Atlas Medical

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Certificate of Analysis for Blood Grouping Kit

1- Product Identification:

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

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	**F13D**	Physical Inspection: S-I	1.0	**B**	**3**	**0**	**1**
07.02.2024	**F13D**	Biochemical Inspection: One sample	**Not Applicable**				

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	■ Pass ☐ Fail
➢ Item Color & Status:	Anti-A: Blue – Liquid	■Pass ☐ Fail
	Anti-B: Yellow – Liquid NA	☐ Pass ☐ Fail
	Anti-D: Yellowish – Liquid NA	☐Pass ☐ Fail
	Anti-AB: Yellowish – Liquid NA	☐Pass ☐ Fail
➢ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A 10 ml	■Pass ☐ Fail
	Anti-B NA	☐ Pass ☐ Fail
	Anti-D NA	☐Pass ☐ Fail
	Anti-AB NA	☐Pass ☐ Fail
➢ Labels:	Correct label orientation	■Pass ☐ Fail
	Correct label position	■Pass ☐ Fail
	Clear printing	■Pass ☐ Fail
➢ Package Insert:	Clear printing and correct folding	■Pass ☐ Fail
	Correct code, version and brand as mentioned in Item Dispense	■Pass ☐ Fail
	Address as mentioned on box design	■Pass ☐ Fail
➢ Closing Cap:	No leakage and closed well	■Pass ☐ Fail
➢ Dropper Coloring / Titer **(CE Blood Grouping):**	Anti A (High titer (1/512): Blue cap with black bulb NA	☐ Pass ☐ Fail
	Anti A (Low titer (1/256): Blue cap with grey bulb NA	☐ Pass ☐ Fail
	Anti B (High titer (1/512): Yellow cap with black bulb NA	☐ Pass ☐ Fail
	Anti B (Low titer (1/256): Yellow cap with grey bulb NA	☐ Pass ☐ Fail

	Anti AB (High titer (1/512): Grey cap with black bulb NA	☐ Pass ☐ Fail
	Anti AB (Low titer (1/256): Grey cap with grey bulb NA	☐ Pass ☐ Fail
	Anti D (High titer (1/128): Black cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (Low titer (1/64): Black cap with grey bulb NA	☐ Pass ☐ Fail
➢ Dropper Coloring / Titer **(None CE Blood Grouping):**	Anti A (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti A (Low titer (1/256): White cap with white bulb	■ Pass ☐ Fail
	Anti B (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti B (Low titer (1/256): White cap with white bulb NA	☐ Pass ☐ Fail
	Anti AB (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti AB (Low titer (1/256): White cap with white bulb NA	☐Pass ☐ Fail
	Anti D (High titer (1/128): Black cap with white bulb NA	☐ Pass ☐ Fail
	Anti D (Low titer (1/64): Gray cap with white bulb NA	☐Pass ☐ Fail
	Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA	☐ Pass ☐ Fail
	Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA	☐ Pass ☐ Fail
➢ Dropper Coloring / Titer **(Real Titer (256) / Non CE Blood Grouping):**	Anti A (White cap with white bulb) NA	☐ Pass ☐ Fail
	Anti B (White cap with white bulb) NA	☐ Pass ☐ Fail
	Anti AB (White cap with white bulb) NA	☐ Pass ☐ Fail
➢ Dropper Function:	Able to withdraw the reagent	■Pass ☐ Fail
➢ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: (2/1)	■Pass ☐ Fail
➢ Final Result:	■Pass ☐ Fail; justify ……NA……..	
Done by QC Officer/Supervisor (Sign.): rayan	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:		■ Pass ☐ Fail; justify ……NA……..					
Done by QC Officer/Supervisor (Sign.): Toga		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:		■ Pass ☐ Fail; justify ……NA……..								
Done by QC Officer/Supervisor (Sign.): *Toqa* 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

Final Conclusion: ■ Pass ☐ Fail	
Final QC Manager Approval (Signature): *Marwa*	**Date: 08.02.2024**

QC Release Stamp:

Certificate of Analysis for Blood Grouping Kit

1- Product Identification:

Product Name : Anti-AB monoclonal Reagent	**Catalog No. (Variant Code) : 8.02.06.0.0010**	**Item Dispense #: 895**	**Minimal Titer Accepted: 1/256**
Lot #: 24030917	**Mfg. Date: NA**	**Exp. Date: 2026/01/04**	

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
12.03.2024	**F13D**	Physical Inspection: S-I	1.0	**B**	**3**	**0**	**1**
12.03.2024	**F13D**	Biochemical Inspection: One sample	**Not Applicable**				

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	■ Pass ☐ Fail
➢ Item Color & Status:	Anti-A: Blue – Liquid NA	☐ Pass ☐ Fail
	Anti-B: Yellow – Liquid NA	☐ Pass ☐ Fail
	Anti-D: Yellowish – Liquid NA	☐Pass ☐ Fail
	Anti-AB: Yellowish – Liquid	■Pass ☐ Fail
➢ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A NA	☐ Pass ☐ Fail
	Anti-B NA	☐ Pass ☐ Fail
	Anti-D NA	☐Pass ☐ Fail
	Anti-AB 10 ml	■Pass ☐ Fail
➢ Labels:	Correct label orientation	■ Pass ☐ Fail
	Correct label position	■Pass ☐ Fail
	Clear printing	■Pass ☐ Fail
➢ Package Insert:	Clear printing and correct folding	■ Pass ☐ Fail
	Correct code, version and brand as mentioned in Item Dispense	■Pass ☐ Fail
	Address as mentioned on box design	■Pass ☐ Fail
➢ Closing Cap:	No leakage and closed well	■Pass ☐ Fail
➢ Dropper Coloring / Titer **(CE Blood Grouping):**	Anti A (High titer (1/512): Blue cap with black bulb NA	☐ Pass ☐ Fail
	Anti A (Low titer (1/256): Blue cap with grey bulb NA	☐ Pass ☐ Fail
	Anti B (High titer (1/512): Yellow cap with black bulb NA	☐ Pass ☐ Fail
	Anti B (Low titer (1/256): Yellow cap with grey bulb NA	☐ Pass ☐ Fail

	Anti AB (High titer (1/512): Grey cap with black bulb NA	☐ Pass ☐ Fail
	Anti AB (Low titer (1/256): Grey cap with grey bulb NA	☐ Pass ☐ Fail
	Anti D (High titer (1/128): Black cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (Low titer (1/64): Black cap with grey bulb NA	☐ Pass ☐ Fail
➢ Dropper Coloring / Titer **(None CE Blood Grouping):**	Anti A (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti A (Low titer (1/256): White cap with white bulb NA	☐ Pass ☐ Fail
	Anti B (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti B (Low titer (1/256): White cap with white bulb NA	☐ Pass ☐ Fail
	Anti AB (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti AB (Low titer (1/256): White cap with white bulb	■Pass ☐ Fail
	Anti D (High titer (1/128): Black cap with white bulb NA	☐ Pass ☐ Fail
	Anti D (Low titer (1/64): Gray cap with white bulb NA	☐Pass ☐ Fail
	Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA	☐ Pass ☐ Fail
	Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA	☐ Pass ☐ Fail
➢ Dropper Coloring / Titer **(Real Titer (256) / Non CE Blood Grouping):**	Anti A (White cap with white bulb) NA	☐ Pass ☐ Fail
	Anti B (White cap with white bulb) NA	☐ Pass ☐ Fail
	Anti AB (White cap with white bulb) NA	☐ Pass ☐ Fail
➢ Dropper Function:	Able to withdraw the reagent	■ Pass ☐ Fail
➢ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: (2/1)	■Pass ☐ Fail
➢ Final Result:	■Pass ☐ Fail; justify ……NA……..	
Done by QC Officer/Supervisor (Sign.): Toga Date: 12.03.2024 Time: 12:20		

