

Scale Set Solutions for PACKS-4[®] Chromogenics (405 nm)

CAT. NO. 1480

Helena Laboratories PACKS-4 Scale Set Method is intended to be used to scale the PACKS-4 in the chromogenic mode (405 nm).

SUMMARY

The read-out of the PACKS-4 instrument may be scaled by presenting two samples of known absorbance at 405 nm to each channel. The samples are designed to encompass the absorbance range encountered in clinical usage. **The low level Scale Set solution is defined as zero O.D.** The high level solution has an absorbance at 405 nm greater than would be encountered in normal usage of chromogenic tests.

The Scale Set solutions supplied by Helena Laboratories offer a safe, convenient, and stable system for use in checking and setting the PACKS-4 in the chromogenics mode.

PRINCIPLE OF THE PROCEDURE

The photometer of the PACKS-4 consists of a tungsten-halide lamp, a heat elimination filter, interference filters with center wavelengths of 405 or 650 nm, a random oriented fiber optics bundle, a system of lenses, the cuvettes, and silicone photodiodes. The current generated by light striking the photodiodes is transformed to a negative log voltage signal which is then presented to an analog to digital converter. The resulting digital count values are scaled by the internal computer based on the Scale Set values. The material in the cuvette determines the light level reaching the photodiode, and thus the level of signal presented to the computer for scaling. Once the Scale Set extremes are established, the signal values of the kinetic chromogenic assays can be observed in (approximate) optical density units instead of arbitrary digital count light levels.

REAGENTS

PACKS-4 Scale Set (405 nm)

Ingredients: Scale Set #1 is an aqueous solution containing buffers and stabilizers. Scale Set #2 is an aqueous solution of FD&C Yellow #5 containing buffers and stabilizers.

WARNING: FOR IN-VITRO DIAGNOSTIC USE.

Scale Set #2 contains yellow dye that may discolor skin or clothing if spilled. No other special precautions are required.

Preparation for Use: Allow solutions to warm to room temperature (15-30°C); no pipets or other preparations are needed.

Storage and Stability: The solutions should be stored at 2-6°C, and are stable until the expiration date indicated on the package.

Signs of Deterioration: Both solutions should be clear liquids as viewed in the cuvette. Solution #2 will also be yellow. Any cloudiness may indicate contamination, and proper values may not be obtained.

INSTRUMENTS

The PACKS-4[®], Cat. No. 1471, is recommended for use in the chromogenics mode.

PROCEDURE

Materials provided: Scale Set Solutions (Scale Set #1 and #2)

Materials needed but not provided: Lint-free tissue wipes (dry), cuvettes, test tube rack.

Step-by-Step Method: Scale Set, perform monthly, and/or after changing lamp.

1. Remove Scale Set #1 & Scale Set #2 from refrigerator and allow to come to room temperature (15-30°C).
2. Fully power-up instrument (PACKS-4, monitor, printer).
3. Wait 30 minutes for "warm-up", or until optics reach 37°C.
4. Begin at the start-up screen – Main Menu.
5. Press Alt-S for setup menu (hold Alt and press S).
6. Select TESTS from setup menu.
7. Select CHROMOGENICS, with use of ENTER key.
8. Press Enter for 1st Assay selection, then down arrow until "Scale Set" is selected.
9. Ctrl S (hold Ctrl and press S).

10. Scale Set value is highlighted.
11. Enter Scale Set #2 value provided at the bottom of this sheet and press Enter. Scale Set value will no longer be highlighted. Proceed to next step.
12. Place three (3) unused cuvettes in rack.
13. Mark one cuvette 1.0 cm (3/8 inch) from the bottom to use as a minimum volume gauge.
14. Gently place at least 400 μL (about 6 drops) of Scale Set #1, into the second cuvette by letting drops run down the side of tilted cuvette. Check volume by comparison with tube from Step 13. Return to rack.
15. Place at least 400 μL of Scale Set #2 in the third cuvette in the same manner. Return to rack.
NOTE: Make sure cuvette is clean, no finger prints or smudges. Wipe cuvette with lint-free tissue to clean. **CLEAN THE CUVETTE EACH TIME IT IS PLACED IN OPTICS CHANNEL.** The slide covers on the channel doors should be pushed back so that pipette access holes are covered.
16. Scale Set #1 is checked first.
 Insert cuvette containing Scale Set #1 into Channel 1, making sure cuvette is clean. Close optics cover. Wait 5 seconds before closing switch. Do not remove cuvette until program countdown is complete.
 Repeat these steps for all optics channels for Scale Set #1. When finished, the channel values will be displayed in the "Results" column.
17. Insert Scale Set #2 into channel 1, making sure cuvette is clean. Close optics cover. Wait 5 seconds before closing switch. Do not remove the cuvette until program countdown is complete. Repeat these steps for all optics channels for Scale Set #2. When finished, the channel values will be displayed in the "Results" column.
18. The values displayed in the "Result" column should be from 0.0020 to 0.0024 for chromogenics. They must be within 0.0002 of each other to be acceptable. See Operator's Manual Section 10.1.7 for the proper Results.
19. Press [ESC] and save values as prompted by the PACKS-4 (answer YES at the SAVE prompt).
20. Return to Optics Scale Set with [Ctrl-S].
21. Press [Print Scrn] to get hard copy. This data should be retained and made available to service personnel and/or inspectors.
22. Escape from Set-up Sub menus by use of [ESC] key, to Main Menu.

LIMITATIONS

Time based drifts in Scale Set values are expected as the instrument lamp ages, but should not adversely affect instrument performance, because the PACKS-4 instrument utilizes delta O.D. kinetic slopes rather than absolute values.

BIBLIOGRAPHY

1. PACKS-4 Operator's Reference Manual.

SCALE SET SOLUTIONS (405 nm)

Cat. No. 1480

Lot No: _____

Exp. Date: _____

Scale Set #1 Lot No: _____

Scale Set #2 Lot No: _____ Value _____

