Guidance Manual
"Quality Control of ABO and Rh blood grouping reagents"

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AMENDMENT SHEET

S.NO	Date	Page no.	Revision No.	Nature of Amendment Section/ details	Authorization

FOREWORD

Blood transfusion is an essential part of health care system and if blood with correct group is transfused it can save precious life. The blood grouping reagents are globally used by blood transfusion services like blood banks, hospitals, diagnostic laboratories etc. The blood grouping reagents are essential tools for diagnostic laboratories and also play a vital role in safe transfusion.

Blood Reagent Laboratory at National Institute of Biologicals, Noida is the only Central Drugs Laboratory for *in-vitro* Blood Grouping Reagents and has been evaluating the reagents forwarded by DCG(I), since 1997.

The Guidance Manual "Quality Control of ABO and Rh blood grouping reagents" describe Quality Control testing of Monoclonal blood grouping reagents – Anti-A, Anti-B, Anti-A,B, Anti-D (IgM) and Anti-D (Blend). These reagents are used for qualitative *in-vitro* determination of human blood groups using agglutination technology. The purpose of preparation of this Guidance Manual is to strengthen Quality Assurance systems in Blood transfusion services and also help manufacturers (imported/ indigenously) of the blood grouping reagents for ensuring standard quality of blood grouping reagents to be used by Blood Transfusion Services.

ABBREVIATIONS USED

BGR	Blood Grouping Reagent
BRL	Blood Reagent Laboratory
BSA	Bovine Serum Albumin
DCG(I)	Drugs Controller General of India
IS	Immediate Spin
IAT	Indirect Agglutination Test
IRCS	Indian Red Cross Society
IP	Indian Pharmacopoeia
IPC	Indian Pharmacopoeia Commission
NABL	National Accreditation Board for Testing and Calibration Laboratories
NIB	National Institute of Biologicals
NIBSC	National Institute of Biological Standards and Control
PBS	Phosphate Buffered Saline
QA	Quality Assurance
QC	Quality Control
RBC	Red Blood Cell
RT	Room Temperature
SOP	Standard Operating Procedure
SR & RDU	Sample Receipt and Report Dispatch Unit

CONTRIBUTORS

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ACKNOWLEDGEMENT

I would take this opportunity to express my gratitude to all the staff members of Blood Reagent Laboratory- Mrs. Kanchan Ahuja, Dr. Meena Kumari and Ms. Priya Bhatt for providing the valuable inputs in the preparation of the Guidance Manual on Quality Control of ABO and Rh blood grouping reagents without which the endeavor would not have been possible. I also wish them good luck in their future scientific work.

I sincerely acknowledge the help rendered by Indian Red Cross Society, New Delhi and Dr. Vanshree Singh, Director, IRCS for providing valuable material for the preparation red cell panel.

The encouragement provided by Dr. Surinder Singh- Director (i/c) to prepare this document is deeply acknowledged.

I hope the Guidance Manual on Quality Control of ABO and Rh blood grouping reagents will go a long way in Blood Transfusion Services.

Dr. C.Sokhey
Laboratory Head
Blood Regeant Laboratory

PURPOSE

The purpose of this guidance manual is to assist manufacturers of blood grouping reagents, including blood banks, transfusion services, and plasmapheresis centers in developing a quality assurance (QA) program and Quality control of ABO and Rh blood grouping reagents which are routinely used in the blood banks. The acceptance criteria for Anti-A, Anti-B, Anti-AB, Anti-D (IgM) and Anti-D (Blend) blood grouping reagents for parameters like potency, Intensity, avidity, prozone, rouleaux, specificity and physical appearance given in this manual are intended to help the Blood Transfusion Services to strengthen their Quality control Department.

SCOPE

This guidance manual provides general information on procedures and practices and may be useful to blood banks in developing and administering a QA program. Transfusion services, manufacturers, Blood banks etc may follow these guidelines or may choose to use alternative procedures not provided in the guidelines, however these alternative procedures must be established by International or National Regulatory Authority.

The methodology, specifications, and other matters referred to in this manual are intended to assist transfusion services, blood banks, manufacturers etc in Quality Control of Blood grouping reagents.

INTRODUCTION

National Institute of Biologicals is an autonomous institute under the Ministry of Health & Family Welfare set for the quality assessment of biological products manufactured indigenously and imported in the country, works in coordination with the Regulatory Authorities such as Drugs Controller General of India DCG (I) and the Indian Pharmacopoeia Commission.

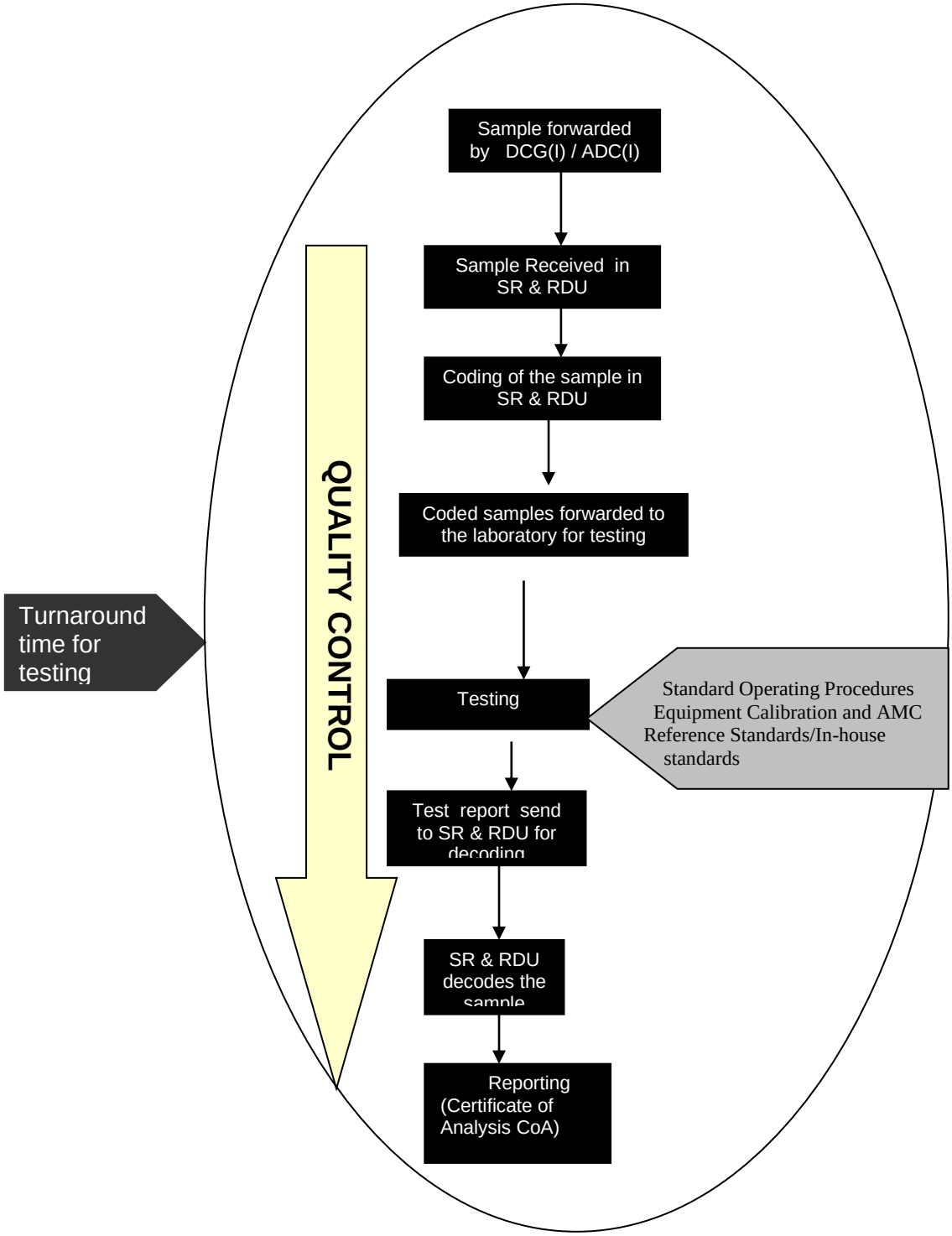
The Blood Reagent Laboratory is a notified laboratory by Government of India vide Gazette No. 158, dated 4th April, 2002 for quality control evaluation of Blood Grouping Reagents. The laboratory is also NABL accredited for Biological and Chemical tests as per ISO 17025:2005. Since 1997 the laboratory has evaluated a total number of 1313 batches of routine and rare blood grouping reagents. The laboratory has a repository of 39 cryopreserved panel members for routine and rare red blood cells.