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:)		AB (Lot no: 942402)		O+(Lot no:)	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination Strength	Reaction time	Agglutination strength
NA	NA	NA	NA	2 Sec	+4	NA	NA
➢ Final Result:		■ Pass ☐ Fail; justify ……NA……..					
Done by QC Officer/Supervisor (Sign.): Toga Date: 12.03.2024 Time: 11:32							

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: NA)	B (Lot no: NA)	A (Lot no: 772404) B (Lot no)	O+ (Lot no)

		Result	1:2	NA	1:2	NA	1:2	+4	1:2	NA
			1:4	NA	1:4	NA	1:4	+3	1:4	NA
			1:8	NA	1:8	NA	1:8	+3	1:8	NA
			1:16	NA	1:16	NA	1:16	+2	1:16	NA
			1:32	NA	1:32	NA	1:32	+2	1:32	NA
			1:64	NA	1:64	NA	1:64	+2	1:64	NA
			1:128	NA	1:128	NA	1:128	+1	1:128	NA
			1:256	NA	1:256	NA	1:256	+1	1:256	NA
			1:512	NA	1:512	NA	1:512	-ve	1:512	NA
			1:1024	NA	1:1024	NA	1:1024	-ve		
➢ Final Result:		■ Pass ☐ Fail; justify ……NA……..								
Done by QC Officer/Supervisor (Sign.): *Toga* Date: 12.03.2024 Time: 11:35										

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: 12.03.2024**

QC Release Stamp:

Certificate of Analysis for Blood Grouping Kit

1- Product Identification:

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

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	**F13D**	Physical Inspection: S-I	1.0	**B**	**3**	**0**	**1**
11.02.2024	**F13D**	Biochemical Inspection: One sample	**Not Applicable**				

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	■ Pass ☐ Fail
➢ Item Color & Status:	Anti-A: Blue – Liquid NA	☐Pass ☐ Fail
	Anti-B: Yellow – Liquid	■ Pass ☐ Fail
	Anti-D: Yellowish – Liquid NA	☐Pass ☐ Fail
	Anti-AB: Yellowish – Liquid NA	☐Pass ☐ Fail
➢ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A NA	☐Pass ☐ Fail
	Anti-B 10 ml	■Pass ☐ Fail
	Anti-D NA	☐Pass ☐ Fail
	Anti-AB NA	☐Pass ☐ Fail
➢ Labels:	Correct label orientation	■Pass ☐ Fail
	Correct label position	■Pass ☐ Fail
	Clear printing	■Pass ☐ Fail
➢ Package Insert:	Clear printing and correct folding	■Pass ☐ Fail
	Correct code, version and brand as mentioned in Item Dispense	■Pass ☐ Fail
	Address as mentioned on box design	■Pass ☐ Fail
➢ Closing Cap:	No leakage and closed well	■Pass ☐ Fail
➢ Dropper Function:	Able to withdraw the reagent	■Pass ☐ Fail
➢ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: 2/1	■Pass ☐ Fail
➢ Final Result:	■Pass ☐ Fail; justify ……NA……..	

Done by QC Officer/Supervisor (Sign.): Toga	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			
Anti A		**Anti –B**		**Anti-AB**		**Anti-D**	
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:		■ Pass ☐ Fail; justify ……NA……..					
Done by QC Officer/Supervisor (Sign.): Toga		Date: 11.02.2024		Time: 08:32			

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: 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:		■ Pass ☐ Fail; justify ……NA……..								
Done by QC Officer/Supervisor (Sign.): Toga		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:

Atlas Medical

Certificate of Analysis for Blood Grouping Kit

1- Product Identification:

Product Name : Anti-D IgG/IgM Blend Reagent	**Catalog No. (Variant Code) : 8.02.07.0.0010**	**Item Dispense #: 617**	**Minimal Titer Accepted: 1/64**
Lot #: 24021223	**Mfg. Date: NA**	**Exp. Date: 2025/12/06**	

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
19.02.2024	**F13D**	Physical Inspection: S-I	1.0	**B**	**3**	**0**	**1**
19.02.2024	**F13D**	Biochemical Inspection: One sample	**Not Applicable**				

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	■ Pass ☐ Fail
➢ Item Color & Status:	Anti-A: Blue – Liquid NA	☐ Pass ☐ Fail
	Anti-B: Yellow – Liquid NA	☐ Pass ☐ Fail
	Anti-D: Yellowish – Liquid	■Pass ☐ Fail
	Anti-AB: Yellowish – Liquid NA	☐ Pass ☐ Fail
➢ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A NA	☐ Pass ☐ Fail
	Anti-B NA	☐ Pass ☐ Fail
	Anti-D 10 ml	■Pass ☐ Fail
	Anti-AB NA	☐Pass ☐ Fail
➢ Labels:	Correct label orientation	■Pass ☐ Fail
	Correct label position	■Pass ☐ Fail
	Clear printing	■Pass ☐ Fail
➢ Package Insert:	Clear printing and correct folding	■Pass ☐ Fail
	Correct code, version and brand as mentioned in Item Dispense	■Pass ☐ Fail
	Address as mentioned on box design	■Pass ☐ Fail
➢ Closing Cap:	No leakage and closed well	■Pass ☐ Fail
➢ Dropper Coloring / Titer **(CE Blood Grouping):**	Anti A (High titer (1/512): Blue cap with black bulb NA	☐ Pass ☐ Fail
	Anti A (Low titer (1/256): Blue cap with grey bulb NA	☐ Pass ☐ Fail
	Anti B (High titer (1/512): Yellow cap with black bulb NA	☐ Pass ☐ Fail
	Anti B (Low titer (1/256): Yellow cap with grey bulb NA	☐ Pass ☐ Fail

	Anti AB (High titer (1/512): Grey cap with black bulb NA	☐ Pass ☐ Fail
	Anti AB (Low titer (1/256): Grey cap with grey bulb NA	☐ Pass ☐ Fail
	Anti D (High titer (1/128): Black cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (Low titer (1/64): Black cap with grey bulb NA	☐ Pass ☐ Fail
➢ Dropper Coloring / Titer **(None CE Blood Grouping):**	Anti A (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti A (Low titer (1/256): White cap with white bulb NA	☐ Pass ☐ Fail
	Anti B (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti B (Low titer (1/256): White cap with white bulb NA	☐ Pass ☐ Fail
	Anti AB (High titer (1/512): White cap with black bulb NA	☐ Pass ☐ Fail
	Anti AB (Low titer (1/256): White cap with white bulb NA	☐ Pass ☐ Fail
	Anti D (High titer (1/128): Black cap with white bulb NA	☐ Pass ☐ Fail
	Anti D (Low titer (1/64): Gray cap with white bulb	■Pass ☐ Fail
	Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA	☐ Pass ☐ Fail
	Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA	☐ Pass ☐ Fail
	Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA	☐ Pass ☐ Fail
➢ Dropper Coloring / Titer **(Real Titer (256) / Non CE Blood Grouping):**	Anti A (White cap with white bulb) NA	☐ Pass ☐ Fail
	Anti B (White cap with white bulb) NA	☐ Pass ☐ Fail
	Anti AB (White cap with white bulb) NA	☐ Pass ☐ Fail
➢ Dropper Function:	Able to withdraw the reagent	■ Pass ☐ Fail
➢ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: (2/1)	■Pass ☐ Fail
➢ Final Result:	■Pass ☐ Fail; justify ……NA……..	
Done by QC Officer/Supervisor (Sign.): rayan Date: 19.02.2024 Time: 11:30		

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:)		AB (Lot no:)		O+(Lot no: fresh sample))	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
NA	NA	NA	NA	NA	NA	2 Sec	+3
➢ Final Result:		■ Pass ☐ Fail; justify ……NA……..					
Done by QC Officer/Supervisor (Sign.): rayan Date: 19.02.2024 Time: 10:40							

