

Scale Set Solutions for PACKS-4® and AggRAM™ Platelet Assays (650 nm) CAT. NO. 1479

Helena Laboratories PACKS-4/AggRAM Scale Set Method is intended to be used to scale the PACKS-4, in the platelet mode, and the AggRAM at 650 nm.

SUMMARY

The read-out of the PACKS-4 and AggRAM instruments may be scaled by presenting two samples of known absorbance at 650 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 optical density (O.D.). The high level solution has an absorbance at 650 nm greater than would be encountered in normal usage of platelet aggregation or Ristocetin Cofactor tests.

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 photo diodes. The AggRAM module consists of 4 laser diodes and photo diodes for signal receiving. The current generated by light striking the photo diodes 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 photo diode, and thus the level of signal presented to the computer for scaling. Once the Scale Set extremes are established, the signal values of the platelet suspensions can be observed in (approximate) optical density units instead of arbitrary digital count light levels.

REAGENTS

Scale Set Solutions (650 nm)

Ingredients: Scale Set #1 is an aqueous solution containing buffers and stabilizers. Scale Set #2 additionally contains cross-linked styrene divinylbenzene copolymer microbeads. No special handling precautions are required.

WARNING: FOR IN-VITRO DIAGNOSTIC USE.

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

Storage and Stability: The solutions should be stored at 2-8°C, and are stable until the expiration date indicated on the package. **DO NOT FREEZE!**

Signs of Deterioration: The Scale Set #1 solution should be clear, homogeneous liquid as viewed in the cuvette. Any cloudiness may indicate contamination. The Scale Set #2 solution should be a whitish, turbid suspension. Any non-white color may indicate contamination. Avoid freezing, which can cause the microbeads to disintegrate.

INSTRUMENTS

PACKS-4, Cat No. 1471
AggRAM, Cat. No. 1484

PROCEDURE

Materials provided: Scale Set Solutions - Scale Set #1 and #2

Materials needed, but not provided: PACKS-4 or AggRAM instrument, Lint-free tissue wipes (dry), cuvettes, and cuvette rack

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Step-by-Step Method

PACKS-4

Perform Scale Set 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 the instrument (printer, monitor and PACKS-4).
3. Allow the instrument to warm up for 20 minutes or until the optics reach 37°C.
4. Perform the daily Optical Calibration Check, see section 10.1.6 of the instrument Operator's Manual.
5. Prepare the instrument to perform the Scale Set adjustment, see section 10.1.7 of the Operator's Manual. Enter the Scale Set #2 value provided at the end of this procedure.
6. Place two cuvettes in the cuvette rack.
7. Gently place at least 400 µL (about 6 drops) of Scale Set #1 into the first cuvette by letting each drop run down the side of the tilted cuvette. Return the cuvette to the rack.
8. Using the same method, place at least 400 µL of Scale Set #2 into the second cuvette.
9. The cuvettes must be cleaned with a lint-free tissue so that they have no fingerprints or smudges where optical readings are taken. **CLEAN THE CUVETTES EACH TIME THEY ARE PLACED INTO A CHANNEL.**
10. Values for Scale Set #1, Scale Set #2, and the Result are displayed. The Result values should be from 0.0020 to 0.0023 and should be within 0.0002 of each other. See section 10.1.7 of the Operator's Manual for additional information on Result values.
11. If the values are unacceptable, repeat the Scale Set procedure and if any values remain unacceptable, see section 10.2 of the Operator's Manual.
11. Print a hard copy of the Scale Set values by pressing **Print Screen**.
13. Save the Scale Set values by pressing **Esc** and selecting 'Yes' in response to the prompt.
14. Exit by pressing **Esc** until the the Main Menu displays.

AggRAM

Perform Scale Set monthly.

1. Remove Scale Set #1 & Scale Set #2 from refrigerator and allow to come to room temperature (15-30°C).
2. Turn on the AggRAM module, printer, monitor, and computer. Once displayed, select the HemoRAM icon. When prompted, enter a Setup or Supervisor User ID and Password.
3. Allow the instrument to warm up for 20 minutes or until the optics reach 37°C.
4. Perform the daily Optical Calibration Check, see section 10.1.1 of the instrument Operator's Manual.
5. Prepare the instrument to perform the Scale Set adjustment, see section 10.1.5 of the Operator's Manual and enter the Scale Set #2 value provided at the end of this procedure.
6. Place two cuvettes in the cuvette rack.
7. Gently place at least 400 µL (about 6 drops) of Scale Set #1 into the first cuvette by letting each drop run down the side of the tilted cuvette. Return the cuvette to the rack.
8. Using the same method, place at least 400 µL of Scale Set #2 into the second cuvette.
9. The cuvettes must be cleaned with a lint-free tissue so that they have no fingerprints or smudges where optical readings are taken. **CLEAN THE CUVETTES EACH TIME THEY ARE PLACED INTO A CHANNEL.**
10. Values for Scale Set #1, Scale Set #2, and Result (V/O.D.) display and are color coded to indicate acceptable/unacceptable values. See section 10.1.5 of the Operator's Manual for information on the color indications.
11. If the values are unacceptable, repeat the Scale Set procedure and if any values remain unacceptable, see section 10.2 of the Operator's Manual.
12. Print a hard copy of the Scale Set values by selecting 'Print'.
13. The Scale Set values are automatically saved when the window is exited.
14. Exit by selecting the **X** located on the top right of the window.

LIMITATIONS

Time based drifts in Scale Set values are expected as the instrument laser/lamp ages, but should not adversely affect instrument performance, because the instruments utilize delta O.D. kinetic slopes rather than absolute values.

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Lot No: _____

Exp. Date: _____

Scale Set #1 Lot No: _____

Scale Set #2 Lot No: _____ Value _____