

# Certificate of Analysis for Blood Grouping Kit

## 1- Product Identification:

<b>Product Name : Anti- A Monoclonal Reagent</b> <b>Clone: A-11h5</b>	<b>Catalog No. (Variant Code) :</b> <b>8.02.04.0.0010</b>	<b>Item Dispense #: 473</b>	<b>Minimal Titer Accepted: 1/256</b>
<b>Lot #: 24020311</b>	<b>Mfg. Date: NA</b>	<b>Exp. Date: 2025/11/09</b>	

## 2- Sampling Plan:

Date	QC Test Method Used	Inspection level	AQL	Determine the following by referring to Sampling Plan Sheet			
				Sample Size Code Letter	Sample Size (Test QTY)	Accepted	Rejected
08.02.2024	<b>F13D</b>	Physical Inspection: S-I	1.0	<b>B</b>	<b>3</b>	<b>0</b>	<b>1</b>
07.02.2024	<b>F13D</b>	Biochemical Inspection: One sample	<b>Not Applicable</b>				

## 3- Physical Check:

Applicable Test Type	Inspected Item and/or Criteria	Inspection Results
➤ Kit Assembly:	All components of the kit are present according to the outer label	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status:	Anti-A: Blue – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B: Yellow – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D: Yellowish – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB: Yellowish – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A                                      10 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B                                      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D                                      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB                                      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in Item Dispense	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (CE Blood Grouping):	Anti A (High titer (1/512): Blue cap with black bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): Blue cap with grey bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): Yellow cap with black bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): Yellow cap with grey bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

	Anti AB (High titer (1/512): Grey cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): Grey cap with grey bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Black cap with grey bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (None CE Blood Grouping):	Anti A (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): White cap with white bulb	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): White cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): White cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Gray cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Dropper Coloring / Titer (Real Titer (256) / Non CE Blood Grouping):	Anti A (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Function:	Able to withdraw the reagent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: (2/1)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA.....	
Done by QC Officer/Supervisor (Sign.): <i>rayan</i> Date: 08.02.2024 Time: 09:40		

#### 4- Biochemical Check:

##### A. Direct Slide Method: Interpret the results by referring to Table (01)

Pipette #: 157				Pipette Code: E21PiQ157			
Anti A		Anti -B		Anti-AB		Anti-D	
A (lot No: Fresh sample )		B ( Lot no: NA )		AB (Lot no: NA )		O+(Lot no: NA )	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
2 Sec	+4	NA	NA	NA	NA	NA	NA
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA.....					
Done by QC Officer/Supervisor (Sign.): <i>Toga</i> Date: 07.02.2024 Time: 15:53							

##### B. Sensitivity test

Pipette #: 157			Pipette Code: E21PiQ157			
Type of Test			Anti-A	Anti-B	Anti-AB	Anti-D
Sensitivity	Tube Test Method	Type of Cell Suspension	A (Lot no: AC240207)	B ( Lot no: NA )	A (Lot no: NA ) B (Lot no NA )	O+ (Lot no NA)

		Result	1:2	+4	1:2	NA	1:2	NA	1:2	NA
			1:4	+3	1:4	NA	1:4	NA	1:4	NA
			1:8	+3	1:8	NA	1:8	NA	1:8	NA
			1:16	+2	1:16	NA	1:16	NA	1:16	NA
			1:32	+2	1:32	NA	1:32	NA	1:32	NA
			1:64	+2	1:64	NA	1:64	NA	1:64	NA
			1:128	+1	1:128	NA	1:128	NA	1:128	NA
			1:256	+1	1:256	NA	1:256	NA	1:256	NA
			1:512	-ve	1:512	NA	1:512	NA	1:512	NA
			1:1024	-ve	1:1024	NA	1:1024	NA		
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA.....								
Done by QC Officer/Supervisor (Sign.): <i>Toga</i>		Date: 07.02.2024			Time: 15:55					

Table (01)			
Blood Grouping Reagents	Control Cell	Reaction Time	Agglutination Strength
Anti-A	A - Cell	Up to 3 second	+4
Anti-B	B-Cell	Up to 3 second	+4
Anti-AB	A B-Cell	Up to 3 second	+3/+4
Anti -D	O RH positive cell	Up to 5 second	+3

<b>Final Conclusion:</b> <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
<b>Final QC Manager Approval (Signature):</b> <i>Marwa</i>	<b>Date:</b> 08.02.2024