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: NA)	B (Lot no: NA)	A (Lot no:) B (Lot no)	O+ (Lot no :OC240219)

		Result	1:2	NA	1:2	NA	1:2	NA	1:2	+3
			1:4	NA	1:4	NA	1:4	NA	1:4	+2
			1:8	NA	1:8	NA	1:8	NA	1:8	+2
			1:16	NA	1:16	NA	1:16	NA	1:16	+2
			1:32	NA	1:32	NA	1:32	NA	1:32	+1
			1:64	NA	1:64	NA	1:64	NA	1:64	+1
			1:128	NA	1:128	NA	1:128	NA	1:128	+/-
			1:256	NA	1:256	NA	1:256	NA	1:256	-ve
			1:512	NA	1:512	NA	1:512	NA	1:512	-ve
			1:1024	NA	1:1024	NA	1:1024	NA		
➢ Final Result:		■ Pass ☐ Fail; justify ……NA……..								
Done by QC Officer/Supervisor (Sign.): rayan Date: 19.02.2024 Time: 10:42										

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: 19.02.2024**

QC Release Stamp:

Atlas Medical

PRODUCT CATALOGUE

2023-2024

TABLE OF CONTENTS

INTRODUCTION

Atlas Medical GmbH was established in 1996 as a manufacturer and supplier of quality Diagnostic Reagents and Kits. Our products are sold in over 80 countries worldwide.

The company is located at the Cambridge Science Park, Cambridge, UK. In addition to the UK site, the company has offices in Germany and Turkey as well as two purpose-built modern facilities in both Jordan and Malaysia. We take quality assurance very seriously and strive to produce goods to the highest standards known in the industry, including, ISO13485 & CE mark and US FDA standards. Our R&D team constantly develops and innovates novel products that significantly contribute to the advancement of the Diagnostic Industry.

Vision

To be a major provider of quality medical diagnostic products to local, regional and international markets.

Mission

Our mission is to develop, produce and provide our customers with high quality products and excellent customer services through deep understanding of customers' needs and perception, recruitment of high caliber professionals & technicians, adopting strict quality assurance and control procedures and embracing new scientific advancements in the medical lab diagnostic field.

Objectives

- *High and Consistent Quality*
- *Satisfied Customer*
- *Continuous Improvement & Innovation*
- *Care for the Environment & Working Conditions*

Sites

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Our Markets

Atlas Medical enjoys a good presence in many international markets. We take pride in our export activities through our dedicated export department. We actively participate in major industry-related exhibitions seeking keen representatives around the globe to sell and distribute our products in their respective countries. We are internationally repre - sented in more than 80 of countries spanning in five continents: Europe, North America, South America, Africa and Asia. Our efforts will continue to increase our representation to include most markets around the globe.

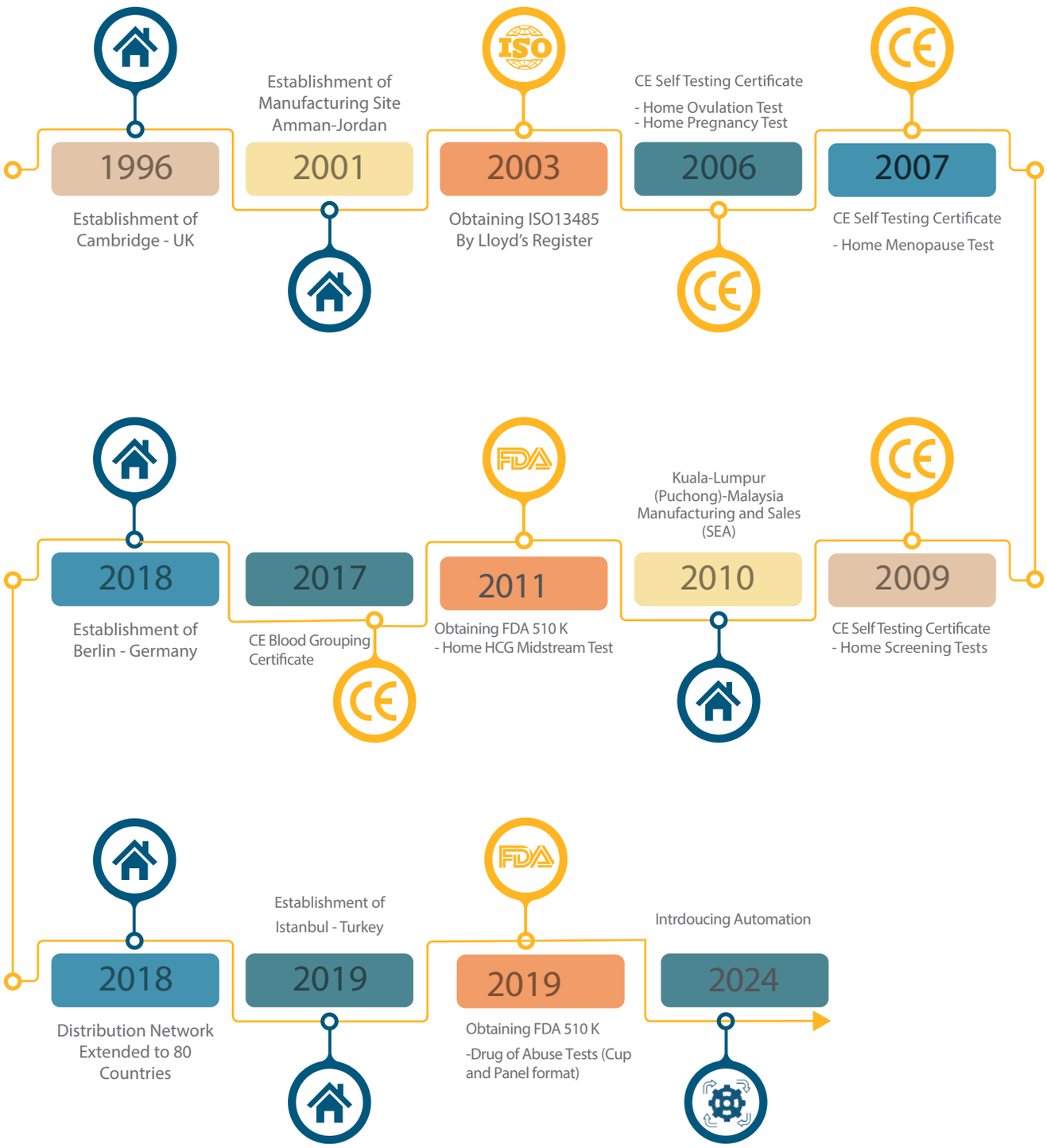
Standards

Our products are manufactured in accordance to the standards as set in the European In-Vitro Diagnostic Directive 98/79/EC. This has led to the successful attainment of Annex IV Full Quality Assurance Certification and the declaration of con
marking purposes for many of our IVD products, either self-declared or through our Notified Bod

To complete the quality assurance scheme the company has put in place a robust Quality Management and Enhancement System that has concluded in the successful attainment of ISO13485: 2016 certificate

the company also adheres to the US-FDA regulations and had already FDA-cleared few products for the US market. Our products are registered in numerous countries.

MILESTONES


1996
Establishment of Cambridge - UK
2001
Establishment of Manufacturing Site Amman-Jordan
2003
Obtaining ISO13485 By Lloyd's Register
2006
CE Self Testing Certificate
- Home Ovulation Test
- Home Pregnancy Test
2007
CE Self Testing Certificate
- Home Menopause Test
2009
CE Self Testing Certificate
- Home Screening Tests
2010
Kuala-Lumpur (Puchong)-Malaysia Manufacturing and Sales (SEA)
2011
Obtaining FDA 510 K
- Home HCG Midstream Test
2017
CE Blood Grouping Certificate
2018
Establishment of Berlin - Germany
2018
Distribution Network Extended to 80 Countries
2019
Establishment of Istanbul - Turkey
2019
Obtaining FDA 510 K
-Drug of Abuse Tests (Cup and Panel format)
2024
Intrdoucing Automation

LATEX KITS

Overview

Latex kits offer a quick and simple assay to diagnose a range of pathogens and medical conditions. The assay is based on an immunological reaction between the detected analyte in the sample and its corresponding antibody or antigen already coated on latex particles.

