AliveDx

Ortho Clinical Diagnostics
Attn: Régine Wolf
1500 Bd Sebastien Brant,
Illkirch (FR), 67400

Expiry and stability data for AlbaQ-Chek® Simulated Whole Blood Controls and FETALSCREEN II Kit

Dear QuidelOrtho,

Alba Product Code	Product Description / Name	Lot Specific Details
Z488	FETALSCREEN II Kit	V269148, Exp 19-MAR-24
Z498	AlbaQ-Chek® Simulated Whole Blood Controls	V269179, Exp 19-MAR-24 V269180, Exp 19-MAR-24 V269181, Exp 19-MAR-24 V269182, Exp 19-MAR-24 V269183, Exp 19-MAR-24

Following delays caused by incoming inspections, and in response to your request for support to lessen any impact caused by the delay of delivery of the next lots of AlbaQ-Chek® Simulated Whole Blood Controls and FETALSCREEN II, please see the information below.

The IFU Warnings and Precautions section includes the statement "Do not use beyond the expiration date" due to the reduction in product performance and stability over time. However, Alba Bioscience, through routine stability testing, has data showing that Z498 AlbaQ-Chek® Simulated Whole Blood Controls and Z488 FETALSCREEN II Kit generated acceptable test results up to the labelled expiry date and beyond expiry as described below.

In accordance with standard operating procedures, routine stability testing is performed by Alba Bioscience to demonstrate expected performance of the product beyond its recommended shelf life by a minimum of one stability testing time point using recommended storage conditions, and at a range of temperatures representing those experienced during transportation. As part of these internal stability monitoring studies, we have demonstrated stable reactivity of open-vials 14 days after the expiration date of the Z498 AlbaQ-Chek® Simulated Whole Blood Controls, and up to 7 days after the expiration date of the Z488 FETALSCREEN II Kit for unopened vials. These studies are performed in an environment controlled by Alba Bioscience and therefore cannot reflect all variations encountered when

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transporting and storing finished goods but provides assurance in the ongoing performance of this product.

Throughout the functional life of these products, ongoing performance must be monitored by the end user by means of Quality Control in accordance with local, state and federal regulations. The following can be recommended as a minimum;

- As always, the products should be visually inspected for signs of discolouration and/or haemolysis and outcome of inspection recorded.
- Deterioration of product quality should be considered when discolouration, haemolysis or unsatisfactory results (unsuccessful demonstration of the appropriate antigens/antibodies when tested using recommended techniques) are noted. Discrepant results must be fully investigated.
- Alba Bioscience has data to show that ongoing performance of Z498 AlbaQ-Chek® Simulated Whole Blood Controls up to 14 days after opening of vials, and Z488 FETALSCREEN II Kit up to 7 days after opening of vials, can be maintained with strict adherence to recommended storage and ongoing visual inspection.

Alba Bioscience have performed studies on these products beyond the shelf life, giving a level of confidence in their ongoing performance. Any decision to use the product beyond shelf life must be taken by the end user after considering the above.

Kind regards,

Janine S. Robb

Dr Janine Robb
Head of Alba Product Development and Support

QuidelOrtho™

March 18, 2024

Expiry and Stability Data for AlbaQ-Chek® Simulated Whole Blood Controls and FETALSCREEN II Kit

Dear Customer,

Enclosed is a letter from AliveDx regarding delay in delivery of the next lots of AlbaQ-Chek® Simulated Whole Blood Controls and FETALSCREEN II due to incorrect storage of the products by the carrier. QuidelOrtho is working with AliveDx on engaging health authorities to discuss an interim mitigation while we work on obtaining new product in an expedited manner. A follow-up communication will be issued promptly.

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If you have questions about this notification, please contact our Global Services Organization at 1-800-421-3311.

Enclosure: AliveDx Notification

Ortho Clinical Diagnostics (Ortho), a wholly owned subsidiary of QuidelOrtho Corporation, is excited to share our new logo and brand with you. Due to legal and regulatory requirements for diagnostic products, you may continue to see the names and brands of Quidel and Ortho in addition to QuidelOrtho on our packaging, contracts, and marketing materials.

Ortho Clinical Diagnostics

* previous notification w/ instructions for use of expired reagents

February 23, 2021

Delay in Shipment – ORTHO® Reagent Red Blood Cells

Dear Valued Customer:

This notification is regarding a delayed delivery of your Reagent Red Cell (RRBC) Product Order and the need to **temporarily** use expired Reagent Red Blood Cells for testing until your normal shipment arrives.

Please do the following:

- Visually inspect each expired red cell reagent prior to continued use. Examine for turbidity, precipitation, discoloration, evidence of contamination and/or hemolysis of the red blood cells, as indicated in the Instructions for Use.
    - If the product shows no signs of contamination and/or hemolysis, follow your routine in-house Quality Control methods to confirm product efficacy.
    - If the product appears abnormal, do not use the product for testing
- Consult your internal processes and procedures to determine acceptable use of these products in your facility and according to your specific circumstances.

If your lot is past its expiration date before you receive replacement red cells, the following option(s) may be utilized within the context of your facility's overall risk management and validation documentation:

- Sourcing of an alternate supplier.
- Evaluation of expired ORTHO Reagent Red Blood Cell products using routine in-house quality control methods to confirm continued product efficacy for use pending receipt of replacement red cell products.

    - **Manual Gel and Tube Customers**
        - Document the use of expired product within your facility and in alignment with your Quality System.
            - NOTE: Regulatory Bodies (AABB/CAP) do allow for the temporary use of expired reagents in emergency situations.

    - **Ortho ProVue® Customers**
        - QC Reagents: No software change is needed, the ORTHO ProVue® software will allow use of expired QC reagents.
        - 0.8% RRBC: Users will need to deface the barcode and enter new expiration date, see instructions for selecting a new expiration date in the ORTHO VISION® instructions below. Users will need to perform this for every batch.

- **ORTHO VISION® Customers**
  - The ORTHO VISION® software will not allow the use of expired reagents (0.8% RRBCs and AlbaQ QC Material). In order to use expired product on the ORTHO VISION® Analyzer, the operator would load the expired reagents such that the barcode is not visible to the on-board scanner and then the operator would modify the expiration date to an "in date" expiration. For instance, the operator can change the expiration date to +1 day forward by following the bar code symbology reference below:

    - OCD 0.8% Red Cell Barcode Format ---- **DDDYPPPLLL** where:
      - DDD = Expiration date in Julian days + 600 Y = Last digit in year
      - PPP = Product ID code
      - LLL = Lot number
      - **Example: In the numeric code 6551103373:**
        - 655 is the expiration date in Julian days + 600 (055 = Feb. 24)
        - 1 is the last digit in the expiration year (2021)
        - 103 is the product ID (0.08% B Cells)
        - 373 is the lot number
    - Quality control material – Operators can manually register each QC sample under run *QC job, change QC sample* using all of the same digits except for the last 6 for expiration. E.g. QC1123210112 Has an expiration date of Jan,12 2021
      - In addition, when loading the QC samples on the sample rack turn the barcode such that it is not read by the on-board scanner and once again enter the barcode as you did to register the QC sample.

We apologize for the delay in the delivery of your product, caused by the unexpected and extreme weather delays across the country. If you have further questions or require additional information please contact Ortho Clinical Diagnostics, at 800-421-3311.

Sincerely,

Kimberley J. Shimits

Kim Shimits, MT(ASCP) SBB
US Marketing Manager
Transfusion Medicine

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