In view to improve the quality of Blood Grouping reagents, the 1st edition of Guidance Manual on "Quality Control of ABO and Rh blood grouping reagents" is developed by National Institute of Biologicals which can be used by the Blood Transfusion Services to improve their quality control department.

The recommended methods are provided to help the user to have consistent and reliable products in conformity with specific standards and help to improve the quality of Blood transfusion Services. To ensure the continued safety of the nation's blood supply, it is essential that Blood transfusion Services implement effective Quality Control testing of Blood Grouping reagents.

SAMPLE RECEIVING

Samples of Blood Grouping Reagents for testing sent by DCG (I)/ADC (I)/Drug Inspectors are received by Sample Receipt and Report Dispatch Unit (SR & RDU) at NIB. Samples are coded by (SR & RDU) and then sent Blood Reagent Laboratory for Quality Control evaluation.



A. PROCEDURE FOR RECEIVING

1. Check whether the cold chain has been maintained.
2. Physically examine and document the following details in the Sample receipt register

I. Date of receiving in the laboratory
II. SR & RDU code
III. Name /type of the sample
IV. No. of vials and volume / vial
V. Check Details of documents, if any, received from SR & RDU with the sample
VI. Mark S.No. n /(1/3 to 3/3) on each of three vials.

B. STORAGE BEFORE TESTING

I. Store all reagents / kits received from SR & RDU at recommended temperature in dedicated refrigerator, cold room in FIFO (First in First out) manner.
II. Store only those samples in the laboratory refrigerator which are under testing/ planned for testing.

C. STORAGE AFTER TESTING

I. Analyst shall put initials on the vials opened and used for evaluation with date of testing.
II. Keep unopened vials of each evaluated sample in an identified location in cold room/ designated area at recommended temperature.

Quality assurance of ABO and Rh Blood Grouping Reagents (Monoclonal)

Good quality of immunohaematology reagents is important to ensure the effective and correct functioning of a blood transfusion service. In most of the developing countries the reagents used in the immunohaematology laboratory are from commercial source, the standardization of which is primarily carried out by the manufacturers and should meet the acceptance criteria. The quality control should be done to check the new batches of the Blood grouping reagents and to be sure that they comply with the established requirements.

REFERENCE STANDARDS (INTERNATIONAL AND IN HOUSE WORKING REFERENCE STANDARDS USED)

a. Anti-A International minimum potency reference preparation from National Institute of Biological Standards and Controls (NIBSC), UK – 03/188
b. Anti-B- International minimum potency reference preparation from National Institute of Biological Standards and Controls (NIBSC), UK – 03/164
c. Anti-D- International minimum potency reference preparation from National Institute of Biological Standards and Controls (NIBSC), UK – 99/836

Reference sera are to be used according to the accompanying package insert only for determining the potency of Blood Grouping Reagents.
Working standards for Anti-A, Anti-B , Anti-A,B, Anti-D (IgM) and Anti-D (Blend) blood grouping reagents are prepared using Secondary Standards (in house standards) which were calibrated against National Institute of Biological Standards and Control (NIBSC, UK).

Test Procedure for Anti-A (Monoclonal) , Anti-B (Monoclonal) and Anti- A,B (Monoclonal) Blood Grouping Reagent

MATERIAL AND EQUIPMENT REQUIRED:

1. Red Blood Cells suspension: 2-5% cells . Use cryopreserved red blood cells if fresh cells are not available.
2. Normal Saline.
3. Phosphate Buffered Saline pH (7.0)
4. Low Ionic Strength Solution.(if recommended)
5. Bovine Serum Albumin (22%) [Recommended concentration of BSA to be prepared freshly].
6. Sodium Hypochlorite (1%).
7. 70% Ethanol.

8. Reference standard for Anti- A , Anti-B and Anti-D
9. Test tubes 5ml (12 x 75mm)
10. Test tubes 10ml (16 x 100mm)
11. Glass Slides
12. Cover Slips
13. Beakers (100ml)
14. Centrifuge
15. Upright Microscope
16. Inverted Microscope
17. Micropipettes
18. pH-Meter
19. Stop watch
20. Refrigerator
21. -70^0C deep freezer
22. Incubator for 37^{o}C

PRE-TEST PREPARATION

Keep the bench ready and bring all the reagents to be evaluated at room temperature.

1. Check the reagent for physical appearance and color and document observations in Proforma
2. Prepare bench protocol for procedure to be followed for Titre, Specificity, Avidity, Intensity, Rouleaux and prozone testing.
3. Use normal saline or any other diluent as per standard instructions.
4. Arrange and label the test tubes for the reagent to be tested and reference standard in separate test tube stands.
5. Use fresh pipette tip for each dilution to avoid carry over of reagent to next higher dilution.

TEST PROCEDURE FOR Anti-A, Anti-B and Anti-AB

PREPARATION OF MASTER DILUTION OF REAGENT UNDER TEST AND REFERENCE STANDARD

1. Arrange and label one row each of test tubes from 1: 2 to 1:4096 for master dilution for reagent under evaluation and reference standard respectively.
2. Beginning with the undiluted reagent, prepare a two fold master serial dilutions (1:2, 1:4 etc. till 1:4096) for Test and standard separately.
3. Prepare 100ul volume of each dilution extra as buffer volume for pipetting following formula 100 x n + 100 where ‘n’ denotes number of reagent RBCs to be used.
4. For example, at each dilution a total of 300ul reagent will be required for using 100ul each for three Reagent red blood cells. Prepare a total of 400ul of each dilution as depicted in the diagram below: -
    A. Add 400ul of reagent diluent (Normal Saline or as per instructions) and 400ul of reagent to tube no 1.
    B. Mix and transfer 400ul to next tube.
    C. Repeat step two till tube no.12 as above

400ul 400ul 400ul 400ul 400ul 400ul 400ul 400ul 400ul 400ul 400ul

Master Dilution	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512	1:1024	1:2048	1:4096
Tube No	1	2	3	4	5	6	7	8	9	10	11	12

TITRATION AND SPECIFICITY:

1. Arrange and label as many rows of test tubes as the number of reagent red cells, to be used for titration of test reagent as above.
2. Arrange identical set of tubes for reference standard.
3. Dispense 100ul of each dilution from respective master dilution tube.
4. Arrange and label the tubes for negative control cells for specificity testing of reagent under test and for reference standard. Use undiluted (100ul neat) reagent for specificity testing for each negative control cell.
5. Dispense 100ul of reagent red blood cell suspension of positive control cells and negative control cells to the respective rows of tubes for reagent under test and reference standard separately.
6. Gently shake test tube stand to mix the contents thoroughly.
7. Centrifuge for 1 minute at 1000rpm.
8. For specificity, observe all the negative control tubes under the microscope for clear-cut negative reaction.
9. Gently dislodge the cell buttons of each test tube and examine grade of reaction macroscopically (as per Annexure -1) and record the readings.

AVIDITY & INTENSITY TESTING BY SLIDE METHOD (at room temperature)

1. Reagent Red Cell Preparation: Prepare 40-50% of reagent red cells suspension
2. Dispense an equal volume of reagent under test (20-50ul) and reagent red blood cells (40-50%) on clean glass slide, adjacently.
3. Mix reagent and cells rapidly in a circular manner using a tooth pick and spread over 1-3 mm diameter area on slide.
4. Observe and measure the time for appearance of the first visible agglutination.
5. For each reagent cell repeat steps 2 to 4 three times and calculate mean of three observations.
6. Mix the contents for 2 minutes by moving slide gently in an orbital manner and note the intensity of the reaction. Record the grade of the reaction.

REACTIVITY

HAEMOLYSIS: Observe all tubes for absence of haemolysis.

ROULEAUX: Check the contents of all the negative control tubes microscopically for absence of rouleaux. Place about 5ul of the mixed contents on a slide and cover with cover slip and observe under the microscope.