# Certificate of Analysis for Blood Grouping Kit

## 1- Product Identification:

<b>Product Name : Anti- A Monoclonal Reagent</b> <b>Clone: 9113D10</b>	<b>Catalog No. (Variant Code) :</b> <b>8.02.04.0.0010</b>	<b>Item Dispense #: 4334</b>	<b>Minimal Titer Accepted: 1/256</b>
<b>Lot #: 23102614</b>	<b>Mfg. Date: NA</b>	<b>Exp. Date: 2025/10/30</b>	

## 2- Sampling Plan:

Date	QC Test Method Used	Inspection level	AQL	Determine the following by referring to Sampling Plan Sheet			
				Sample Size Code Letter	Sample Size (Test QTY)	Accepted	Rejected
01.11.2023	<b>F13D</b>	Physical Inspection: S-I	1.0	<b>B</b>	<b>3</b>	<b>0</b>	<b>1</b>
01.11.2023	<b>F13D</b>	Biochemical Inspection: One sample	<b>Not Applicable</b>				

## 3- Physical Check:

Applicable Test Type	Inspected Item and/or Criteria	Inspection Results
➤ Kit Assembly:	All components of the kit are present according to the outer label	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status:	Anti-A: Blue – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B: Yellow – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D: Yellowish – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB: Yellowish – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A                              10 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B                              NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D                              NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB                              NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in Item Dispense	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (CE Blood Grouping):	Anti A (High titer (1/512): Blue cap with black bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): Blue cap with grey bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): Yellow cap with black bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): Yellow cap with grey bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

	Anti AB (High titer (1/512): Grey cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): Grey cap with grey bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Black cap with grey bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (None CE Blood Grouping):	Anti A (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): White cap with white bulb	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): White cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): White cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Gray cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Dropper Coloring / Titer (Real Titer (256) / Non CE Blood Grouping):	Anti A (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Function:	Able to withdraw the reagent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: (2/1)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....	
Done by QC Officer/Supervisor (Sign.): <i>rayan</i> Date: 01.11.2023 Time: 16:00		

#### 4- Biochemical Check:

##### A. Direct Slide Method: Interpret the results by referring to Table (01)

Pipette #: 157				Pipette Code: E21PiQ157			
Anti A		Anti -B		Anti-AB		Anti-D	
A (lot No: 942309 )		B ( Lot no: )		AB (Lot no: )		O+(Lot no: )	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
2 Sec	+4	NA	NA	NA	NA	NA	NA
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....					
Done by QC Officer/Supervisor (Sign.): <i>rayan</i> Date: 01.11.2023 Time: 15:23							

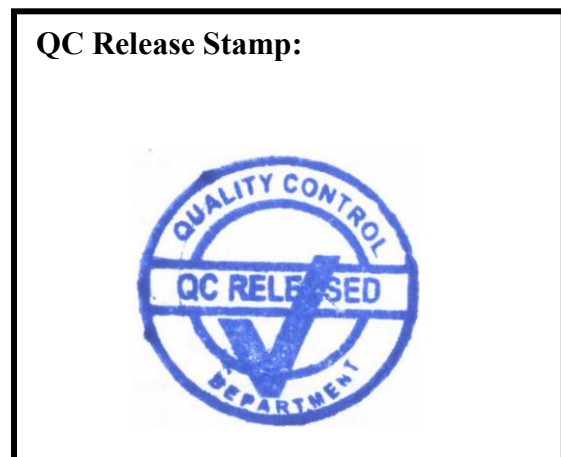
##### B. Sensitivity test

Pipette #: 157			Pipette Code: E21PiQ157			
Type of Test			Anti-A	Anti-B	Anti-AB	Anti-D
Sensitivity	Tube Test Method	Type of Cell Suspension	A (Lot no: ABWB231101 )	B ( Lot no: NA )	A (Lot no: ) B (Lot no: )	O+ (Lot no )

Result	1:2	+4	1:2	NA	1:2	NA	1:2	NA	
	1:4	+3	1:4	NA	1:4	NA	1:4	NA	
	1:8	+3	1:8	NA	1:8	NA	1:8	NA	
	1:16	+2	1:16	NA	1:16	NA	1:16	NA	
	1:32	+2	1:32	NA	1:32	NA	1:32	NA	
	1:64	+2	1:64	NA	1:64	NA	1:64	NA	
	1:128	+1	1:128	NA	1:128	NA	1:128	NA	
	1:256	+1	1:256	NA	1:256	NA	1:256	NA	
	1:512	+/-	1:512	NA	1:512	NA	1:512	NA	
	1:1024	-ve	1:1024	NA	1:1024	NA			
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....							
Done by QC Officer/Supervisor (Sign.):		<i>rayan</i>		Date: 01.11.2023		Time: 15:25			