Features

- They cover a selection of routine tests in serology and microbiology.
- They are conveniently packed in sizes of 50 or 100 tests and includes all the necessary reagents, controls, stirrers and slides to conduct the test.
- Affordable, easy to use, dependable and offer a clear and visible agglutination for doubt-free results.
- Some Latex Kits come with a Buffer.

Item Code	Item Description	Sizes
8.00.00.0.0050 8.00.00.0.0100	CRP Latex Kit	50 Tests 100 Tests
8.00.01.0.0050 8.00.01.0.0100	CRP Latex Kit with Buffer	50 Tests 100 Tests
8.00.02.0.0050 8.00.02.0.0100	ASO Latex Kit	50 Tests 100 Tests
8.00.03.0.0050 8.00.03.0.0100	ASO Latex Kit with Buffer	50 Tests 100 Tests
8.00.04.0.0050 8.00.04.0.0100	RF Latex Kit	50 Tests 100 Tests
8.00.05.0.0050 8.00.05.0.0100	RF Latex Kit with Buffer	50 Tests 100 Tests
8.00.07.0.0050 8.00.07.0.0100	hCG Latex Kit	50 Tests 100 Tests
8.00.11.0.0050 8.00.11.0.0100	SLE Latex Kit	50 Tests 100 Tests
8.00.17.0.0050 8.00.17.0.0100	D-Dimer Latex Kit	50 Tests 100 Tests
8.00.21.0.0050 8.00.21.0.0100	Waaler Rose Kit	50 Tests 100 Tests
8.00.08.0.0050 8.00.08.0.0100	IM Latex Kit	50 Tests 100 Tests
8.00.12.0.0050 8.00.12.0.0100	Staphylococcus Latex Kit	50 Tests 100 Tests
8.00.13.0.0300	Streptococcus Latex Kit	50 Tests

Item Code	Item Description	Sizes
8.00.09.0.0050 8.00.09.0.0100	Toxo Latex Kit	50 Tests 100 Tests
8.00.10.0.0050 8.00.10.0.0100	Toxo Latex Kit with Buffer	50 Tests 100 Tests
8.00.14.0.0100	Rubella Latex Kit	100 Tests

TURBIDIMETRIC LATEX KITS

Overview

The turbidimetric assay is based on the agglutination reaction between latex particles coated with antibody and the antigen in solution. The intended use for Turbilatex products is to detect and quantify the antigen present in human serum or plasma samples.

Features

- Atlas Medical offers a dynamic range of Turbidimetric Latex Kits which are conveniently packed in sizes of 50, 100 and 250 tests and include all the necessary accessories.

Item Code	Item Description	Sizes
8.44.00.0.0050	RF Turbidimetric Latex Kit	50 Tests
8.44.01.0.0050	CRP Turbidimetric Latex Kit	50 Tests
8.44.02.0.0050	ASO Turbidimetric Latex Kit	50 Tests
8.44.03.0.0050	D-Dimer Turbidimetric Latex Kit	50 Tests
8.44.04.0.0050	Microalbumine Turbidimetric Latex Kit	50 Tests
8.44.05.0.0050	Ferritin Turbidimetric Latex Kit	50 Tests
8.44.06.0.0050	Transferrin Turbidimetric Latex Kit	50 Tests
8.44.08.0.0050	HbA1C Turbidimetric Latex Kit	50 Tests

SYPHILIS KITS

Overview

Atlas Medical offers a number of assays to detect Syphilis that include: TPHA kits which are used for the detection of antibodies to Treponema pallidum in human Serum or plasma using micro haemagglutination ; VDRL and RPR kits which are based on non-Treponemal floccuation to detect reagin antibodies in serum or plasma .

Item Code	Item Description	Sizes
8.00.18.0.0100	RPR Carbon Antigen Kit	100 Tests
8.00.18.0.0500		500 Tests
8.00.19.0.0100	TPHA Kit	100 Tests
8.00.19.0.0200		200 Tests
8.00.20.0.0250	VDRL Kit	250 Tests
8.00.20.0.0500		500 Tests
8.00.20.0.2500		2500 Tests
8.00.20.1.0250	VDRL Kit with controls	250 Tests
8.00.20.1.2500		2500 Tests

Features

- Easy to use, affordable and conveniently packed in different sizes to suit all needs.
- They include all the necessary reagents/devices, controls, stirrers and slides to conduct the test

FEBRILE ANTIGENS

Overview

Febrile antigen kits are based on bacterial suspensions that agglutinate in the presence of antibodies formed in human infection by certain fever-causing microbial agents. In positive samples, the agglutination is macroscopically visible at certain antibody levels in serum. These antigen reagents are used for the qualitative and semi quantitative febrile screening purposes.

Features

- Atlas Medical Febrile Antigen kits contain various types of antigens for Brucella, Proteus, Salmonella typhi and paratyphi, and their controls as needed.

- Atlas Medical Febrile Antigen kits are competitively priced and easy to use, and give clear results within 2 minutes

Item Code	Item Description	Sizes
8.01.17.0.0050	Febrile Antigen Set (10 Antigens: Salmonella OA, OB, OC, OD, HA, HB, HC, HD, Brucella abortus, melitensis)	10x5 ml
8.01.17.1.0050	Febrile Antigen Set (10 Antigens: Salmonella OA, OB, OC, OD,HA, HB, HC, HD, Brucella abortus, melitensis) with 3x1.0ml Controls	10x5 ml
8.01.18.0.0030	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD,HA, HB, HD)	6x5 ml
8.01.18.1.0030	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD) with 2x1.0ml Controls	6x5 ml
8.01.19.0.0005	Febrile Antigens Positive Control	5 ml/vial
8.01.20.0.0005	Febrile Antigen Negative Control	5 ml/vial

Item Code	Item Description	Sizes
8.01.00.0.0005 8.01.00.0.0050 8.01.00.0.0100	Brucella Rose Bengal Kit	5ml/vial 50 Tests 100 Tests
8.01.01.0.0005 8.01.01.1.0040 8.01.01.0.0050	Salmonella OA Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.02.0.0005	Salmonella OB Reagent	5 ml/vial
8.01.03.0.0005	Salmonella OC Reagent	5 ml/vial
8.01.04.0.0005	Salmonella OD Reagent	5 ml/vial
8.01.05.0.0005	Salmonella HA Reagent	5 ml/vial
8.01.06.0.0005	Salmonella HB Reagent	5 ml/vial
8.01.07.0.0005	Salmonella HC Reagent	5 ml/vial
8.01.08.0.0005	Salmonella HD Reagent	5 ml/vial
8.01.10.0.0005	Brucella Abortus Reagent	5 ml/vial
8.01.11.0.0005	Brucella Melitensis Reagent	5 ml/vial
8.01.12.0.0005	Proteus OX2 Reagent	5 ml/vial
8.01.13.0.0005	Proteus OX19 Reagent	5 ml/vial
8.01.14.0.0005	Proteus OXK Reagent	5 ml/vial
8.01.15.0.0010	Brucella Antigen Kit (Brucella melitensis, Brucella abortus)	2 vials/Box
8.01.15.2.0010	Brucella Antigen Kit with Controls, (5ml Brucella melitensis, 5ml Brucella abortus, 2x0.5 ml Controls)	2 vials/Box
8.01.16.0.0040	Salmonella Antigen Set (8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD)	8x5 ml
8.01.16.1.0040	Salmonella Antigen Set (8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD) with 2x1.0 ml Controls	8x5 ml

BLOOD GROUPING REAGENTS

Overview

Blood Grouping reagents are used for the identification of blood types. The test procedure is based on the agglutination principle, where red cells possessing the typing antigen agglutinate in the presence of the corresponding antibody in the testing reagent indicating the presence of the tested antigen. No agglutination indicates the absence of the tested antigen.