PROZONE: TESTING BY TUBE METHOD

1. Arrange and label 3 tubes for each reagent RBC to be tested, "15 Minutes", "30 Minutes" and "60 Minutes" respectively.
2. Add 100ul of neat reagent to all tubes or as per manufacturer's instructions.
3. Use 2-5 % suspension of positive control reagent red cells (same as used for titration).
4. Add 100ul (or as per manufacturer's instructions) of each RBC sample to respective tubes.
5. Mix and incubate at RT for the duration indicated in the tube or as per manufacturer's instructions.
6. Centrifuge at 1000 rpm for 1 minute or as per manufacturer's instructions.
7. Record the grade of the reaction as in the case of titration.
8. At least a 2+-reaction grade should be obtained with all samples at all incubation times.
9. Interpretation of the test:

   NO PROZONE is present - *if the reaction grades are the same or increase as the incubation time increases*,
   A PROZONE is present - If *the reaction grade decreases as the incubation time increases*.

10. **Recording of Results** : Record all the raw data, test results, observations in Proforma
    A. The test results should show at least one tube with no agglutination after the end point.
    B. The Cell control / Diluent control should show negative reaction.

a) Acceptance Criteria for Titre, Specificity and Avidity for Anti-A (Monoclonal) Reagent

Name of the Reagent	Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (time in Seconds)	Intensity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti- A	Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and blue colored liquid	A_1	≥1:256	3 - 4 sec	3+	Positive	↑
			A_2	≥1:128	5 – 6 sec	2+ to 3+	Positive	
			A_2B	≥1:64	5 – 6 sec	3+ to 4+	Positive	Absent
			B	---	---	---	Negative	
			O	---	---	---	Negative	↓

b) Acceptance Criteria for Titre, Specificity and Avidity for Anti B (Monoclonal) Reagent

Name of the Reagent	Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (time in Seconds)	Intensity	Specificity	Reactivity Rouleaux/ Haemolysis/ Prozone
Anti- B	Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and yellow colored liquid	B	≥1:256	3 - 4	4+	Positive	↑
			A_1B	≥1:128	5 – 6	2+ to 3+	Positive	
			A_1	---	---	----	Negative	Absent
			O	---	---	---	Negative	↓

c) Acceptance Criteria for Titre, Specificity and Avidity for Anti-A,B (Monoclonal) Reagent

Name of the Reagent	Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (Seconds)	Intensity	Specificity	Reactivity Rouleaux/ Haemolysis/ Prozone
Anti-A,B	Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colorless or cherry colored liquid	A_1	≥1:256	3 - 4 sec	4+	Positive	↑
			B	≥1:256	3 – 4 sec	4+	Positive	
			A_2	≥1:128	5 – 6 sec	3+	Positive	Absent
			A_x	---	---	---	Positive	↓
			O	---	---	---	Negative	

Titre

1.
2. The test results should show at least one tube with no agglutination after the end point.
3. The Cell control / Diluent control should show negative reaction.

Specificity: Red Blood Cells with 'A' antigen (A_1, A_2, A_2B) shows positive reaction and red blood cells without 'A' antigen (B and O) shows negative reaction with Anti-A (Monoclonal) reagent.

Red Blood Cells with 'B' antigen (B, A_1B) shows positive reaction and red blood cells without 'B' antigen (A_1 and O) shows negative reaction with Anti-B (Monoclonal) reagent.

Red Blood Cells with 'AB' antigen (A_1, A_2 , B, A_x) shows positive reaction and red blood cells without 'AB' antigen (O) shows negative reaction with Anti-A,B (Monoclonal)

Avidity: Grade of reaction at the end of 2 minutes and mean time observed as per the acceptance criteria

Reactivity: No haemolysis, rouleaux and prozone should be observed.

Test Procedure For Anti-D (IgM) and Anti-D (Blend) blood grouping reagent

PREPARATION OF MASTER DILUTION OF REAGENT UNDER TEST AND IN-HOUSE CONTROL

1. Arrange and label one row each of test tubes from 1:2 to 1:4096 for master dilution for reagent under evaluation and In-house control respectively.
2. Beginning with the undiluted Anti-D (IgM) Monoclonal reagent, prepare a two fold master serial dilutions (1:2, 1:4 etc. till 1:4096) for test and In-house reagent separately.
3. Prepare 100ul volume of each dilution extra as buffer volume for pipetting, following formula 100 x n+ 100 where 'n' denotes number of reagent RBC to be used.
4. For example, at each dilution a total of 300ul reagent will be required for using 100ul each for three Reagent red blood cells. Prepare a total of 400ul of each dilution as depicted in the diagram below: -
    A. Add 400ul of reagent diluent (Normal Saline or as per manufacturer's instructions) and 400ul of neat reagent to tube no 1.
    B. Mix and transfer 400ul to next tube.
    C. Repeat step two till tube no.12 as above

400ul 400ul 400ul 400ul 400ul 400ul 400ul 400ul 400ul 400ul 400ul

Master Dilution	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512	1:1024	1:2048	1:4096
Tube No	1	2	3	4	5	6	7	8	9	10	11	12

TITRATION AND SPECIFICITY

1. Arrange and label as many rows of test tubes as the number of reagent red cells, to be used for titration of test reagent at RT.
2. Arrange identical sets of tubes for In-house control.
3. Arrange two more sets, as above, for titration at 37^0C, as per manufacturers' protocol if recommended.
4. Dispense 100ul of each dilution from respective master dilution tube.
5. Arrange and label the tubes for negative control cells for specificity testing of test reagent and In-house control. Use undiluted (100ul neat) reagent for specificity testing for each negative control cell.
6. Dispense 100ul of reagent red blood cell suspension of positive control cells and negative control cells to the respective rows of tubes for test reagent and In-house control separately.
7. Gently shake test tube stand to mix the contents thoroughly.
8. Centrifuge for 1 minute at 1000rpm OR as per manufacturer's instructions.
9. For specificity, observe all the negative control tubes under the microscope for clear-cut negative reaction.

10. Gently dislodge the cell button and examine grade of reaction macroscopically (as per Annexure -1) and record the readings.

AVIDITY TESTING BY SLIDE METHOD (at room temperature)

1. Reagent Red Cell 40-50% suspension OR as per manufacturer's protocol for all positive control cells.
2. Perform the test as per manufacturer's protocol or as per SOP. Dispense an equal volume of reagent under test (20-50ul) and reagent red blood cells on clean glass slide, adjacently.
3. Mix reagent and cells rapidly in a circular manner using a tooth pick and spread over 1-3 mm diameter area on slide.
4. Observe and measure the time for appearance of the first visible agglutination.
5. For each reagent cell repeat steps 2 to 4 three times and calculate mean of three measurements.
6. Mix the contents for 2 minutes by moving slide gently in an orbital manner and note the intensity of the reaction. Record the grade of the reaction.

REACTIVITY

HAEMOLYSIS: Observe all tubes for haemolysis.

ROULEAUX: Check the contents of all the negative control tubes microscopically for absence of rouleaux. Place about 5ul of the mixed contents on a slide and cover with cover slip and observe under the microscope.

PROZONE: TESTING BY TUBE METHOD

1. Arrange and label 3 tubes for each reagent RBC to be tested, "15 Minutes", "30 Minutes" and "60 Minutes" respectively.
2. Add 100ul of neat reagent to all tubes or as per manufacturer's instructions.
3. Use 2-5 % suspension of positive control reagent red cells (same as used for titration).
4. Add 100ul (or as per manufacturer's instructions) of each reagent RBC to respective tube.
5. Mix and incubate at RT for the duration indicated on the tube or as per manufacturer's instructions.
6. Centrifuge at 1000 rpm for 1 minute or as per manufacturer's instructions.
7. Record the grade of the reaction.
8. At least a 2+-reaction grade should be obtained with all samples at all incubation times.
9. **Interpretation of the test:**
   - **NO PROZONE is present** - *If the reaction grades are the same or increase as the Incubation time increases*,.
   - **A PROZONE is present** - *If the reaction grade decreases as the incubation time increases*.

