issued calibration certificate states the results for measured volume as well as an assessment "pass/fail" for accuracy and precision according to desired specifications (acceptance criteria).

Pre-calibration (as found) – Calibration before service/adjustment

Pre-calibration is performed to document the functionality of the pipette in the intervening period before service or adjustment and is offered in following calibration levels as described below. Pre-calibration can be selected on **Formular 12**.

Level 5.2 – Standard calibration

The pipette performance is tested for accuracy and precision with 5 measurements in 2 volume points (10% and 100% of max volume). The calibration is suitable for work in GLP laboratories and as an Entry Level Calibration in GMP laboratories.

Level 5.3 – Standard calibration

The pipette performance is tested for accuracy and precision with 5 measurements in 3 volume points (10%, 50% and 100% of max volume). The calibration is suitable for "GMP"-pipettes, which are used throughout the volume range.

Level 6.3 – Standard calibration

The pipette performance is tested for accuracy and precision with 6 measurements in 3 volume points (10%, 50% and 100% of max volume). The calibration is suitable for "GMP"-pipettes (in the pharmaceutical industry), which are used throughout the volume range.

Level 10.1 – Standard calibration - Fixed volume

The pipettes performance is tested for accuracy and precision with 10 measurements in the fixed nominal volume. The calibration is suitable for pipettes used in a GMP laboratory.

Level 10.1 – Standard Calibration. D-mode (multi-dispensing, only electronic piston operated pipettes)

The pipette performance is tested in the D-mode function for accuracy and precision with 10 measurements in volume point 10% of the pipette max volume, whereby the entire piston movement in is tested. The pipette aspirates liquid in max volume, which is dispensed in 10 steps (10 equivalent volumes). The result describes the pipettes functionality in D-mode. The calibration is suitable for pipettes used in a GMP laboratory.

Level 10.1 – Standard calibration D-mode (Dispensers e.g., Multipettes)

D-mode in level 10.1 with 10 measurements in volume point 10% of the pipette max volume is the optimal way to test a dispenser. It is considered sufficient to test only one tip size (5ml tip) since the piston passage is the same regardless the tip size. The dispenser aspirates liquid in max volume, which is dispensed in 10 measurements (10 measurements of 500µl with a 5ml tip). The dispenser can be tested in level 10.3 (10 measurements in 3 volume points 10%, 50% and 100% of the tip size) to verify that the dispenser tips comply with the manufacturer's specifications. The calibration is recommended for work in a GMP laboratory.

Level 10.2 – Standard calibration

The pipette performance is tested for accuracy and precision with 10 measurements in 2 volume points (10% and 100% of max volume). The calibration is suitable for work in a GLP laboratory and as an Entry Level Calibration in a GMP laboratory.

Level 10.3 – Standard calibration

The pipette performance is tested for accuracy and precision with 10 measurements in 3 volume points (10%, 50% and 100% of max volume). The calibration is suitable for "GMP"-pipettes, which are used throughout the volume range.