

Wednesday, February 25, 2026

Subject: Letter of Equivalency – HemoPoint® H2 n.x.t Microcuvette and Hemo Control Hemoglobin Microcuvette

To Whom It May Concern,

This letter serves to confirm the equivalency between the HemoPoint® H2 n.x.t Microcuvette and the Hemo Control Hemoglobin Microcuvettes, which are used with the HemoPoint® H2 and Hemo Control analyzers respectively.

Additionally, we would like to confirm that the HemoPoint® H2 analyzers already purchased may continue to be utilized through their end-of-life use. There are no restrictions on the continued use, and customers may rely on the analyzer's performance until end-of-life, in accordance with standard maintenance and servicing protocols.

As part of ongoing product harmonization efforts within the EKF Diagnostics organization, the HemoPoint® H2 n.x.t Microcuvette will be phased out and replaced by the Hemo Control cuvette. Stanbio, the Legal Manufacturer for the HemoPoint® H2 system, and EKF Diagnostics GmbH, the Legal Manufacturer for the Hemo Control system, are both part of the EKF Diagnostics Plc group. Although the Hemo Control Hemoglobin Microcuvette is manufactured by EKF Diagnostics GmbH, it is distributed in the United States by EKF Diagnostics, Inc.

Please note that the HemoPoint® H2 analyzer was discontinued February 15, 2024, this was communicated via a discontinuation notice. While the analyzer is no longer available for sale, consumables, including the HemoPoint® H2 n.x.t Microcuvette have remained available to support existing users. As part of our ongoing discontinuation strategy, this letter also serves as formal notification that the HemoPoint® H2 n.x.t Microcuvette will be discontinued. The Hemo Control Hemoglobin Microcuvette is intended to replace the HemoPoint® H2 n.x.t Microcuvette, with availability anticipated in June 2026 as the analyzers have the same intended use, operating principle and methodology. The Hemo Control Hemoglobin Microcuvette is fully compatible with both the HemoPoint® H2 and Hemo Control analyzers. **As part of this transition, Hemo Control product numbers have been updated (see Appendix 1 below). While the product itself remains unchanged, customers should review the table below to ensure future orders reference the correct part numbers.** To ensure we can fully support your needs and plan production appropriately, any preliminary pre-order quantities you're able to share would be greatly appreciated.

Following a comprehensive technical review, we confirm the following:

1. Equivalency

1.1 Product

- The Hemo Control Hemoglobin Microcuvette is identical in design, materials, and manufacturing process to the HemoPoint® H2 n.x.t Microcuvette.
- The cuvettes are fully compatible with both the HemoPoint® H2 and Hemo Control analyzers, with no changes required to device configuration, calibration, or user instructions.
- There is no impact on product safety, performance, and/or existing registrations.
- There is no impact or change to the intended use, indications, or contraindications of the cuvette. The transition does not introduce new risks or require additional training for end users.

1.2 Technical

The Hemo Control Hemoglobin Microcuvette is scientifically and functionally equivalent to the HemoPoint® H2 n.x.t Microcuvette. This equivalency is supported by:

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- Identical analytical principles: Both cuvettes utilize the same photometric measurement method for hemoglobin determination.
- Same material composition and design specifications: No changes have been made to the cuvette geometry, optical path length, or reagent chemistry.
- Cross-platform compatibility: The Hemo Control Hemoglobin Microcuvette has been validated for use on both the HemoPoint® H2 and Hemo Control analyzers without requiring software updates, recalibration, or changes to operating procedures.
- Performance verification: Internal comparative testing has confirmed that results obtained using the Hemo Control Hemoglobin Microcuvette on the HemoPoint® H2 analyzer are consistent with historical performance data, meeting all acceptance criteria for accuracy, precision, and reproducibility.

2. Customer Impact

- Customers may begin using the Hemo Control Hemoglobin Microcuvettes immediately in place of the HemoPoint® H2 n.x.t Microcuvettes.
- No additional validation or requalification is required at the customer site due to the equivalency of the products.
- Product labelling and documentation will reflect the updated Legal Manufacturer, but the cuvette itself remains unchanged in form and function.

We trust this letter provides sufficient regulatory and scientific assurance regarding the equivalency and continued compliance of the Hemo Control Hemoglobin Microcuvettes.

To support this transition, the following table outlines the previous HemoPoint® H2 products and their corresponding Hemo Control replacements.

Appendix 1: Product Number Conversion Table (Former vs. Current Catalog Numbers)

Cuvettes			
Previous Product	Previous Catalog #	Replacement Product	New Catalog #
HemoPoint® H2 n.x.t Microcuvettes (individually foil wrapped 50pcs)	3025-50	Hemo Control Hemoglobin Microcuvettes (individually foil wrapped - 50 pcs)	3000-3113-0278
HemoPoint® H2 n.x.t Microcuvettes (100 pcs)	3015-100	Hemo Control Hemoglobin Microcuvette (100 pcs)	3000-3112-01
HemoPoint® H2 n.x.t Microcuvettes (200 pcs)	3015-200	Hemo Control Hemoglobin Microcuvette (200 pcs)	3000-3112-02

Cleaners, Controls, and Accessories			
Previous Product	Previous Catalog #	Replacement Product	New Catalog #
HemoPoint® H2 Optics Cleaner (5 pcs)	3050-005	Hemo Control Cleaner (5 pcs)	3000-6235
HemoPoint® H2 Optics Cleaner (3 pcs)	3050-003	Hemo Control Cleaner (3 pcs)	3000-6233
N/A	N/A	Hemo Control Low Control (3 x 1.5 mL)	3061-003

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N/A	N/A	Hemo Control Medium Control (3 x 1.5 mL)	3062-003
N/A	N/A	Hemo Control High Control (3 x 1.5 mL)	3063-003
N/A	N/A	Hemo Control Low Control (6 x 1.5 mL)	3061-006
N/A	N/A	Hemo Control Medium Control (6 x 1.5 mL)	3062-006
N/A	N/A	Hemo Control High Control (6 x 1.5 mL)	3063-006
HemoPoint® H2 Hgb Controls (Bi-Level)	3065-201	Hemoglobin Controls (Bi-Level)	3065-201
HemoPoint® H2 Hgb Controls (Bi-Level)	3065-601	Hemoglobin Controls (Bi-Level)	3065-601
Power Adaptor for HemoPoint® H2	3040-001	Hemo Control Power Adaptor	3000-1901-0537
HemoPoint® H2 Cuvette Holder	3030-001	Hemo Control Cuvette Holder	3000-1104
Printer Thermal Paper (Product discontinued)	3180-005	N/A	N/A

We appreciate your continued partnership and trust in our products. Should you have any questions or need support during this transition, please don't hesitate to reach out to your sales representative or Technical Support at 1-800-531-5535 or techsupport@ekfdiagnostics.com.

Our team is here to ensure a smooth and confident experience as you move forward with the Hemo Control Hemoglobin Microcuvette.

Sincerely,

Nicole Njuguna, Lead Product Manager – US Portfolio

Name and Title

Nicole Njuguna

Signature

2026-Feb-25

Date

Lisa Trow, Global Head of Compliance

Name and Title

Lisa Trow

Signature

2026-Feb-25

Date

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