10. **Recording of Results:** Record all the raw data, test results, observations, trouble shooting, deviations, amendment, repeat test and reasons for repeat testing, etc. in Proforma and respective register.

a) Acceptance Criteria for Titre, Specificity and Avidity for Anti-D(IgM) Monoclonal Reagent:

Name of the Reagent and Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (Seconds)	Intensity	Specificity	Reactivity (Rouleaux, Haemolysis Prozone)
Anti-D (IgM) Blend Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colorless liquid	O +ve R_1 r (or) R_1R_2	IS - 1:64 – 1:128 37^0C x 30" 1:128 – 1:256	5 - 10 sec	3+	Positive	Absent
		Rh-negative (IAT)	----	----	---	Negative	

b) Acceptance Criteria for Titre, Specificity and Avidity for Reagent Anti- D (IgM+IgG) (Blend):

Name of the Reagent and Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (Seconds)	Intensity	Specificity	Reactivity (Rouleaux, Haemolysis Prozone)
Anti-D (IgG+ IgM) Blend Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colorless liquid	O +ve R_1 r (or) R_1R_2	IS - 1:32 – 1:64 37^0C x 30" 1:128 – 1:256	10 - 20 sec	3+	Positive	Absent
		Rh-negative (IAT)	----	----	---	Negative	

Titre:

1. The titre is the reciprocal of the greatest reagent dilution for which the reaction is graded at 1+.
2. The test results should show at least one tube with no agglutination after the end point.
3. The Cell control / Diluent control should show negative reaction

Specificity: Red Blood Cells with and without Rh - D antigen show positive and negative reaction respectively.
Avidity & Intensity: Grade of reaction at the end of 2 minutes and mean time observed as per above table.
Reactivity: No haemolysis, rouleaux and prozone should be observed.

ANNEXURE: 1- Grading agglutination reactions for titre@

Grade	Appearance
Complete or 4+	A single agglutinate. No free red cells detected.
$4+^{w}$ or $3+^{s}$	Strong reaction with a large agglutinate and 1or 2 small agglutinate. No free red cells detected.
3+	Strong reaction. A number of large agglutinates. No free red cells detected.
$3+^{w}$ or $2+^{s}$	Strong reaction with a number of small and large agglutinates. No free red cells detected.
2+	Large agglutinates in a sea of smaller clumps, no free red cells.
$2+^{w}$	Many agglutinates-medium and small no free red cells.
$1+^{s}$	Many medium and small agglutinates and free red cells in the background.
1+	Many small agglutinates and a background of free red cells.
$1+^{w}$	Many very small agglutinates with a lot of free red cells.
$\pm$ Macro*	Weak granularity in the RBC suspension. A few macroscopic agglutinates but numerous agglutinates microscopically.
(+) Micro**	Appears negative macroscopically. A few agglutinates of 6-8 red cells in most fields.
(0^{R})Rough	Rare agglutinates observed microscopically.
0	An even red cells suspension. No agglutinates detected.
***Macro = Macroscopic**	****Micro = Microscopic**

@ Marsh WL. Scoring of hemagglutination reactions.Transfusion 1972; 12:352-3

Format for Evaluation of Anti-A (Monoclonal)

EVALUATION ALLOCATION

Lab. Head/In-Charge	Analyst:	Supervisor:_____
Signature	Signature	Signature
Date:		

DETAILS OF TEST SAMPLE – ANTI-A (MONOCLONAL) REAGENT

SRRDU Code	Lab S. No in (BRL/REG/03/ Evaluation BGR)	Date of receiving	Date of opening /Testing	Appearance / Color	Vial ID
Remarks					

DETAILS OF IN-HOUSE CONTROL – ANTI-A (MONOCLONAL) REAGENT

S.No in (BRL/REG/04/ Reagent Calibration)	Vial ID	Exp.Dt.	Titre	Avidity	Specificity	Reactivity
Remarks						

Reagent Red Cell Suspension required:

S.No	Blood group	Date of Collection / Preservation	Sl.No in BRL Lab.Reg	% & volume Required			Remarks
				Titration	Avidity	Specificity	
1.	A_1						
2.	A_2						
3.	A_2B						
4.	B						
5.	O						

Diluent used for cell suspension & Reagent Dilution

SALINE / PBS / BSA
pH
Date of preparation

Testing Details

Incubation	Centrifugation	Method	Temperature

Signature of the Analyst: _____Checked by: _____

WORKSHEET FOR QUALITY CONTROL EVALUATION

TITRATION & SPECIFICITY

S.N0	Red Cells Used	REAGENT DILUTION													Cell Control
		N	2	4	8	16	32	64	128	256	512	1024	2048	4096	
TEST															
1.	B														
2.	A_1B														
3.	A_1														
4.	O														
IN-HOUSE CONTROL															
1.	B														
2.	A_1B														
3.	A_1														
4.	O														

REACTIVITY

Haemolysis _____ **Rouleaux _____**

Signature of the Analyst: _____Checked by: _____

PROZONE RESULTS:

Red Cells Used	REACTION GRADE OBSERVED AT INCUBATION TIME			**Prozone**
	15 MINUTES	30 MINUTES	60 MINUTES	
A_1				
A_2				
A_2B				

AVIDITY & INTENSITY RESULTS:

Red Cells Used	AVIDITY (SECONDS)			MEAN	INTENSITY
	I	II	III		
A_1					
A_2					
A_2B					

Signature of the Analyst: _____ Checked by: _____

COMPILED RESULTS

Cells Used	Avidity	Intensity (Grade)	Titre	Specificity	Reactivity
A_1					
A_2					
A_2B					
B					
O					
FINAL CONCLUSION					
SATISFACTORY (YES/NO)					

REMARKS

Troubleshooting (if any)	
Repeat Test (if any)	
Reasons for repeat test	

Signature of the Analyst: _____Checked by: _____

Format for Evaluation of Anti-B (Monoclonal)

EVALUATION ALLOCATION

Lab. Head /In-Charge	Analyst:_____	Supervisor:_____
Signature	Signature	Signature
Date: _____		

DETAILS OF TEST SAMPLE - ANTI-B (MONOCLONAL) REAGENT

SRRDU Code	Lab S. No in (BRL/REG/03/ Evaluation BGR)	Date of receiving	Date of opening / Testing	Appearance / Color	Vial ID
Remarks					

DETAILS OF IN-HOUSE CONTROL – ANTI-B (MONOCLONAL) REAGENT

S.No in (BRL/REG/04/ Reagent Calibration)	Vial ID	Exp.Dt.	Titre	Avidity	Specificity	Reactivity
Remarks						

I Reagent Red Cell Suspension required:

S.No	Blood group	Date of Collection / Preservation	Sl.No in BRL Lab.Reg	% & volume Required		
				Titration	Avidity	specificity
1.	B					
2.	A_1B					
3.	A_1					
4.	O					

II Diluent used for cell suspension & Reagent Dilution

SALINE / PBS / BSA
pH
Date of preparation

III TESTING DETAILS

Incubation	Centrifugation	Method	Temperature

Signature of the Analyst: _____ Checked by: _____

WORKSHEET FOR QUALITY CONTROL EVALUATION

IV TITRATION & SPECIFICITY

S.N0	Red Cells Used	REAGENT DILUTION													Cell Control
		N	2	4	8	16	32	64	128	256	512	1024	2048	4096	
TEST															
1.	B														
2.	A_1B														
3.	A_1														
4.	O														
IN-HOUSE CONTROL															
1.	B														
2.	A_1B														
3.	A_1														
4.	O														

REACTIVITY

Haemolysis _____ **Rouleaux _____**

Signature of the Analyst: _____ Checked by: _____

WORKSHEET FOR QUALITY CONTROL EVALUATION

V PROZONE RESULTS:

Red Cells Used	REACTION GRADE OBSERVED AT INCUBATION TIME			**Prozone**
	15 MINUTES	30 MINUTES	60 MINUTES	
B				
A_1B				

VI AVIDITY AND INTENSITY RESULTS:

Red Cells Used	AVIDITY (SECONDS)			MEAN	INTENSITY
	I	II	III		
B					
A_1B					

Signature of the Analyst: _____ Checked by: _____

COMPILED RESULTS

Cells Used	Avidity	Intensity	Titre	Specificity	Reactivity
B					
A_1B					
A_1					
O					
FINAL CONCLUSION					
SATISFACTORY (YES/NO)					

REMARKS

Troubleshooting (if any)	
Repeat Test (if any)	
Reasons for repeat test	

Signature of the Analyst: _____ Checked by: _____

Format for Evaluation of Anti-A,B (Monoclonal)