Table (01)			
Blood Grouping Reagents	Control Cell	Reaction Time	Agglutination Strength
Anti-A	A - Cell	Up to 3 second	+4
Anti-B	B-Cell	Up to 3 second	+4
Anti-AB	A B-Cell	Up to 3 second	+3/+4
Anti -D	O RH positive cell	Up to 5 second	+3

<b>Final Conclusion:</b> <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
<b>Final QC Manager Approval (Signature):</b> <i>Tasneem</i>	<b>Date:</b> 01.11.2023



# Certificate of Analysis for Blood Grouping Kit

## 1- Product Identification:

<b>Product Name : Anti-B monoclonal Reagent</b> <b>Clone: B-6F9</b>	<b>Catalog No. (Variant Code) :</b> <b>8.02.05.0.0010</b>	<b>Item Dispense #: 481</b>	<b>Minimal Titer Accepted: 1/256</b>
<b>Lot #: 24020316</b>	<b>Mfg. Date: NA</b>	<b>Exp. Date: 2025/11/28</b>	

## 2- Sampling Plan:

Date	QC Test Method Used	Inspection level	AQL	Determine the following by referring to Sampling Plan Sheet			
				Sample Size Code Letter	Sample Size (Test QTY)	Accepted	Rejected
11.02.2024	<b>F13D</b>	Physical Inspection: S-I	1.0	<b>B</b>	<b>3</b>	<b>0</b>	<b>1</b>
11.02.2024	<b>F13D</b>	Biochemical Inspection: One sample	<b>Not Applicable</b>				

## 3- Physical Check:

Applicable Test Type	Inspected Item and/or Criteria	Inspection Results
➤ Kit Assembly:	All components of the kit are present according to the outer label	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status:	Anti-A: Blue – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B: Yellow – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D: Yellowish – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB: Yellowish – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B      10 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in Item Dispense	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Function:	Able to withdraw the reagent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: 2/1	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA.....	

Done by QC Officer/Supervisor (Sign.): *Toqa* Date: 11.02.2024 Time: 11:20

**4- Biochemical Check:**

**A. Direct Slide Method:** Interpret the results by referring to Table (01)

Pipette #:157				Pipette Code: E21PiQ157			
<b>Anti A</b>		<b>Anti -B</b>		<b>Anti-AB</b>		<b>Anti-D</b>	
A (lot No: NA)		B ( Lot no: fresh sample)		AB (Lot no: NA )		O+(Lot no: NA )	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
NA	NA	2 Sec	+4	NA	NA	NA	NA
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA.....					
Done by QC Officer/Supervisor (Sign.): <i>Toqa</i>				Date: 11.02.2024		Time: 08:32	

**B. Sensitivity test**

Pipette #: 157				Pipette Code: E21PiQ157						
<b>Type of Test</b>		<b>Anti-A</b>		<b>Anti-B</b>		<b>Anti-AB</b>		<b>Anti-D</b>		
Sensitivity	Tube Test Method	Type of Cell Suspension	A (Lot no: NA )		B ( Lot no: BC240211)		A (Lot no: NA ) B (Lot no NA )		O+ (Lot noNA )	
		Result	1:2	NA	1:2	+4	1:2	NA	1:2	NA
			1:4	NA	1:4	+3	1:4	NA	1:4	NA
			1:8	NA	1:8	+3	1:8	NA	1:8	NA
			1:16	NA	1:16	+2	1:16	NA	1:16	NA
			1:32	NA	1:32	+2	1:32	NA	1:32	NA
			1:64	NA	1:64	+2	1:64	NA	1:64	NA
			1:128	NA	1:128	+1	1:128	NA	1:128	NA
			1:256	NA	1:256	+1	1:256	NA	1:256	NA
			1:512	NA	1:512	-ve	1:512	NA	1:512	NA
1:1024	NA	1:1024	-ve	1:1024	NA					
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA.....								
Done by QC Officer/Supervisor (Sign.): <i>Toqa</i>				Date: 11.02.2024		Time: 08:35				



Table (01)			
Blood Grouping Reagents	Control Cell	Reaction Time	Agglutination Strength
Anti-A	A - Cell	Up to 3 second	+4
Anti-B	B-Cell	Up to 3 second	+4
Anti-AB	A B-Cell	Up to 3 second	+3/+4
Anti -D	O RH positive cell	Up to 5 second	+3

