Information sheet 1 (ENG)

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, **Form11.**
If standard calibration is desired (see from page 2); please fill out the order- and decontamination-form, **Form12.**
Both forms contain options of calibration levels etc., which are described in the following.

As of May 2025, it is possible to order an accredited pipette calibration performed at the customer's location (in situ) - please contact Booking@dandiag.dk for more information. See also Infoblad 4

Method: Pipettes are calibrated as a volume determination based on gravimetric weighing with distillated water (grade 1). The method follows the guidelines described in ISO 8655:2022, part 7, Annex A. It is possible to get a metrological reference calibration performed at level 10.3 according to ISO 8655:2022, part 6. Only performed in the Dandiag calibration laboratory.

DANAK accredited calibration

Dandiag A/S is approved by **DANAK under reg. no. CAL 490** to perform accredited calibrations of pipettes, dispensers, piston burettes, bottle-top dispensers, and non-automatic balances. Dandiag A/S hereby fulfills the requirements in the quality standard ISO 17025:2017 "General requirements for the competence of testing and calibration laboratories".
Accredited calibration is suitable for accredited laboratories, which work according to ISO 17025 or ISO 15189.

The issued DANAK calibration certificate gives the measurement results for the pipette per test volume together with the associated calculated expanded calibration uncertainty, U, stated with a 95% confidence interval. Indication of declarations of conformity in the form of pass/fail in relation to desired specifications are indicated in the certificate. The pass/fail statement do not take the calibration uncertainty, U, into account.

DANAK pre-calibration / calibrate, only. "As Found"
According to ISO 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 (as found) if the costumer must be able to document the functionality of the pipette in the intervening period. Pre-calibration (as found) is offered in following calibration levels as described below. Pre-calibration / calibrate, only can be selected on **Form 11.**
All pipettes sent in for "calibration only" are booked in for an As Found calibration and can be supplemented with an As Left calibration, if the As Found calibration indicates that the pipette needs adjustment or service.

Level 5.3 – DANAK accredited calibration
The pipette is tested for systematic error and random error with 5 measurements at 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 is tested for systematic error and random error with 6 measurements at 10, 50 and 100% of max. volume.
Calibration level 10.3 is recommended for pipettes, which are used throughout the volume range.
Level 10.3 – DANAK accredited calibration (metrological reference calibration)
The pipette is tested for systematic error and random error with 10 measurements at 10, 50 and 100% of max. volume.
Calibration level 10.3 is recommended for pipettes, which are used throughout the volume range.
Level 10.1 – DANAK fixed volume pipette
The pipette is tested for systematic error and random error with 10 measurements at 100% of max. 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 systematic error and random error with 10 measurements in volume point 10% of max. vol. 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 10% of the tip 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 500 µl with a 5 ml tip).
A Dispenser can be tested in level 10.3 (10 measurements in 10%, 50% and 100% of the tip size) to verify that the dispenser tips comply with the manufacturer's specifications.

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Information sheet 1 (ENG) - continued

CALIBRATION LEVELS, pipettes, dispensers etc.

Standard (traceable) calibration

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

Please note: As of May 2025, it is possible to order an accredited pipette calibration performed at the customer's location (in situ) – please contact Booking@dandiag.dk for more information. See also infoblad 4

The issued calibration certificate gives the results for measured volume as well as an assessment "pass/fail" for measured systematic error and random error according to desired specifications.

Pre-calibration / Calibrate, only. "As found"
Pre-calibration (as found) is performed to document the functionality of the pipette in the intervening period before service, repair or adjustment and is offered in following calibration levels as described below**.** Pre-calibration (As found) / calibrate, only can be selected on **Form 12.**
All pipettes sent in for "calibration only" are booked in for an As Found calibration and can be supplemented with an As Left calibration, if the As Found calibration indicates that the pipette needs adjustment or service.

Level 5.2 – Standard calibration
The pipette is tested for systematic error and random error with 5 measurements at 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 10.2 – Standard calibration
The pipette is tested for systematic error and random error with 10 measurements at 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 5.3 – Standard calibration
The pipette is tested for systematic error and random error with 5 measurements at 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 is tested for systematic error and random error with 6 measurements at 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 10.3 – Standard calibration
The pipette is tested for systematic error and random error with 10 measurements at 10, 50 and 100% of max. volume.
The calibration is suitable for "GMP"-pipettes, which are used throughout the volume range.

Level 10.1 – Standard calibration - Fixed volume
The pipette is tested for systematic error and random error with 10 measurements at 100% of max. 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 systematic error and random error 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 10% of the tip 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 500 µl with a 5 ml tip). The dispenser can be tested in level 10.3 (10 measurements in 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.

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