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EIGHTCHECK-3WP X-TRA™

CE

HEMATOLOGY CONTROL FOR SYSMEX® ANALYZERS WITH 3-PART DIFFERENTIAL

INTENDED USE AND SUMMARY

EIGHTCHECK-3WP X-TRA is a stabilized whole blood matrix designed for statistical process control of Sysmex hematology analyzers. This product is for in vitro use only, by laboratory professionals or appropriately trained personnel.

FORMULATION

EIGHTCHECK-3WP X-TRA control consists of stabilized human erythrocytes, mammalian and simulated leukocytes, and a platelet component in a plasma-like medium. This product is provided in three levels: low, normal and high concentrations.

WARNING: POTENTIALLY INFECTIOUS MATERIAL

All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS) using techniques specified by the U.S. Food and Drug Administration. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions

STORAGE AND STABILITY

1. EIGHTCHECK-3WP X-TRA is shipped every 84 days, with a 100 day closed vial product life.
2. Store EIGHTCHECK-3WP X-TRA vials at 2-8°C. Storage outside this temperature range risks product damage. When properly stored, unused vials are stable to the expiration date on vial. Unused product is stable for 14 days when promptly refrigerated after each use. Unused material from open vials should be discarded after 14 days. Do not add residual to a new vial.

PACKAGE CONFIGURATION

Item number: 140-3004-0. Tri-pack consists of 3 levels: Low, Normal and High. There are 4 vials for each level. Each vial contains 2.0 mL of product.

QC Targets

Assay means are not intended for use as analyzer QC file target values. For effective QC, each laboratory should set its own target values. Sysmex recommends that each laboratory establish this QC target value by collecting at least 10 data points per control level over 5 days. The mean QC target values from this initial data collection should be within the expected ranges listed on the package insert. Sysmex recommends as an option that each laboratory either establish their own QC file limits based on the laboratory's historical coefficient of variation (CV) by using historical data or by using the limits provided in the package insert with each lot of EIGHTCHECK-3WP X-TRA.

QC Limits

Assay expected ranges represent variation between analyzers. Meaningful statistical QC suggests that each laboratory establish control limits based on the analyzer's nominal CV. Sysmex recommends as an option one of two methods: 1) establish laboratory limits based on the Lab historical CV or 2) enter the limits provided on the assay sheet provided with each lot of EIGHTCHECK 3-WP X-TRA. The CV values are available in analyzer QC files and from inter-laboratory QA program reports. Average the CV of each parameter from three control lots in which analyzer performance was stable and acceptable. The three CV limits are recommended as they represent the analyzer's statistical process capability. Using three CV limits with three control levels should provide error detection that meets most laboratories medical quality requirements while minimizing false run rejection.

Suggested QC limits are available from Sysmex for new users to ensure stable performance until a laboratory's own control limits can be set.

INSTRUCTIONS FOR USE

1. Remove vial(s) from refrigeration and packaging.
2. Allow at least 15 minutes to warm vials to room temperature (18-25°C).
3. Verify cap is secure and mix vial by gentle end-to-end inversion until the cell button in the bottom of the vial is completely suspended.
4. Analyze the control vial in the appropriate aspiration mode(s) according to your laboratory's quality procedures.

INSTRUCTIONS FOR BARCODED ENTRY OF TARGET AND LIMIT VALUES FOR THE pocH-100*i* AND THE XP-Series.

1. Touch **[QC]** on instrument LCD. Select correct file corresponding to the QC vial.
2. In QC function, touch **[SETTINGS]**.
3. Scan lot from assay sheet. Lot number loads automatically.
4. Manually input expiration date.
5. Using the right arrow, scroll to the **PARAMETER** page beginning with WBC.
6. Scan in WBC. Target and Limit values load automatically.
7. Continue to scan in all parameters. *Note that you must scroll to the right to advance the screen to input data from all parameters.*
8. Select **[SAVE]**.
9. Repeat steps 1-8 above for input of QC data for the other levels of QC.
10. Select **[SAVE]** after entry of each level.

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INSTRUCTIONS FOR ENTRY OF TARGET AND LIMIT VALUES FOR THE KX21N:

1. Touch **[QC]** on instrument LCD. Select correct file corresponding to the QC vial.
2. In QC function, touch **[SETTINGS]**.
3. Manually input the lot number and expiration date.
4. Using the right arrow, scroll to the **PARAMETER** page beginning with WBC.
5. Manually enter the target for each parameter. *Note that you must scroll to the right to advance the screen to input data from all parameters.*
6. Select **[SAVE]**.
7. Repeat steps 1-8 above for input of QC data for the other levels of QC.
8. Select **[SAVE]** after entry of each level.

INDICATION OF PRODUCT DETERIORATION

Temperature extremes can alter performance without visible changes to the control. Moderate hemolysis is normal. Suspect deterioration when a series of control analysis results are reproducible yet the mean falls outside the assay's expected range.

Troubleshoot by considering the following items:

1. Verify the product has been shipped and stored properly.
2. Verify reagents and control vials have not expired.
3. If the QC values are out of expected range, repeat analysis with a new vial warmed to room temperature and mixed thoroughly. Good results indicate a vial specific problem.
4. If all control levels are similarly biased, this tends to support an analyzer and/or reagent problem.
5. Perform routine maintenance and reanalyze control.
6. To verify analyzer open mode calibration accuracy, use Sysmex SCS-1000™.

When a problem persists after troubleshooting, call Customer Technical Support at 1-888-879-7639. *pocH-100i users should call the pocH-100i Customer Technical Support at* 1-866-879-7639

LIMITATIONS

1. EIGHTCHECK-3WP X-TRA is for use on analyzers using Sysmex reagents.
2. EIGHTCHECK-3WP X-TRA should not be run in both the Open and Closed mode within the same QC file.
3. The cells used in EIGHTCHECK-3WP X-TRA cannot be completely stabilized and still retain their sensitivity to reagents. Some parameter results can change slowly over the life of a control lot, independent of analyzer or reagent performance. Though the amount of change is usually small, it is useful to recognize these "drifters" when evaluating QC charts.
4. Product is to be used as supplied. Dilution or mixing of levels invalidates stability and intended use.

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