Features

- Atlas Medical ABO reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines.
- The reagents are formulated and optimized for use in tube and slide methods.
- Atlas Medical provides high quality blood grouping reagents that are accurate, easy to use, competitively priced, and conveniently packed in different sizes and options.

Item Code	Item Description	Sizes
8.02.14.0.0010	Anti-D Monoclonal (IgM), Clone 1, 10ml/vial	10 ml/vial
8.02.16.0.0005	Anti-A1, Lectin (Dolichosbiflorus),	5 ml/vial
8.02.17.0.0005	Anti-H, Lectin (Ulexeuropaeus),	5 ml/vial
8.02.18.0.0005	Anti-C Monoclonal,	5 ml/vial
8.02.19.0.0005	Anti-c Monoclonal,	5 ml/vial
8.02.20.0.0005	Anti-E Monoclonal,	5 ml/vial
8.02.21.0.0005	Anti-e Monoclonal,	5 ml/vial
8.02.22.0.0005	Anti-C+D+E Monoclonal,	5 ml/vial
8.02.27.0.0002	Anti-Fya, Human,	2 ml/vial
8.02.28.0.0002	Anti-Fyb, Human,	2 ml/vial
8.02.29.0.0002	Anti-k, Human,	2 ml/vial
8.02.30.0.0002	Anti-Kpa, Human,	2 ml/vial
8.02.31.0.0002	Anti-Kpb, Human,	2 ml/vial
8.02.32.0.0002	Anti-Jka, Human,	2 ml/vial
8.02.36.0.0005	Anti-K Monoclonal,	5 ml/vial
8.02.54.0.0002	Anti-Cw,	2 ml/vial

Item Code	Item Description	Sizes
8.02.00.0.0010 8.02.00.1.0100	Anti-A Monoclonal reagent (titer: 1/512)	10 ml/vial 10x10 ml
8.02.01.0.0010 8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512)	10 ml/vial 10x10 ml
8.02.02.0.0010 8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512)	10 ml/vial 10x10 ml
8.02.03.0.0010 8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128)	10 ml/vial 10x10 ml
8.02.04.0.0010 8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256	10 ml/vial 10x10 ml
8.02.05.0.0010 8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256)	10 ml/vial 10x10 ml
8.02.06.0.0010 8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256)	10 ml/vial 10x10 ml
8.02.07.0.0010 8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64)	10 ml/vial 10x10 ml
8.02.08.0.0010 8.02.08.1.0100	Bovine Albumin 22%	10 ml/vial 10x10 ml
8.02.09.0.0010 8.02.09.1.0100	Bovine Albumin 30%	10 ml/vial 10x10 ml
8.02.10.0.0010 8.02.10.1.0100	Anti-Human Globulin (Green) (Titer 1/512)	10 ml/vial 10x10 ml
8.02.11.0.0010 8.02.11.1.0100	Anti-Human Globulin (Green) (Titer 1/256)	10 ml/vial 10x10 ml
8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128))	3x10 ml
8.02.47.1.0030	ABO Set (Anti-A (1/265), Anti-B (1/265), Anti-D (1/64))	3x10 ml
8.02.49.0.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64))	4x10 ml
8.02.53.0.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128))	4x10 ml
8.02.52.0.0010	Rh-D Negative Control	10 ml/vial
8.02.63.1.0010	Antibody Enhancement Solution (LISS)	10 ml/vial
8.02.23.0.0002	Anti-M, Human,	2 ml/vial
8.02.24.0.0002	Anti-N, Lectin (Viciagraminea),	2 ml/vial
8.02.25.0.0002	Anti-S, Human,	2 ml/vial
8.02.26.0.0002	Anti-s, Human,	2 ml/vial
8.02.37.0.0002	Anti-Lea, Monoclonal,	2 ml/vial
8.02.38.0.0002	Anti-Leb, Monoclonal,	2 ml/vial
8.02.39.0.0002	Anti-P1, Monoclonal,	2 ml/vial

HEMATOLOGY TESTS

Overview

Atlas Medical supplies coagulation reagents.
The coagulation regents include PT,PTT and fibronogen in liquidformats and in various sizes to suit most lab applications.
The range also includes normal and abnormal coagulation controls.

Features

- Some kits includes normal and abnormal controls .
- The Kit comes in sizes of 50 and 100 tests.
- Atlas Medical provides high quality coagulation reagents that are accurate, easy to use, competitively priced, and conveniently packed in different sizes and options.

Co-aggulation Reagents

Item Code	Item Description	Sizes
8.02.40.1.0010 8.02.40.1.0050 8.02.40.1.0100	PT Calcium Rabbit Brain Thromboplastin, Liquid	2ml (20 Tests) 5ml (50 Tests) 10ml (100 Tests)
8.02.41.1.0040 8.02.41.1.0050 8.02.41.1.0100	APTT (PTT) Micronised Silica Platelet Substitute	2ml (40 Tests) 2.5ml (50 Tests) 5ml (100 Tests)
8.02.44.0.0040 8.02.44.0.0100	PT Kit with Normal Control	2x2ml + 1ml 2x10ml + 1ml
8.02.45.0.0080 8.02.45.0.0200	APTT (PTT) Kit with Normal Control	2x2ml + 1ml 2x10ml + 1ml
8.02.48.0.0010 8.02.48.0.0100	Calcium Chloride, 25 mM	10ml/vial 10ml/vial / 10 Vials / Box
8.02.60.0.0006	Normal Coagulation Control	6x1ml
8.02.61.0.0006	Abnormal Coagulation Control	6x1ml
8.02.45.1.0080	APTT (PTT) Kit (Calcium Chloride reagent + Normal Control)	80 Tests
8.02.69.0.0100	Fibronogen Test kit KIT	100 Tests

Hemoglobin Reagents

Item Code	Item Description	Sizes
8.02.46.1.0500 8.02.46.1.1000 8.02.46.1.3000	Drabkins Reagent,	50ml/Bottle 2x50ml 6x50ml
8.02.50.0.0010	Haemoglobin Standard	10ml/vial

SICKLE CELL KITS

Overview

Sickle cell disease (also called sickle cell anemia) is an inherited blood disorder that affects red blood cells. The sickle cell gene causes the body to produce abnormal hemoglobin.

Features

- Atlas Sickle Cell Kits is a qualitative solubility test for Sickle Haemoglobin.
- The test can be performed in two ways:
  1. A screening test to detect sickle haemoglobin (HbS)
  2. A centrifugation test to differentiate the sickle cell trait (AS) from sickle cell anaemia (SS).

Item Code	Item Description	Sizes
8.02.67.0.0050 8.02.67.0.0100	Sickle Cell Kit, 50 Tests Sickle Cell Kit,	50 Test 100 Test
8.02.68.0.0001	Sickle Cell positive & negative control set	1ml each

INFECTIOUS DISEASE RAPID TESTS

ANTIBODY TESTING

Overview

Atlas Medical offers an extensive range of lateral flow immunoassay tests for the rapid detection of antibodies and antigens in human samples (blood, serum, plasma, urine, oral swabs, nasal swabs, and feces). This range includes tests to detect a wide variety of viruses, microorganisms and parasites.

Features

- Atlas Medical infectious disease rapid tests are reliable, accurate and supplied in both cassette and strip formats.
- The kits are conveniently packed in different sizes of 20, 25, 30, 40, 50 and 100 tests per kit and include the necessary test accessories to perform the assay.