EVALUATION ALLOCATION

Lab. Head/ In-Charge	Analyst:	Supervisor:_____ _
Sig	Sig.	Sig.
Date:		

DETAILS OF TEST SAMPLE – ANTI-A,B (MONOCLONAL) REAGENT

SRRDU Code	Lab S. No in (BRL/REG/03/ Evaluation BGR)	Date of receiving	Date of opening / Testing	Appearance / Color	Vial ID

DETAILS OF IN-HOUSE CONTROL – ANTI-A,B (MONOCLONAL) REAGENT

S.No in (BRL/REG/04/ Reagent Calibration)	Vial ID	Exp.Dt.	Titre	Avidity	Specificity	Reactivity
Remarks						

I. Reagent Red Cell Suspension required:

S.No	Blood group	Date of Collection / Preservation	Sl.No in BRL Lab.Reg	% & volume Required			Remarks
				Titration	Avidity	Specificity	
1.	A_1						
2.	A_2						
3.	B						
4.	A_x						
5.	O						

II. Diluent used for cell suspension & Reagent Dilution

SALINE / PBS / BSA
pH
Date of preparation

III. Testing Details

Incubation	Centrifugation	Method	Temperature

Signature of the Analyst_____ Checked by_____

IV TITRATION & SPECIFICITY

S.N0	Red Cells Used	REAGENT DILUTION													Cell Control
		N	2	4	8	16	32	64	128	256	512	1024	2048	4096	
TEST															
1.	A_1														
2.	A_2														
3.	B														
4.	A_x														
5.	O														
IN-HOUSE CONTROL															
1.	A_1														
2.	A_2														
3.	B														
4.	A_x														
5.	O														

V REACTIVITY

Haemolysis _____ Rouleaux _____

Signature of the Analyst_____ Checked by_____

VI PROZONE RESULTS:

Red Cells Used	REACTION GRADE OBSERVED AT INCUBATION TIME			**Prozone**
	15 MINUTES	30 MINUTES	60 MINUTES	
A_1				
A_2				
B				

VII AVIDITY AND COMPILED RESULTS:

Red Cells Used	AVIDITY (SECONDS)			MEAN	INTENSITY
	I	II	III		
A_1					
A_2					
B					

Signature of the Analyst: _____ Checked by: _____

COMPILED RESULTS

Cells Used	Avidity	Intensity (Grade)	Titre	Specificity	Reactivity
A_1					
A_2					
B					
A_X					
O					
FINAL CONCLUSION					
SATISFACTORY (YES/NO)					

REMARKS

Troubleshooting (if any)	
Deviation (if any)	
Repeat Test (if any)	
Reasons for repeat test	

Signature of the Analyst: _____ Checked by: _____

Format for Evaluation of Anti-D IgM (Monoclonal)

EVALUATION ALLOCATION

Lab. Head / In-Charge	Analyst:	Supervisor:_____
Signature	Signature	Signature
Date:		

DETAILS OF TEST SAMPLE (ANTI-D- IgM) MONOCLONAL

SRRDU Code	Lab S. No in (BRL/REG/03/ Evaluation BGR)	Date of receiving	Date of opening/Testing	Appearance / Color	Vial ID

DETAILS OF IN-HOUSE CONTROL (ANTI-D- IgM) MONOCLONAL

S.No in (BRL/REG/04/ Reagent Calibration)	Vial ID	Exp.Dt.	Title	Avidity/ Intensity	Specificity	Reactivity
Remarks						

I. Reagent Red Cell Suspension required:

S.No	Blood group	Date of Collection / Preservation	Sl.No in BRL Lab.Reg	% & volume Required			Remarks
				Titration	Avidity	Specificity	
1.	O +ve (R_1r) OR (R_1R_2)						
2.	O Rh D Neg (IAT neg) (rr / r'r / r''r)						

II. Diluent used for cell suspension & Reagent Dilution

SALINE / PBS / BSA
pH
Date of preparation

III. TEST CONDITIONS

Incubation	Centrifugation	Method	Temperature

Signature of the Analyst_____ Checked by_____

WORKSHEET FOR QUALITY CONTROL EVALUATION

IV TITRATION & SPECIFICITY

S.No	Red Cells Used	REAGENT DILUTION													Cell Control
		N	2	4	8	16	32	64	128	256	512	1024	2048	4096	
TEST – AT ROOM TEMPERATURE															
6.	O +ve (R_1R_2)/ (R_1r)														
7.	Rh D Neg(IATneg)														
TEST – AT 37^{0}C															
8.	O +ve (R_1R_2)/ (R_1r)														
9.	Rh D Neg (IAT neg)														
IN-HOUSE CONTROL – AT ROOM TEMPERATURE															
4.	O +ve (R_1R_2)/ (R_1r)														
5.	Rh D Neg (IAT neg)														
IN-HOUSE CONTROL – AT 37^{0}C															
6.	O +ve (R_1R_2) (R_1r)														
7.	Rh D Neg (IAT neg)														

V REACTIVITY

Haemolysis _____ **Rouleaux _____**

Signature of the Analyst_____ Checked by_____

WORKSHEET FOR QUALITY CONTROL EVALUATION

VI PROZONE RESULTS :

Red Cells Used	REACTION GRADE OBSERVED AT INCUBATION TIME			Prozone
	15 MINUTES	30 MINUTES	60 MINUTES	
O +ve $(R_1R_2)/(R_1r)$				

VII AVIDITY & INTENSITY RESULTS:

Red Cells Used	AVIDITY (SECONDS)			MEAN	INTENSITY
	I	II	III		
O +ve $(R_1R_2)/(R_1r)$					

Signature of the Analyst_____ Checked by_____

COMPILED RESULTS

Cells Used	Avidity	Intensity (Grade)	Titre	Specificity	Reactivity
O +ve (R_1R_2)/(R_1r)					
Rh D Neg (IAT neg)					
FINAL CONCLUSION					
SATISFACTORY (YES/NO)					

REMARKS

Troubleshooting (if any)	NIL
Repeat Test (if any)	NIL
Reasons for repeat test	NIL

Signature of the Analyst: _____ Checked by: _____

Format for Evaluation of Anti-D (IgG + IgM) (Monoclonal)

EVALUATION ALLOCATION

Lab Head/ In-Charge	Analyst:	Supervisor:_____
Signature	Signature	Signature
Date:		

DETAILS OF TEST SAMPLE (ANTI-D- BLEND)

SRRDU Code	Lab S. No in (BRL/REG/03/ Evaluation BGR)	Date of receiving	Date of opening/Testing	Appearance / Color	Vial ID
Remarks					

DETAILS OF IN-HOUSE CONTROL (ANTI-D- BLEND)

S.No in (BRL/REG/04/ Reagent Calibration)	Vial ID	Exp.Dt.	Titre	Avidity	Specificity	Reactivity
Remarks						

I. Reagent Red Cell Suspension required:

S.No	Blood group	Date of Collection / Preservation	Sl.No in BRL Lab.Reg	% & volume Required			Remarks
				Titration	Avidity	Specificity	
1.	O +ve (R_1r OR R_1R_2)						
2.	O Rh D Neg (IAT neg) (rr / r'r / r''r)						

II. Diluent used for cell suspension & Reagent Dilution

SALINE / PBS / BSA
pH
Date of preparation

III. TEST CONDITIONS

Incubation	Centrifugation	Method	Temperature

Signature of the Analyst_____ Checked by_____

WORKSHEET FOR QUALITY CONTROL EVALUATION

IV TITRATION & SPECIFICITY

S.N0	Red Cells Used	REAGENT DILUTION													Cell Control
		N	2	4	8	16	32	64	128	256	512	1024	2048	4096	
TEST – AT ROOM TEMPERATURE															
1.	O +ve (R_1r OR R_1R_2)														
2.	Rh D Neg (IAT neg)														
TEST – AT 37^{0}C															
3.	O +ve (R_1r OR R_1R_2)														
4.	Rh D Neg (IAT neg)														
IN-HOUSE CONTROL – AT ROOM TEMPERATURE															
8.	O +ve (R_1r OR R_1R_2)														
9.	Rh D Neg (IAT neg)														
IN-HOUSE CONTROL – AT 37^{0}C															
10.	O +ve (R_1r OR R_1R_2)														
11.	Rh D Neg (IAT neg)														

