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MQC (Manual QC for Tube Technology)

Intended Use:

MQC is intended for the quality control of routine blood bank reagents and for the quality control of certain antigen typing reagents by tube techniques.

Summary and Explanation:

Quality control of blood bank reagents should be performed to ensure they are functioning correctly. ² Reagent performance may be impaired by improper technique, defective equipment and/or contamination of reagents. MQC provides a standardized control which can confirm expected testing results for routine blood bank reagents and certain antigen typing reagents.

Principle of the Procedure:

Using hemagglutination technology MQC Reagent Red Cells and MQC Reagent Plasma confirm reactivity of the reagents used for ABO and Rh(D) blood typing as well as the reverse grouping cells. MQC reagent plasmas act as positive and negative controls for the performance of anti-human globulin containing Anti-IgG as well as any potentiators used in the antibody detection system. Additionally, the MQC reagent red cell antigen profile is documented and provided for use as a blood typing reagent quality control. MQC kit components should produce readily visible agglutination reactions where positive test results are expected. If unexpected results are observed the problem may be due to improper test procedures, defective equipment and/or contamination of reagents.

Reagent Description:

MQC Reagent Red Cells (2 vials): Red cells used to evaluate, assess, and control the performance of anti-A, anti-B, Anti-A,B, anti-D and Rh control and may be used for certain other antigen typing reagents. They may also be used certain antigen typing reagents. Both MQC Reagent Red Cells are typed for the following antigens: for, C, c, E, e, Jk^a, Jk^b, K, Fy^a, and Fy^b. These antigen profiles are documented on the

antigen profile sheet (enclosed). One of the cells is selected to be K (Kell) positive. The closure caps are color coded black (NEG) and white (POS) to prevent errors.

REAGENT RED CELLS	Specification
MQC RBC-POS	Group A ₂ B RhD positive
MQC RBC-NEG	Group O RhD negative

These reagents contain a 3-5% suspension of red blood cells in a preservative solution containing chloramphenicol (0.34g/L), neomycin sulfate (0.1g/L) and levofloxacin (0.12 g/L).

MQC Reagent Plasma (2 vials): Simulated human plasma used to evaluate the performance of ABO reverse grouping and antibody screen/identification reagents. The closure caps are color coded black (NEG) and white (POS) to prevent errors.

REAGENT PLASMA	Specification
MQC PLASMA-POS	Antibody Screen Positive (panagglutinin) anti-A, anti-B
MQC PLASMA -NEG	Antibody Screen Negative

This reagent contains 0.1% (w/v) sodium azide.

This reagent contains bovine material (6.0%) obtained from a USDA approved source free of Transmissible Spongiform Encephalopathies (TSEs).

The products should be clear. Turbidity may indicate bacterial contamination.

The lot number and expiration date are displayed on the vial label.

The format for the expiration date is expressed as YYYY-MM-DD (year-month-day).

Precautions:

1. This reagent contains human source material and should be handled and disposed of as if it is potentially infectious. Source material has been tested in accordance with FDA requirements and found negative.
2. The source of bovine albumin is either USDA approved or from sources where origin information is available. The donor animals have been inspected and certified disease free and are deemed to have a low TSE (Transmissible Spongiform Encephalopathy) risk.
3. Slight hemolysis or turbidity may be observed; however, do not use the product if grossly discolored, hemolyzed, or turbid.

4. This reagent is designed for use by operators trained in serological techniques.
5. MQC is for in vitro diagnostic use only as a quality control product for evaluating the performance of blood bank reagents.
6. The packaging of this product contains dry natural rubber.
7. This reagent contains 0.1% (w/v) sodium azide which is below the national and international regulatory thresholds and, when used in normal conditions, is not chemically hazardous. If this reagent is discarded in the sink, flush with large volumes of water to prevent the buildup of azide.

Storage

Store the product at 2-8°C until the expiry date detailed on the product label. Prolonged storage at incorrect temperatures may result in accelerated loss of reagent reactivity.

Procedure:

Materials Provided

MQC Reagent Red Cells
MQC Reagent Plasma
HBS-Antigen Profile Information Sheet
MQC Worksheet

Materials Required But Not Provided

Glass test tubes
Centrifuge capable of 1000rcf
Isotonic saline or phosphate buffered saline (PBS)
Timer
Red cells suitable to be used as negative and positive controls
Pipettes

Recommended Technique:

MQC should be used in accordance with the manufacturer's Instructions for Use accompanying each blood bank reagent under testing.

Inspect reagents under test for signs of deterioration or contamination.

Quality Control of Typing Reagent

1. POSITIVE CONTROL: Add MQC RBC-POS red cells to each reagent anti-sera to be tested.
2. NEGATIVE CONTROL: Add MQC RBC-NEG red cells to each reagent anti-sera to be tested.

- For quality control of typing reagents, consult the enclosed antigen profile to select the appropriate positive and negative red cell.

Quality Control of Reverse and Antibody Screening Cells

- POSITIVE CONTROL:** Add MQC PLASMA-POS to each reagent red cell to be tested.
- NEGATIVE CONTROL:** Add MQC PLASMA-NEG to each reagent red cell to be tested.

Interpretation of Results:

Positive test: Agglutination of the red cells.

Negative test: No agglutination of the red cells.

The expected results are given in the table below. Results obtained in testing should be compared to this chart. Reaction strengths using the same methods and lot of Reagent Red Cells and anti-sera should be comparable. A significant decrease in reaction strength should be investigated.

MQC Reagent	Reagent Under Test	Expected Results
MQC RBC-POS	Anti-A	+
	Anti-B	+
	Anti-A,B	+
	Anti-D	+
	Rh Control	0
MQC RBC-NEG	Anti-A	0
	Anti-B	0
	Anti-A,B	0
	Anti-D	0
	Rh Control	0
MQC PLASMA-POS	A1 cells	+
	A2 cells	+
	B cells	+
	Screening Cells	+
MQC PLASMA-NEG	A1 cells	0
	A2 cells	0
	B cells	0
	Screening Cells	0

Limitations:

- False positive or negative reactions may occur due to contamination of test material, improper reaction temperatures,

improper storage of materials, omission of test reagents and deviation from the manufacturer's Instruction for Use.

Specific Performance Characteristics:

MQC Reagent Red Cells and MQC Reagent Plasma have been manufactured to provide a standardized reaction in hemagglutination procedures with blood bank reagents. When properly stored and used according to manufacturer's instructions these reagents will provide an appropriate level of quality control.

For technical support, contact Hemo bioscience at 1-866-332-2835.

Bibliography:

- Fung, M.K., ed. Technical Manual. 18th ed. Bethesda, MD: AABB, 2014.
- CLIA Reagent Quality requirements clarified. Newsbriefs. Bethesda, MD: American Association of Blood Banks, 1993; 14(3): 1.

Glossary of Symbols:

Symbol	Definition
	Batch code
	Manufacturer
	Temperature limitation
	Consult instructions for use.
	Use by YYYY-MM-DD
	For <i>in vitro</i> diagnostic use.
	Caution, consult documents.