Item Code	Item Description	Sizes
8.04.27.0.0001 8.04.27.0.0020	HIV 1/2 Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.28.0.0001 8.04.28.0.0020	HIV 1/2 Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.29.0.0001 8.04.29.0.0100	HIV 1/2 Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.30.0.0001 8.04.30.0.0020	HCV Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.31.0.0001 8.04.31.0.0020	HCV Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.32.0.0001 8.04.32.0.0100	HCV Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.35.0.0001 8.04.35.0.0020	HBs Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.36.0.0001 8.04.36.0.0100	HBs Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box

Item Code	Item Description	Sizes
8.04.20.0.0001 8.04.20.0.0020	H.pylori Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.21.0.0001 8.04.21.0.0020	H.pylori Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.22.0.0001 8.04.22.0.0100	H.pylori Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.41.0.0001 8.04.41.0.0020	Syphilis Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.42.0.0001 8.04.42.0.0020	Syphilis Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.43.0.0001 8.04.43.0.0100	Syphilis Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box

INFECTIOUS DISEASE RAPID TESTS

ANTIGEN TESTING

Item Code	Item Description	Sizes
8.04.23.1.0020	H.pylori Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.24.1.0025	H.pylori Antigen Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.04.69.0.0020	Rotavirus Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.70.0.0025	Rotavirus Antigen Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.04.71.0.0020	Adenovirus Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.72.0.0025	Adenovirus Antigen Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.04.73.0.0020	Rota-Adeno Antigens Combo test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.74.0.0025	Rota-Adeno Antigens Combo test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.01.0.0020	Crypto Virus Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.02.0.0025	Crypto Virus Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.31.0.0020	Giardia Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.30.0.0025	Giardia Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.33.0.0020	Crypto-Giardia Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.32.0.0025	Crypto-Giardia Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.16.41.0.0020	E.coli Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.16.40.0.0025	E.coli Test Strip, Stool Sample, Individually Pouched	25 Tests/Box
8.66.01.0.0001 8.66.01.0.0020	**COVID-19 Antgen Test Cassette, Nasal Swab, Individually pouched**	**Bulk 20Test/ Box**
8.66.02.0.0001 8.66.02.0.0020	**COVID-19 Combo Antigen & Influenza, A+B Test , Individually pouched**	**Bulk 20Test/ Box**

Item Code	Item Description	Sizes
8.04.25.0.0020	Strep A Test Cassette, Swab Sample	20 Tests/Box
8.45.00.0.0020	Strep B Test Cassette, Swab Sample	20 Tests/Box
8.45.01.0.0020	Strep A+B Test Cassette, Swab Sample	20 Tests/Box
8.04.86.0.0020	Influenza A+B Test Cassette, Nasal Sample	20 Tests/Box
8.04.96.0.0025	Influenza A+B Test Strip, Nasal Sample	25 Tests/Box
8.16.20.0.0020	RSV Test Cassette, Swab Sample	20 Tests/Box
8.16.22.0.0025	RSV Test Strip, Swab Sample	25 Tests/Box
8.16.37.0.0020	Adeno Respiratory Antigen Test Cassette, Swab Sample	20 Tests/Box
8.16.36.0.0025	Adeno Respiratory Antigen Test Strip, Swab Sample	25 Tests/Box
8.16.39.0.0020	Adeno - RSV Respiratory Test Cassette, Swab Sample	20 Tests/Box
8.16.38.0.0025	Adeno - RSV Respiratory Test Strip, Swab Sample	25 Tests/Box

Item Code	Item Description	Sizes
8.04.37.0.0020	Malaria Pf. Test Cassette, Whole Blood, Individually Pouched	20 Tests/Box
8.16.14.0.0020	Malaria Pf/Pv. Test Cassette, Whole Blood, Individually Pouched	20 Tests/Box

Item Code	Item Description	Sizes
8.16.24.0.0001 8.16.24.0.0020	HBsAg Test Cassette (Whole Blood/Serum/ Plasma), Individually Pouched	Bulk 20 Tests/Box
8.04.33.0.0001 8.04.33.0.0020	HBsAg Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.34.0.0001 8.04.34.0.0100	HBsAg Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.26.0.0020	Chlamydia Test Cassette, Urine or Swab	20 Tests/Box
8.63.00.0.0025	Chlamydia + Gonorrhea Rapid Test Cassette (Cervical/Urethral swab)	25 Tests/Box

URINE REAGENT STRIPS

Overview

Urine Reagent Strips (URS) are widely used in Urinalysis to determine pathological changes in urine. The strips contain dry-chemistry pads that, when dipped in urine, change their colors. The color change allows for the semi-quantitative measurement of various urine parameters. The strips are suitable for lab, point-of-care and even home use.

Features

- Atlas Medical Urine Reagent Strips can be used to detect up to 14 urine parameters.
- They are simple to use and the results are visually read within a minute.
- The strips are packed in desiccated bottles of 50 or 100 strips.

Item Code	Item Description	Sizes
8.03.00.0.0050 8.03.00.0.0100	URS 1 Parameter: Glucose	50 Strips 100 Strips
8.03.01.0.0050 8.03.01.0.0100	URS 1 Parameter: Protein	50 Strips 100 Strips
8.03.02.0.0050 8.03.02.0.0100	URS 1 Parameter: Ketone	50 Strips 100 Strips
8.03.45.0.0050	URS 1 Parameter Blood, (5mm)	50 Strips
8.03.03.0.0050 8.03.03.0.0100	URS 2 Parameters: Glucose, Ketone	50 Strips 100 Strips
8.03.04.0.0050 8.03.04.0.0100	URS 2 Parameters: Glucose, Protein	50 Strips 100 Strips
8.03.05.0.0100	URS 2 Parameters: Sample end: Urobilinogen, Bilirubin	100 Strips
8.03.19.0.0050 8.03.19.0.0100	URS 2 Parameters(5mm): Sample End: Creatinine, pH	50 Strips 100 Strips
8.03.06.0.0050 8.03.06.0.0100	URS 3 Parameters: Protein, pH, Glucose	50 Strips 100 Strips
8.03.07.0.0100	URS 3 Parameters: Glucose, Protein, Ketone	100 Strips
8.03.08.0.0100	URS 3 Parameters: Sample end:pH, Ketone, Glucose	100 Strips
8.03.09.0.0100	URS 3 Parameters: Sample end:Leukocytes, Nitrite, Blood	100 Strips
8.03.10.0.0050 8.03.10.0.0100	URS 3 Parameters: Sample end:Protein, Specific Gravity, Creatinine	50 Strips 100 Strips
8.03.11.0.0100	URS 4 Parameters: Protein, pH, Specific Gravity, Glucose	100 Strips
8.03.12.0.0100	URS 4 Parameters: Protein, pH, Blood, Glucose	100 Strips
8.03.13.0.0050 8.03.13.0.0100	URS 5 Parameters: Glucose, Protein, Ketone, pH, Blood	50 Strips 100 Strips
8.03.25.0.0100	URS 5 Parameters(5mm): Blood, Glucose, Protein, Nitrite, Leucocytes	100 Strips
8.03.14.0.0100	URS 6 Parameters: Leukocytes, Nitrite, Protein, pH, Blood, Glucose	100 Strips
8.03.44.0.0100	URS 7 Parameter: Glucose, Ketone, Protien, PH, Blood, Bilirubin, Urobilinogen	100 Strips
8.03.23.0.0100	URS 8 Parameters: Glucose, Protein, pH, Ketone, Urobilinogen, Bilirubin, Blood, Nitrite	100 Strips
8.03.15.0.0100	URS 9 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose	100 Strips
8.03.16.0.0100	URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose	100 Strips
8.03.17.0.0050 8.03.17.0.0100	URS 10 Parameters: Sample end: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone,Bilirubin, Glucose, Ascorbic Acid	50 Strips 100 Strips
8.03.18.0.0100	URS 11 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid	100 Strips
8.03.47.0.0100	URS 14 Parameters (ASC, GLU, BIL, KET, SG, BLO, PH, PRO, URO, NIT, LEU, ALB, CRE, CA)	100 Strips