**Final Conclusion:**  Pass  Fail

**Final QC Manager Approval (Signature):** *Marwa*

**Date:** 11.02.2024

**QC Release Stamp:**



# Certificate of Analysis for Blood Grouping Kit

## 1- Product Identification:

<b>Product Name : Anti-B monoclonal Reagent</b> <b>Clone: 9621A8</b>	<b>Catalog No. (Variant Code) :</b> <b>8.02.05.0.0010</b>	<b>Item Dispense #: 4336</b>	<b>Minimal Titer Accepted: 1/256</b>
<b>Lot #: 23102806</b>	<b>Mfg. Date: NA</b>	<b>Exp. Date: 2025/10/19</b>	

## 2- Sampling Plan:

Date	QC Test Method Used	Inspection level	AQL	Determine the following by referring to Sampling Plan Sheet			
				Sample Size Code Letter	Sample Size (Test QTY)	Accepted	Rejected
02.11.2023	<b>F13D</b>	Physical Inspection: S-I	1.0	<b>B</b>	<b>3</b>	<b>0</b>	<b>1</b>
02.11.2023	<b>F13D</b>	Biochemical Inspection: One sample	<b>Not Applicable</b>				

## 3- Physical Check:

Applicable Test Type	Inspected Item and/or Criteria	Inspection Results
➤ Kit Assembly:	All components of the kit are present according to the outer label	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status:	Anti-A: Blue – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B: Yellow – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D: Yellowish – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB: Yellowish – Liquid      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B      10 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in Item Dispense	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (CE Blood Grouping):	Anti A (High titer (1/512): Blue cap with black bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): Blue cap with grey bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): Yellow cap with black bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): Yellow cap with grey bulb      NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

	Anti AB (High titer (1/512): Grey cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): Grey cap with grey bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Black cap with grey bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (None CE Blood Grouping):	Anti A (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): White cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): White cap with white bulb	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (High titer (1/512): White cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): White cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Gray cap with white bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Dropper Coloring / Titer (Real Titer (256) / Non CE Blood Grouping):	Anti A (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (White cap with white bulb) NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Function:	Able to withdraw the reagent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: : (2/1)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....	
Done by QC Officer/Supervisor (Sign.): <i>rayan</i>		Date: 02.11.2023 Time: 10:15

#### 4- Biochemical Check:

##### A. Direct Slide Method: Interpret the results by referring to Table (01)

Pipette #: 157				Pipette Code: E21PiQ157			
Anti A		Anti -B		Anti-AB		Anti-D	
A (lot No:)		B ( Lot no: 942309)		AB (Lot no: )		O+(Lot no: )	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
NA	NA	2 Sec	+4	NA	NA	NA	NA
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....					
Done by QC Officer/Supervisor (Sign.): <i>Toga</i>				Date: 02.11.2023		Time: 08:27	

##### B. Sensitivity test

Pipette #: 157			Pipette Code: E21PiQ157			
Type of Test			Anti-A	Anti-B	Anti-AB	Anti-D
Sensitivity	Tube Test Method	Type of Cell Suspension	A (Lot no: )	B ( Lot no: BC231031 )	A (Lot no: ) B (Lot no )	O+ (Lot no )

Result	1:2	NA	1:2	+4	1:2	NA	1:2	NA	
	1:4	NA	1:4	+3	1:4	NA	1:4	NA	
	1:8	NA	1:8	+3	1:8	NA	1:8	NA	
	1:16	NA	1:16	+2	1:16	NA	1:16	NA	
	1:32	NA	1:32	+2	1:32	NA	1:32	NA	
	1:64	NA	1:64	+2	1:64	NA	1:64	NA	
	1:128	NA	1:128	+1	1:128	NA	1:128	NA	
	1:256	NA	1:256	+1	1:256	NA	1:256	NA	
	1:512	NA	1:512	-ve	1:512	NA	1:512	NA	
	1:1024	NA	1:1024	-ve	1:1024	NA			
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....							
Done by QC Officer/Supervisor (Sign.): <i>Toqa</i>		Date: 02.11.2023			Time: 08:30				

Table (01)			
Blood Grouping Reagents	Control Cell	Reaction Time	Agglutination Strength
Anti-A	A - Cell	Up to 3 second	+4
Anti-B	B-Cell	Up to 3 second	+4
Anti-AB	A B-Cell	Up to 3 second	+3/+4
Anti -D	O RH positive cell	Up to 5 second	+3

<b>Final Conclusion:</b> <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
<b>Final QC Manager Approval (Signature):</b> <i>Tasneem</i>	<b>Date:</b> 02.11.2023