V REACTIVITY

Haemolysis _____ Rouleaux _____

Signature of the Analyst_____ Checked by_____

WORKSHEET FOR QUALITY CONTROL EVALUATION

VI PROZONE RESULTS:

Red Cells Used	REACTION GRADE OBSERVED AT INCUBATION TIME			**Prozone**
	15 MINUTES	30 MINUTES	60 MINUTES	
O +ve (R_1r OR R_1R_2)				

VII AVIDITY AND INTENSITY RESULTS:

Red Cells Used	AVIDITY (SECONDS)			MEAN	INTENSITY
	I	II	III		
O +ve (R_1r OR R_1R_2)					

Signature of the Analyst_____ Checked by_____

COMPILED RESULTS

Cells Used	Avidity	Intensity (Grade)	Titre	Specificity	Reactivity
O +ve (R_1r OR R_1R_2)					
Rh D Neg (IAT neg)					
FINAL CONCLUSION					
SATISFACTORY (YES/NO)					

REMARKS

Troubleshooting (if any)	
Repeat Test (if any)	
Reasons for repeat test	

Signature of the Analyst: _____ Checked by: _____

Bio-safety in laboratory and safe disposal of biomedical waste

Introduction

Bio-safety, is a key component of total quality control programme. There is a potential risk of infection to the workers (Scientists, doctors, Laboratory technicians) who handle samples of body fluids/tissues and workers (laboratory attendants) which handle infected waste and transport potentially infected specimens. They are exposed to certain infections by nature of their profession. These infections could be bacterial, viral, parasitic or fungal. Some of these are serious like hepatitis (B & C), Human Immunodeficiency Virus (HIV) etc. and may even result in death, whereas, others are not serious and only cause morbidity.

Bio- hazards in laboratory

Laboratories are exposed to biological hazards, besides common hazards like fire, chemical and electrical. Safety is one aspect which minimizes the risks of injury, infection or other dangers related to laboratory services. Safety is an important factor to prevent transmission of infection such as Hepatitis B and C and HIV while collecting blood for grouping and evaluation of blood grouping reagents.

There are several ways that workers can acquire blood borne infection from a donor or from his/her specimen either by:

1. direct contact with blood / body fluids
2. accidental inoculation of infected blood/body fluids
3. accidental cuts with contaminated sharps
4. indirect contact with contaminated equipment or any other inanimate infected object

In a laboratory, all bio-safety measures should be ensured and workers must take all precautionary measures to protect themselves from accidental injury while handling the blood.

Bio-safety procedures

Infrastructural requirements

1. Ensure that there is adequate working area for a particular laboratory work for smooth and safe functioning.
2. The walls, ceiling and floor should be smooth, easy to clean, impermeable and resistant to chemicals and disinfectants.
3. The bench tops should be impervious and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.
4. Lab furniture to be sturdy and easy to clean.
5. Wash –basin to be provided in each lab preferably near the exit.

6. Illumination should be adequate for work.
7. Doors to be self – closing with vision panel.
8. Lockers for personal items to be outside the working area.
9. Space for eating/drinking/smoking to be provided outside laboratory/area.
10. Availability of medical room in case of any emergency.

Universal Bio-safety procedures

1. All laboratory staff shall be vaccinated against Hepatitis B and immunization records be maintained
2. Only authorized persons enter the laboratory working areas.
3. Keep laboratory doors closed.
4. Keep children out of laboratory areas.
5. Do not wear open toed footwear /street shoes in laboratories- change footwear before entering /leaving.
6. Wear protective clothing when working in the laboratory and remove before leaving the laboratory.
7. Store used protective laboratory clothing in separate lockers or cupboards.
8. Eating, drinking, smoking, applying cosmetics and handling contact lenses is prohibited in the laboratory.
9. Storing foods or drinks for consumption anywhere in the laboratory areas is prohibited.
10. Wear protective gloves and personnel should disinfect their hands before and after using gloves.
11. Gloves must be removed and discarded correctly in order to avoid contamination.

Follow steps given below, to remove gloves safely

- Pull one glove near your wrist towards your fingertips until the glove folds over.

Step 1

- Carefully grab the fold and pull towards your fingertips. As you pull you are turning the inside of the glove outwards.

Step 2

- Pull the fold until the glove is almost off. To avoid contamination of your environment, continue to hold the removed glove. Completely remove your hand from the glove.

Step 3

- Slide a finger from your glove-free hand under the remaining glove. Continue to slide your finger towards your fingertips until almost half of your finger is under the glove.

Step 4

- Turn you finger 180 degrees and pull the glove outwards and towards your fingertips. As you do this, the first glove will be encased in the second glove. The inside of the second glove will also be turned outwards.

Step 5

- Grab the gloves firmly, by the uncontaminated surface (the side that was originally touching your hand). Release your grasp of the first glove you removed. Pull your second hand free from its glove. **Tear/cut gloves and place in designated container.**

Step 6

12. When working with hazardous materials, the glove should overlap the lower sleeve and the cuff of the protective clothing.
13. Remove and dispose of gloves when torn or contaminated.
14. Do not touch eyes, nose and other exposed membranes or skin with gloved hands.
15. Handle blood/bio hazardous material only in designated area.
16. Work surfaces must be decontaminated after completing bench work in routine and after any spill of any hazardous material.
17. Segregate and decontaminate all bio hazardous waste before disposal .
18. Use dedicated pens for bench work.
19. Take help of co worker for recording observations to prevent contamination of papers / proforma used.

Safe procedure for using centrifuge

1. Disinfect rotors with 70% alcohol after each use.
2. Centrifuges should be operated according to manufacturer's instructions.
3. Always balance tubes properly before centrifugation.
4. Always cap tubes with the specimen securely (screw –capped, if possible) for centrifugation.
5. Keep the level of the sample/fluid lower than the rim of the tube to avoid spillage.
6. Add disinfectant to the space between the tube and the bucket to disinfect material in the event of breakage during centrifugation.
7. Use color-coded biohazard bags for specific waste disposal, as per Government of India Gazette Notification No. 460 dated 20th July 1998.

Safe pipetting procedure

1. No pipetting by mouth to be done.
2. Never blow air through hazardous liquid solutions etc.
3. Do not expel liquids forcibly from pipettes.
4. Do not discharge material from a pipette at a height and allow the discharge to run down the container wall.
5. Decontaminate used pipette tips by soaking in 1% Sodium hypochlorite overnight before disposal.

Management of Spills and Accidents:

Spill

1. Always wear good quality gloves while handling spills and accidents in the laboratory.
2. Alert others to the spill.
3. Spill of infected material to be covered with adequate filter sheets or absorbent material (cotton/tissue paper).
4. Pour neat sodium hypochlorite over and around the absorbent material and leave for 30 min.
5. Wipe off the spilled material in a circular and inward manner and place the absorbent material in contaminated waste.
6. Wipe surface again with disinfectant.
7. In case of spillage of chemical, wash exposed area with running water and consult Material Safety Data Sheet for appropriate remedy / medical treatment.

Accidents

1. In case of breakage of glass container, carefully collect broken glass with a dustpan and brush and discard in a sharp container.
2. In case of any sharp injury/ skin contamination by spills or splashes of specimen material thoroughly wash with soap and water.

Procedure to handle emergencies and accidents

1. Any injury to a laboratory worker should be reported immediately to the Laboratory In charge, and take an appropriate and timely action to obtain appropriate medical treatment if required.
2. If an accident involves a bio hazardous spill, move the injured person away from the spill.
3. Inactivate the spill after attending to the injured person.
4. Loosen and remove the soiled protective clothing (i.e., lab coat) if necessary with minimum movements of the person in case of injury.

Reporting and Documentation

1. Report all spills and accidents to Lab In charge / concerned officials.
2. Promptly document spills and accidents in the register and Proforma for Reporting Accident & Spillage.
3. Ensure prompt and appropriate medical aid/Retroviral therapy- as per organization policy.

