HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Quality Control of Serological Blood Bank Reagents		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

1.1 Ensure the reliability of the blood bank serological test results.

2. DEFINITONS:

2.1 N/A

3. POLICY:

3.1 Transfusion guidelines recommend regular checking of test materials, test methods, personnel working procedures and automated equipment/instruments used.
3.2 Monitoring the quality of reagents in blood bank is important for the reliability of the test results and benefit of patients.
3.3 The control sample should always have the same characteristics as a patient sample and therefore be treated identically.
3.4 Quality control starts at the time of receiving the reagents.
3.5 All reagents are used and controlled according to the supplier's recommendations.
3.6 All reagents are labeled with the content, expiration date and the date of opening.
3.7 All reagents are not used beyond their intended expiry date.
3.8 The reagent's quality control is performed on each day of use.
3.9 Anti-sera are checked against known positive and negative cells.
3.10 Reagent Red Blood Cells are checked against known positive and negative anti-sera.
3.11 Quality control of reagents is tested in the same manner as patient's specimens.
3.12 The control is used regularly and by each member of the laboratory staff who routinely perform patient or donor testing.
3.13 Results are checked against predefined acceptable results before reporting the patient's results.
3.14 Results are reviewed and reagents are approved before use for patient testing.
  3.14.1 If the expected results are observed, this means that the reagents are approved before use for patient testing.
  3.14.2 If unexpected results are observed, the problem must be resolved (before test results are reported) and a corrective action must be taken.
3.15 In MCH blood bank, it is widely dependent on "Gel microtyping system" rather than any other reagents.

4. PROCEDURE:

4.1 Check water bath temperature to ensure it is 37°C ± 2 °C and record it on the Q.C. worksheet.
4.2 Check all reagents for appearance (turbidity, hemolysis, precipitate, gel formation and change in colour) and record observation .
4.3 Check and record manufacturer, lot number and expiration date of reagents .
4.4 **ABO grouping and Rh typing reagents:**
  4.4.1 Set 7 test tubes in a rack.

4.4.2 Put one drop from routine reagents, plus two drops from QC. Reagents (or 5 % pooled cell suspensions).

4.4.3 Mix and centrifuge

4.4.4 Resuspend and read macroscopically, and record the results in the Q.C worksheet .

4.5 **Coombs, 22% albumin and Coombs control cells (C.C.) reagents:**

4.5.1 Set 2 test tubes in a rack.

4.5.2 In one test tube put one drop from Coombs reagent, plus two drops from Coombs control cells Reagents.

4.5.3 In the other tube put one drop from 22% albumin reagent, plus two drops from Coombs control cells Reagents.

4.5.4 Mix and centrifuge 15 sec.

4.5.5 Resuspend and read macroscopically, and record the results in the Q.C worksheet.

4.6 **Antibody screen reagents:**

4.6.1 Label one test tube for Ab. Screening as Q.C. for each screening cell S_I, S_{II}, S_{III} against two known antibody sera.

4.6.2 Add 2 drops of known reagent antibody specific to one antigen of each screening cells, to 1 drop from each corresponding screening cells in the labelled Ab. screening test tubes.

4.6.2.1 e.g. anti-e for vial I and anti-c for vial II.

4.6.3 Centrifuge, resuspend test tubes and read, in room temperature, and record results.

4.6.4 Incubate test tubes in 37 °C for 30 minutes, centrifuge, resuspend, read and record results.

4.6.5 Wash 3 times, add Coombs reagent, centrifuge 15 sec., resuspend, read and record results.

4.6.6 Add Coombs control cells to the negative result, centrifuge 15 sec., resuspend, read and record results in Q.C. worksheet.

4.7 **Documentation:**

4.7.1 Record results on daily Quality control of serology reagents worksheet .

4.7.2 Check all reagents for appearance and performance and mark either satisfactory or unsatisfactory.

4.7.3 Put notes on Q.C. worksheet, if there are any changes in lot number or expiration data.

4.7.4 Tests are signed by those performing the test.

4.7.5 Clearly mark outdated reagents in use, and Q.C. results should be acceptable.

4.8 **Interpretation:**

Routine reagents	Q.C. reagents	Interpretation
Anti - A	Pooled A Cells	A positive agglutination reaction test +3 to +4 is the expected result.
Anti-B	Pooled B Cells	A positive agglutination reaction test +3 to +4 is the expected result.
Anti-AB	Pooled A, Pooled B Cells	A positive agglutination reaction test +3 to +4 is the expected result.
Anti-D	RhD- positive cells (any ABO group)	A positive agglutination reaction test +3 to +4 is the expected result.
Rh-control	RhD- positive cells (any ABO group)	A negative reaction is the expected result.
A1-cells	Anti-A	A positive agglutination reaction test 3+ to 4+ is the expected result.
B-cells	Anti-B	A positive agglutination reaction test 3+ to 4+ is the expected result.
Coombs reagent	Coombs control cells	A positive agglutination reaction test 2+ to 3+ is the expected result.
22% Albumin	Coombs control cells	A positive agglutination reaction test 2+ to 3+ is the expected result.
Coombs control cells	Coombs reagent	A positive agglutination reaction test 2+ to 3+ is the expected result.
Antibody	Antisera specific to one	A positive agglutination reaction test 1+ to 2+ is

screening cells	antigen of each screening cells.	the expected result.

4.9 If the results are accepted, fix 'QC passed' label on the reagent vials and keep them in the reagent refrigerator for use.

4.10 If the results are not accepted, the problem may be due to improper test procedure, faulty equipment or reagents:

4.10.1 Inform the supervisor of blood bank technicians to take the necessary action

4.10.2 Fix a label on the vials "do not use".

4.10.3 Repeat the tests on other vials with the same and different lot numbers.

4.10.4 The supervisor of blood bank technician may repeat the tests again, check the equipment and the storage conditions and call the supplier to discuss the situation.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Daily Quality Control of Blood Bank Serological Reagents Form

5.2 **Materials:**

5.2.1 Reagents Anti-A, Anti-B, Anti-D, and Rh-Control.

5.2.2 Anti-Human Globulin (AHG) or Coombs reagent .

5.2.3 A, B, Weak D cells reagent (If available) or Group A. B and O pooled Cells .

5.2.4 Screening cells.

5.2.5 Coombs control cells.

5.2.6 Water bath/ dry bath, Centrifuge, Cell washer, and Timer.

5.2.7 Test tubes, Disposable transfer pipettes.

5.2.8 Isotonic saline solution.

5.2.9 Other Antisera as indicated

6. RESPONSIBILITIES:

6.1 Blood Bank technicians/ specialists to follow the detailed procedure and supervisor of blood bank technicians or his deputy to review the results and approve the reagent before use.

7. APPENDICES:

N/A

8. REFERENCES:

8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.

8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014

8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.

8.4 AABB Technical manual, 18th edition, 2014.

8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.

8.6 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

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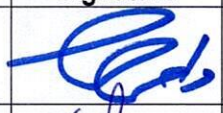
Prepared by:	Dr. Mohammed Amer	Blood Bank Physician		January 06, 2025
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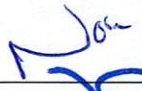
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 12, 2025
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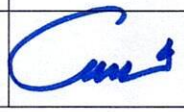
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025