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**MQC-CAT (Manual QC for Column Agglutination Technology)**

**Intended Use:**

MQC-CAT is intended for the quality control of routine blood bank reagents when tested by CAT techniques.

**Summary and Explanation:**

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

**Principle of the Procedure:**

Using hemagglutination technology, MQC-CAT Reagent Red Cells and MQC-CAT Reagent Plasma confirm reactivity of the reagents used for ABO, Rh(D) blood typing and antibody detection reagents. MQC-CAT Reagent Red Cells are suspended in a low ionic strength (LIS) solution suitable for testing in CAT. Additionally, the MQC-CAT Reagent Red Cell antigen profile is documented and provided for use as a blood typing reagent quality control. The MQC-CAT 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. The MQC-CAT 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, faulty equipment and/or contamination of reagents.

**Reagent Description:**

**MQC-CAT 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 other blood typing reagents. Both MQC-CAT reagent red cells are typed for the following antigens: C, c, E, and e. The antigen profiles are documented on the antigen profile sheet (enclosed). The closure caps are color coded black (NEG) and white (POS) to prevent errors.

REAGENT RED CELLS	Specification
MQC-CAT RBC-POS	Group A <sub>1</sub> B RhD positive
MQC-CAT RBC-NEG	Group O RhD negative

These reagents contain a 4%±1% suspension of red cells in a Low Ionic Strength Solution that contains Neomycin and Gentamicin Sulfate as a preservative.

**MQC-CAT 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-CAT PLASMA-POS	Antibody Screen Positive (panagglutinin) anti-A, anti-B
MQC-CAT 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. 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-CAT is for in vitro diagnostic use only as a quality control product for evaluating the performance of blood bank reagents.
6. 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-CAT Reagent Red Cells
- MQC-CAT Reagent Plasma
- MQC-CAT Worksheet
- HBS Antigen Profile Information Sheet

**Materials Required But Not Provided**

- CAT card
- Manufacturer's diluent
- Micropipettes capable of delivering 25 and 50 µl
- Isotonic saline or phosphate buffered saline (PBS)
- Timer
- Red cells suitable to be used as negative and positive controls
- Centrifuge compatible with CAT cards

**Recommended Technique:**

**The MQC-CAT products 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.

	Screening Cells	0
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**Quality Control of Typing Reagent**

1. POSITIVE CONTROL: Add MQC-CAT RBC-POS red cells to each reagent anti-sera to be tested.
2. NEGATIVE CONTROL: Add MQC-CAT RBC-NEG red cells to each reagent anti-sera to be tested.
3. 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**

1. POSITIVE CONTROL: Add MQC-CAT PLASMA-POS to each reagent red cell to be tested.
2. NEGATIVE CONTROL: Add MQC-CAT 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-CAT Reagent	Reagent Under Test	Expected Results
MQC-CAT RBC-POS	Anti-A	+
	Anti-B	+
	Anti-A,B	+
	Anti-D	+
	Rh Control	0
MQC-CAT RBC-NEG	Anti-A	0
	Anti-B	0
	Anti-A,B	0
	Anti-D	0
	Rh Control	0
MQC-CAT PLASMA-POS	A1 cells	+
	A2 cells	+
	B cells	+
	Screening Cells	+
MQC-CAT PLASMA-NEG	A1 cells	0
	A2 cells	0
	B cells	0

**Limitations:**

1. 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.
2. MQC-CAT Reagent Red Cells are suspended in a low ionic strength solution and are intended for use only in CAT tests or tests that require a LIS medium.

**Specific Performance Characteristics:**

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








Performance study was conducted using Ortho Clinical Diagnostic ID-MTS™ Gel System and Grifols DG Gel® 8 System.

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

**Bibliography:**

1. Fung, M.K., ed. Technical Manual. 18<sup>th</sup> ed. Bethesda, MD: AABB, 2014.
2. CLIA Reagent Quality requirements clarified. Newsbriefs. Bethesda, MD: American Association of Blood Banks, 1993; 14(03): 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.