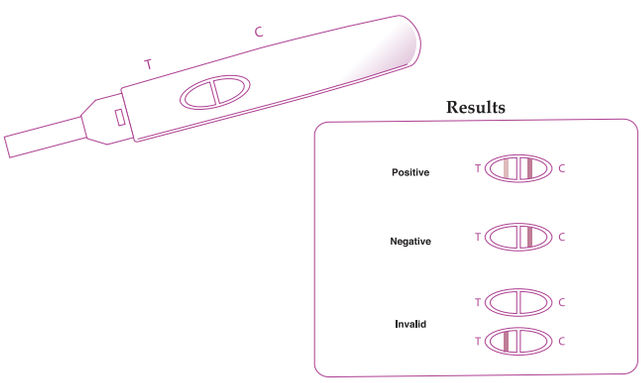
FERTILITY RAPID TESTS

Overview

Atlas Medical Fertility Rapid Tests are based on lateral flow immunoassay for the detection of human chorionic gonadotropin (hCG), Ovulation (LH), and Human Follicular Stimulating Hormone (FSH) in urine. Each of the three tests comes in strip, cassette, or midstream formats and are conveniently packed in sizes to suit lab, point-of-care and home uses.

Features

- Accurate.
- Convenient.
- Easy to use (add or dip in urine).
- Competitively priced.
- Results are obtained in 1 to 5 minutes.
- Different strip sizes are available.



Item Code	Item Description	Sizes
8.04.00.0.0001 8.04.00.0.0020	hCG Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.01.0.0001 8.04.01.0.0020	hCG Test Cassette, Urine/Serum, Individually Pouched	Bulk 20 Tests/Box
8.04.04.0.0001 8.04.04.0.0100	hCG Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.10.0.0001 8.04.10.0.0100	hCG Test Strip, Urine/Serum, Individually Pouched	Bulk 100 Tests/Box
8.04.13.0.0001 8.04.13.0.0015	hCG Midstream Test, Individually Pouched	Bulk 15 Tests/Box
8.04.14.0.0001 8.04.14.0.0020	LH Test Cassette, Urine, Individually pouched	Bulk 20 Tests/Box
8.04.15.0.0001 8.04.15.0.0100	LH Test Strip, Urine, Individually pouched	Bulk 100 Tests/Box
8.04.16.0.0001 8.04.16.0.0015	LH Midstream Test, Individually Pouched	Bulk 15 Tests/Box
8.04.17.0.0001 8.04.17.0.0020	FSH Test Cassette, Urine, Individually pouched	Bulk 20 Tests/Box
8.04.18.0.0001 8.04.18.0.0100	FSH Test Strip, Urine, Individually pouched	Bulk 100 Tests/Box
8.04.19.0.0001 8.04.19.0.0015	FSH Midstream Test, Individually Pouched	Bulk 15 Tests/Box

INFLAMMATION AND CANCER MARKERS

Overview

All the tests in this group are qualitative and based on lateral flow immunoassay for the detection of various inflammation and cancer markers.

Item Code	Item Description	Sizes
8.04.38.0.0020	Fecal Occult Blood Test (FOB) Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box
8.04.85.0.0050	Fecal Occult Blood Test (FOB) Test Strip Stool Sample, Individually Pouched	50 Tests/Box
8.04.109.0.0020	Procalcitonin Test Cassette (PCT), (Serum/Plasma)	20 Tests/Box
8.48.00.0.0020	Procalcitonin Test Cassette (PCT), (Whole Blood / Serum/ Plasma)	20 Tests/Box
8.16.78.0.0025	Calprotectin Test Cassette	25 Tests/Box

Features

- Atlas Medical inflammation and cancer markers rapid tests are supplied in both cassette and strip formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30 and 100 tests per kit.

Item Code	Item Description	Sizes
8.16.28.0.0001 8.16.28.0.0020	PSA Test Cassette, Whole Blood/Serum/Plasma), Individually Pouched	Bulk 20 Tests/Box
8.04.39.0.0001 8.04.39.0.0020	PSA Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.40.0.0001 8.04.40.0.0100	PSA Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box

CARDIAC MARKERS RAPID TESTS

Overview

Atlas Medical offers lateral flow immunoassay rapid tests to detect the three major cardiac markers namely: Troponin I, Myoglobin and CK-MB, as an aid in the diagnosis of myocardial infarction (MI).

Item Code	Item Description	Sizes
8.04.45.0.0001 8.04.45.0.0020	Troponin I Test Cassette, Whole Blood/Serum/ Plasma, Individually Pouched	Bulk 20 Tests/Box

Features

- They can be used on whole blood (in addition to serum/plasma) making them ideal for emergency rooms.
- They come in single test or triple combo test cassette formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30 tests per kit.

DOA RAPID TESTS

Overview

All the tests in this group are qualitative and based on lateral flow immunoassay for the detection of various Drug of Abuse .

Features

- Can be supplied in cassette , strip, panel and cup formats.
- The kits are conveniently packed in different kitsizes of 20,25,30,50 and 100 tests per kit.

STRIP AND CASSETTE FORMAT

Item Code	Item Description	Sizes
8.04.49.0.0001 8.04.49.0.0020	Morphine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.50.0.0001 8.04.50.0.0100	Morphine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.51.0.0001 8.04.51.0.0020	Marijuana (THC) Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.52.0.0001 8.04.52.0.0100	Marijuana (THC) Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.53.0.0001 8.04.53.0.0020	Amphetamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.54.0.0001 8.04.54.0.0100	Amphetamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.55.0.0001 8.04.55.0.0020	Barbiturates Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.56.0.0001 8.04.56.0.0100	Barbiturates Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.57.0.0001 8.04.57.0.0020	Benzodiazepines Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.58.0.0001 8.04.58.0.0100	Benzodiazepines Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.59.0.0001 8.04.59.0.0020	Cocaine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.60.0.0001 8.04.60.0.0100	Cocaine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.61.0.0001 8.04.61.0.0020	Methamphetamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.62.0.0001 8.04.62.0.0100	Methamphetamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.63.0.0001 8.04.63.0.0020	Methadone Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.64.0.0001 8.04.64.0.0100	Methadone Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.65.0.0001 8.04.65.0.0020	Phencyclidine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.66.0.0001 8.04.66.0.0100	Phencyclidine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.47.0.0001 8.16.47.0.0020	Fentanyl Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box

Item Code	Item Description	Sizes
8.04.67.0.0001 8.04.67.0.0020	Tricyclic Anti-Depressants Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.68.0.0001 8.04.68.0.0100	Tricyclic Anti-Depressants Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.99.0.0001 8.04.99.0.0020	Buprenorphine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.23.0.0001 8.16.23.0.0100	Buprenorphine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.68.0.0001 8.16.68.0.0020	Tramadol Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.44.0.0001 8.16.44.0.0100	Tramadol Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.15.0.0001 8.16.15.0.0020	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Cassette,Urine,Individually Pouched	Bulk 20 Tests/Box
8.16.05.0.0001 8.16.05.0.0100	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Strip, Urine,Individually Pouched	Bulk 100 Tests/Box
8.16.06.0.0001 8.16.06.0.0020	Opiates Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.07.0.0001 8.16.07.0.0100	Opiates Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.58.0.0001 8.16.58.0.0020	Cotinine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.59.0.0001 8.16.59.0.0100	Cotinine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.62.0.0001 8.16.62.0.0020	Oxycodone Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.63.0.0001 8.16.63.0.0100	Oxycodone Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.64.0.0001 8.16.64.0.0020	Ketamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.65.0.0001 8.16.65.0.0100	Ketamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.66.0.0001 8.16.66.0.0020	Proxyphene Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.67.0.0001 8.16.67.0.0100	Proxyphene Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.68.0.0001 8.16.68.0.0020	Tramadol Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.69.0.0001 8.16.69.0.0020	EDDP Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.70.0.0001 8.16.70.0.0100	EDDP Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.60.0.0001 8.16.60.0.0020	Dolantin Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.61.0.0001 8.16.61.0.0100	Dolantin Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box

ANTIBIOTIC SENSITIVITY DISCS

Overview

Antibiotic sensitivity is a term used to describe the susceptibility of bacteria to antibiotics. Antibiotic susceptibility testing (AST) is usually carried out to determine which antibiotic will be most successful in treating a bacterial infection in vivo.