Packaging and Transporting Specimen

1. Collected blood samples are transported in a tight container that is labeled and marked with " biohazard" symbol given below:

   BIOHAZARD SYMBOL

2. Tubes and Specimen containers carrying the specimen should always be securely capped.

Safe disposal of biomedical waste

Biomedical Waste is defined as unwanted trash generated during diagnosis, treatment and immunization of human beings, during research activities or testing of biologicals. Laboratories are major source of biomedical waste. These are:

1. Biologicals /blood /body fluids, etc.: Blood samples collected and stored to use as red blood cell, panel, serum and plasma.
2. Biotechnology waste: Materials generated as waste from the kit like any reagent buffers, diluents etc.
3. Sharps waste: Glass slides, cover slips, test tubes etc.
4. Solid waste other than sharps waste: Pipette tips, plastic vials, cotton, tissue paper contaminated with blood.
5. Liquid waste: Generated during testing, from washing

Name of the Product: Anti-A (Monoclonal)

NATIONAL INSTITUTE OF BIOLOGICALS
(Ministry of Health & Family Welfare)
An ISO 17025: 2005 Accredited Institute

Certificate No: T- 2010 **Certificate No: T- 2011**
Dated:

CERTIFICATE OF ANALYSIS

Date of Performance of test :
Date of Sample Receipt :
CDR NO. :
Analytical Report No. :
Name of Product & Dosage Form : Anti- A (Monoclonal)
Name of the Manufacturer :
Marketed by :
Batch / lot No. :
Manufacturing date :
Expiry date :

S.No.	Test(s) Conducted	Specification		Result
		Test RBC	Specification	
1.	Titre	A1 A2 A2B	≥ 1:256 ≥ 1:128 ≥ 1:64	
2.	Avidity (Sec) /Intensity	A1 A2 A2B	3-4 Sec/3+ 5-6 Sec/2+ to 3+ 5-6 Sec/3+ to 4+	
3.	Specificity	A1 A2 A2B B O	Positive Positive Positive Negative Negative	
4.	Rouleaux	B O	Absent Absent	
5.	Haemolysis	A1 A2 A2B B O	Absent Absent Absent Absent Absent	
6.	Prozone	A1 A2 A2B	Absent Absent Absent	
7.	Physical Appearance and Colour	Clear and Blue Colored Liquid		

CONCLUSION: Anti-A (Monoclonal) Batch/Lot No…. comply the requirement(s) as mentioned in the Transfusion Medicine Technical Manual (2003), IP 2010 and as per manufacturer's specifications.

Signature of the Analyst
Name:
Designation:

Signature of the Lab. Head
Name:
Designation:

Name of the Product: Anti-B (Monoclonal)

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An ISO 17025: 2005 Accredited Institute

Certificate No: T- 2010 **Certificate No: T- 2011**

Dated :

CERTIFICATE OF ANALYSIS

Date of Performance of test :
Date of Sample receipt :
CDR NO. :
Analytical Report No. :
Name of Product & Dosage Form : Anti-B (Monoclonal)
Name of the Manufacturer :
Marketed by :
Batch / lot No. :
Manufacturing date :
Expiry date :

S.No.	Test(s) Conducted	Specification		Result
		Test RBC	Specification	
1.	Titre	B A1B	≥1:256 ≥1:128	
2.	Avidity (Sec) /Intensity	B A1B	3-4 Sec/4+ 5-6 Sec/2+ to 3+	
3.	Specificity	B A1B A1 O	Positive Positive Negative Negative	
4.	Rouleaux	A1 O	Absent Absent	
5.	Haemolysis	B A1B A1 O	Absent Absent Absent Absent	
6.	Prozone	B A1B	Absent Absent	
7.	Physical Appearance and Colour	Clear and Yellow colored Liquid		

CONCLUSION: Anti-B (Monoclonal), Batch/Lot No…. comply the requirement(s) as mentioned in the Transfusion Medicine Technical Manual (2003), IP 2010 and as per manufacturer's specifications.

Signature of the Analyst
Name:
Designation:

Signature of the Lab Head
Name:
Designation:

Name of the Product: Anti-A,B (Monoclonal)

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An ISO 17025: 2005 Accredited Institute

Certificate No: T- 2010 Certificate No: T- 2011

Dated:

CERTIFICATE OF ANALYSIS

Date of Performance of test :
Date of Sample receipt :
CDR NO. :
Analytical Report No. :
Name of Product & Dosage Form : Anti-A,B (Monoclonal)
Name of the Manufacturer :
Marketed by :
Batch / lot No. :
Manufacturing date :
Expiry date :

S.No.	Test(s) Conducted	Specification		Remarks
		Test RBC	Specification	
1.	Titre	A1 A2 B	≥1:256 ≥1:128 ≥1:256	
2.	Avidity (Sec) /Intensity	A1 A2 B	3-4 Sec/4+ 5-6 Sec/ 3+ 3-4 Sec/4+	
3.	Specificity	A1 B A2 Ax O	Positive Positive Positive Positive Negative	
4.	Rouleaux	O	Absent	
5.	Haemolysis	A1 B A2 Ax O	Absent Absent Absent Absent Absent	
6.	Prozone	A1 B A2	Absent Absent Absent	
7.	Physical Appearance and Colour	Clear, Colorless or Cherry colored Liquid		

CONCLUSION: Anti-A,B (Monoclonal) Batch/Lot No. …….. comply the requirement(s) as mentioned in the Transfusion Medicine Manual (2003), IP 2010 and as per manufacturer's specifications.

Signature of the Analyst
Name:
Designation:

Signature of the Lab. Head
Name:
Designation:

Name of the Product: Anti- D IgM (Monoclonal)

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Certificate No: T- 2010 **Certificate No: T- 2011**
Dated:

CERTIFICATE OF ANALYSIS

Date of Performance of test :
Date of Sample receipt :
CDR NO. :
Analytical Report No. :
Name of Product & Dosage Form : Anti-D (IgM) Monoclonal
Name of the Manufacturer :
Marketed by :
Batch / Lot No. :
Manufacturing date :
Expiry date :

S.No.	Test(s) Conducted	Specification			Result
		Test RBC	Specification Immediate Spin	37°C at 30"	
1.	T itre	O+ve(R1r) Or O+ve (R1R2)	1:64 - 128 1:64 – 128	1:128 – 256 1:128 - 256	
2.	Avidity (Sec) /Intensity	O+ve(R1r) Or O+ve (R1R2)	5-10 Sec/3+ 5-10 Sec/3+		
3.	Specificity	O+ve(R1r) or O+ve (R1R2) O neg • rr or • r'r or • r"r	Positive Negative		
4.	Rouleaux	O neg • rr or • r'r or • r"r	Absent		
5.	Haemolysis	O+ve(R1r) or O+ve (R1R2) O neg • rr or • r'r or • r"r	Absent Absent		
6.	Prozone	O+ve(R1r) Or O+ve (R1R2)	Absent Absent		
7.	Physical Appearance and Colour	Clear and colorless Liquid			

CONCLUSION: Anti-D (IgM) Monoclonal Batch No./ Lot No. comply the requirement(s) as mentioned in the Transfusion Medicine Manual (2003), IP 2010 and as per manufacturer's specifications.

Signature of the Analyst
Name:
Designation:

Signature of the Lab.Head
Name:
Designation:

Name of the Product: Anti- D (IgG+IgM) (Monoclonal)

NATIONAL INSTITUTE OF BIOLOGICALS
(Ministry of Health & Family Welfare)
An ISO 17025: 2005 Accredited Institute

Certificate No: T- 2010 **Certificate No: T- 2011**

Dated :

CERTIFICATE OF ANALYSIS

Date of Performance of test :
Date of Sample Receipt :
CDR NO. :
Analytical Report No. :
Product & Dosage Form : Anti-D (IgG + IgM) Monoclonal
Name of the Manufacturer :
Marketed by :
Batch No. :
Manufacturing date :
Expiry date :

S.No.	Test(s) Conducted	Specification			Result
		Test RBC	Specification ImmediateSpin	37°C at 30"	
1.	Titre	O+ve(R1r) Or O+ve (R1R2)	1:32 - 64 1:32 - 64	1:128 – 256 1:128 - 256	
2.	Avidity (Sec) /Intensity	O+ve(R1r) Or O+ve (R1R2)	10-20 Sec/3+ 10-20 Sec/3+		
3.	Specificity	O+ve(R1r) or O+ve (R1R2) O neg • rr/ r'r /r"r	Positive Negative		
4.	Rouleaux	O neg • rr/ r'r/ r"r	Absent		
5.	Haemolysis	O+ve(R1r) or O+ve (R1R2) O neg • rr /r'r /r"r	Absent Absent		
6.	Prozone	O+ve(R1r) Or O+ve (R1R2)	Absent Absent		
7.	Physical Appearance and Colour	Clear and colorless Liquid			

CONCLUSION: Anti-D (IgG + IgM) Monoclonal Blend Batch/Lot No. ……. comply the requirement(s) as mentioned in the Transfusion Medicine Manual (2003), IP 2010 and as per manufacturer's specifications.

Signature of the Analyst
Name:
Designation:

Signature of the Lab Head
Name:
Designation:

PARTICIPATION IN WHO (World Health Organization) COLLABORATIVE STUDY

1. The laboratory participated in an International collaborative study to evaluate candidate international minimum potency reference preparations for Anti-A and Anti-B blood grouping reagents in 2004.

2. The laboratory participated in an International collaborative study to evaluate candidate international minimum potency reference preparations for Anti-D grouping reagent in 2004.

LIST OF STANDARD OPERATING PROCEDURES OF BLOOD REGAENT LABORATORY

	OPERATING PROCEDURES (SOPs)	**BLOOD REAGENT LABORATORY**	COPIES	EFFECTIVE DATE	ISSUE DATE	PAGE NO (s)	REVISION STATUS
1	NIB/BRL/SOP/01/R1	Blood Sample Collection and Processing	2	24.2.2012	29.2.2012	8	1
2	NIB/BRL/SOP/02/R1	Grouping and Sub grouping of Blood Samples	2	09.2.2012	13.2.2012	9	1
3	NIB/BRL/SOP/03/R1	Rh- typing of Blood Samples	2	09.2.2012	13.2.2012	9	1
4	NIB/BRL/SOP/04/R1	Cryopreservation and Thawing of Reagent Red Cell	2	09.2.2012	13.2.2012	13	1
5	NIB/BRL/SOP/05/R1	Sample Receipt, Handling and Storage	2	24.2.2012	29.2.2012	5	1
6	NIB/BRL/SOP/06/R1	Preparation steps for Reagent Evaluation	2	24.2.2012	29.2.2012	6	1
7	NIB/BRL/SOP/08	Preparation of In-house for Anti-C,Anti-c and Anti-E Rh phenotype reagent for minimum potency	2	01.2.2012	03.02.2012	14	1
8	NIB/BRL/SOP/09/R1	Calibration of In house Controls	2	24.2.2012	09.3.2012	6	1
9	NIB/BRL/SOP/10/R1	Calibration of candidate Anti-A with NIBSC minimum potency reference reagent (03/188)	2	24.2.2012	29.2.2012	11	1
10	NIB/BRL/SOP/11/R1	Calibration of candidate Anti-B with NIBSC minimum potency reference reagent (03/164)	2	24.2.2012	29.2.2012	12	1
11	NIB/BRL/SOP/12/R1	Calibration of candidate Anti-AB with calibrated in-house Anti-A and Anti-B Blood Grouping Reagents for minimum potency.	2	24.2.2012	29.2.2012	12	1
12	NIB/BRL/SOP/13/R1	Preparation of in-house Anti-D (IgG)	2	07.2.2012	09.2.2012	13	1
13	NIB/BRL/SOP/14/R1	Calibration of candidate Anti-D (IgM) with NIBSC minimum potency reference reagent (99/836)	2	02.2.2012	07.2.2012	11	1
14	NIB/BRL/SOP/15/R1	Calibration of candidate Anti-D (IgM + IgG) with NIBSC minimum potency reference reagent (99/836)	2	19.3.2012	23.3.2012	12	1
15	NIB/BRL/SOP/16	Forward and Reverse grouping of blood samples by Antibody coated Microplate technology	2	15.7.2011	20.7.2011	11	0

16	NIB/BRL/SOP/17	Subgrouping of blood samples by Gel Technology	2	28.9.2011	30.9.2011	11	0
17	NIB/BRL/SOP/18/R1	Evaluation of Anti-A (Monoclonal) Reagent	2	24.2.2012	29.2.2012	17	1
18	NIB/BRL/SOP/19/R1	Evaluation of Anti-B (Monoclonal) Reagent	2	24.2.2012	29.2.2012	17	1
19	NIB/BRL/SOP/20/R1	Evaluation of Anti-A,B (Monoclonal) Reagent	2	24.2.2012	29.2.2012	17	1
20	NIB/BRL/SOP/21/R1	Evaluation of Anti-D (IgG) (Monoclonal) Reagent	2	24.2.2012	29.2.2012	14	1
21	NIB/BRL/SOP/22/R1	Evaluation of Anti-D (IgM) (Monoclonal) Reagent	2	24.2.2012	29.2.2012	17	1
22	NIB/BRL/SOP/23/R1	Evaluation of Anti-D (IgM + IgG) (Blend) Reagent	2	24.2.2012	29.2.2012	17	1
23	NIB/BRL/SOP/24/R1	Evaluation of Anti-A1 (Lectin) Reagent	2	24.2.2012	29.2.2012	17	1
24	NIB/BRL/SOP/25/R1	Evaluation of Anti-H (Lectin) Reagent	2	29.2.2012	09.3.2012	15	1
25	NIB/BRL/SOP/26	Detection of rare blood group by direct and indirect agglutination method	2	21.11.2011	24.11.2011	10	0
26	NIB/BRL/SOP/27	Calibration of AHG reagent	2	28.9.2011	30.9.2011	21	0
27	NIB/BRL/SOP/28	Antiglobulin test of blood samples by Gel technology	2	29.9.2011	30.9.2011	13	0
28	NIB/BRL/SOP/29	Determination of Anti-A , Anti-B heamagglutination in blood products	2	28.9.2011	10.10.2011	9	0
29	NIB/BRL/SOP/30/R1	Maintenance & Calibration of Micropipettes	2	24.2.2012	29.2.2012	7	1
30	NIB/BRL/SOP/34/R1	Operation & Maintenance of Bench Top Centrifuge	2	24.2.2012	16.3.2012	6	1
31	NIB/BRL/SOP/35/R1	Maintenance of Cold room (4oC)	2	29.2.2012	09.3.2012	5	1
32	NIB/BRL/SOP/36/R1	Preparation of Reagents & buffer	2	24.2.2012	09.3.2012	11	1
33	NIB/BRL/SOP/37/R1	Disposal of Expired & Unused grouping Reagents	2	24.2.2012	29.2.2012	7	1
34	NIB/BRL/SOP/40/R1	Disposal of Laboratory waste	2	24.2.2012	29.2.2012	6	1
35	NIB/BRL/SOP/41/R1	Laboratory Biosafety	2	24.2.2012	29.2.2012	10	0
36	NIB/BRL/SOP/42/R1	Washing and Preparation of glassware	2	24.2.2012	29.2.2012	6	1
37	NIB/BRL/SOP/43/R1	Autoclaving Biological waste and Date Expired Blood Grouping kits	2	09.2.2012	13.2.2012	7	1

38	NIB/BRL/SOP/44/R1	Preparing and winding up of work bench	2	09.2.2012	13.2.2012	5	1
39	NIB/BRL/SOP/45/R1	Data / Raw Data Documentation	2	09.2.2012	13.2.2012	6	1
40	NIB/BRL/SOP/48/R1	Documentation of Correspondences from Blood Reagent Laboratory	2	24.2.2012	29.2.2012	4	1
41	NIB/BRL/SOP/50/R1	Introducing and Updating Documents	2	24.2.2012	29.2.2012	6	1
42	NIB/BRL/SOP/52/R1	Evaluation of Anti-Human Globulin (AHG) reagent	2	24.2.2012	09.3.2012	25	1
43	NIB/BRL/SOP/53	Preparation of In-house for Bovine Serum Albumin Reagent	2	24.2.2012	29.2.2012	12	0
44	NIB/BRL/SOP/54/R1	Evaluation of Bovine Serum Albumin Reagent	2	24.2.2012	9.3.2012	15	0
45	NIB/BRL/SOP/55/R1	Grouping & Reverse grouping of Blood Samples by Gel Technology	2	24.2.2012	9.3.2012	12	1
46	NIB/BRL/SOP/56/R1	Preparation of In-house for Anti-A1 (Lectin) Reagent	2	24.2.2012	29.2.2012	14	1
47	NIB/BRL/SOP/57/R1	Preparation of In-house for Anti-H (Lectin) Reagent	2	19.3.2012	23.3.2012	15	1

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