Small discs containing antibiotics are placed onto a plate upon which bacteria are growing. If the bacteria are sensitive to the antibiotic, a clear ring, or zone of inhibition, is seen around the disc indicating poor growth.

Features

- Atlas Medical offers a wide range of antibiotics discs at competitive prices.
- Easy to use.
- The kit comes with a Cartridge Applicator.
- Reliable quality.
- Comprehensive range of antibiotics at different concentrations.

Item Code	Item Description	Sizes
8.39.48.0.0250	NORFLOXACIN (10 µg) - NX	5x50 Discs
8.39.49.0.0250	OFLOXACIN (5 µg) - OF	5x50 Discs
8.39.50.0.0250	PEFLOXACIN (5 µg) – PF	5x50 Discs
8.39.51.0.0250	PENICILLIN –G (10 IU) – P	5x50 Discs
8.39.52.0.0250	PIPERACILLIN (100 µg) – PI	5x50 Discs
8.39.53.0.0250	PIPERACILLIN / TAZOBACTAM (100 µg + 10 µg) - PTZ	5x50 Discs
8.39.54.0.0250	RIFAMPIN (5 µg) – RIF	5x50 Discs
8.39.55.0.0250	ROXITHROMYCIN (30 µg) – RO	5x50 Discs

Item Code	Item Description	Sizes
8.39.01.0.0250	AMIKACIN (30 µg) – AK	5x50 Discs
8.39.02.0.0250	AMOXICILLIN (10 µg) – AX	5x50 Discs
8.39.03.0.0250	AMOXICILLIN / CLAVULANATE (20 µg + 10 µg) - AMC	5x50 Discs
8.39.04.0.0250	AMPICILLIN (10 µg) – AMP	5x50 Discs
8.39.05.0.0250	AMPICILLIN / SULBACTAM (10 µg - 10 µg) – AS	5x50 Discs
8.39.06.0.0250	AZITHROMYCIN (15 µg) – AZM	5x50 Discs
8.39.07.0.0250	AZTREONAM (30 µg) – AT	5x50 Discs
8.39.08.0.0250	CEFACLOR (30 µg) - CF	5x50 Discs
8.39.09.0.0250	CEFADROXIL (30 µg) - CD	5x50 Discs
8.39.10.0.0250	CEFAZOLIN (30 µg) - CZ	5x50 Discs
8.39.11.0.0250	CEFDINIR (5µg) - CDR	5x50 Discs
8.39.12.0.0250	CEFIXIME (5 µg) - CFM	5x50 Discs
8.39.13.0.0250	CEFOPERAZONE (75 µg) - CPZ	5x50 Discs
8.39.14.0.0250	CEFOPERAZONE / SULBACTUM (75 µg + 30 µg) - CS	5x50 Discs
8.39.15.0.0250	CEFOTAXIME (30 µg) - CTX	5x50 Discs
8.39.16.0.0250	CEFPIROME (30 µg) - CE	5x50 Discs
8.39.17.0.0250	CEFPODOXIME (10 µg) – CPD	5x50 Discs
8.39.18.0.0250	CEFPROZIL (30 µg) - CPR	5x50 Discs
8.39.19.0.0250	CEFTAZIDIME (30 µg) – CAZ	5x50 Discs
8.39.20.0.0250	CEFTIZOXIME (30 µg) - CZX	5x50 Discs
8.39.21.0.0250	CEFTRIOXONE (30 µg) - CTR	5x50 Discs
8.39.22.0.0250	CEFUROXIME (30 µg) - CXM	5x50 Discs
8.39.23.0.0250	CEPHALEXIN (30 µg) - CN	5x50 Discs
8.39.24.0.0250	CEPHALORIDINE (30 µg)- CH	5x50 Discs
8.39.25.0.0250	CEPHALOTHIN (30 µg) - CEP	5x50 Discs
8.39.26.0.0250	CHLORAMPHENICOL (30 µg) - C	5x50 Discs
8.39.27.0.0250	CIPROFLOXACIN (5 µg) - CIP	5x50 Discs
8.39.28.0.0250	CLARITHROMYCIN (15 µg) - CLR	5x50 Discs
8.39.29.0.0250	CLINDAMYCIN (2 µg) - CD	5x50 Discs
8.39.30.0.0250	CLOXACILLIN (5 µg) - COX	5x50 Discs
8.39.32.0.0250	DOXYCYCLINE (30 µg) - DOX	5x50 Discs
8.39.33.0.0250	ERYTHROMYCIN (15 µg) - E	5x50 Discs
8.39.34.0.0250	FURAZOLIDONE (100 µg) - FZ	5x50 Discs
8.39.35.0.0250	GATIFLOXACIN (5 µg) - GAT	5x50 Discs
8.39.36.0.0250	GENTAMYCIN (10 µg) - GEN	5x50 Discs
8.39.38.0.0250	KANAMYCIN (30 µg) - K	5x50 Discs
8.39.39.0.0250	LEVOFOLXACIN (5 µg) - LE	5x50 Discs
8.39.40.0.0250	LINCOMYCIN (15 µg) - LN	5x50 Discs
8.39.41.0.0250	LINEZOLID (30 µg) - LZ	5x50 Discs
8.39.42.0.0250	LOMEFLOXACIN (10 µg) - LOM	5x50 Discs
8.39.43.0.0250	MEROPENEM (10 µg) - MRP	5x50 Discs
8.39.44.0.0250	MINOCYCLINE (30 µg) - MI	5x50 Discs
8.39.45.0.0250	MOXIFLOXACIN (5 µg) - MXF	5x50 Discs
8.39.46.0.0250	NALIDIXIC ACID (30 µg) - NA	5x50 Discs
8.39.47.0.0250	NITROFURANTOIN (300 µg) - NIT	5x50 Discs

ANTIBIOTIC SENSITIVITY DISCS

Item Code	Item Description	Sizes
8.39.56.0.0250	SPARFLOXACIN (5 µg) – SPX	5x50 Discs
8.39.57.0.0250	STREPTOMYCIN (10 µg) – S	5x50 Discs
8.39.58.0.0250	SULFADIAZINE (300 µg) - SD	5x50 Discs
8.39.59.0.0250	TEICOPLANIN (30 µg) – TEI	5x50 Discs
8.39.60.0.0250	TETRACYCLINE (30 µg) – TE	5x50 Discs
8.39.61.0.0250	TICARCILLIN / CLAVULANATE (75 µg + 10 µg)-TCC	5x50 Discs
8.39.62.0.0250	TOBRAMYCIN (10 µg) – TOB	5x50 Discs
8.39.63.0.0250	TRIMETHOPRIM (5 µg) – TR	5x50 Discs
8.39.64.0.0250	VANCOMYCIN (30 µg) – VA	5x50 Discs
8.39.65.0.0250	POLYMYXIN-B (300 UNITS) -PB	5x50 Discs
8.39.66.0.0050	CEFOXITIN (30 µg) - CX	1x50 Discs
8.39.67.0.0250	CEFEPIME (30 µg) - CPM	5x50 Discs
8.39.69.0.0050	NOVOBIOCIN (5 µg) -NV	1x50 Discs

Item Code	Item Description	Sizes
8.39.70.0.0050	CARBENICILLIN (100 µg) - CB	1x50 Discs
8.39.71.0.0050	BACITRACIN - B (10 Unit)	1x50 Discs
8.39.72.0.0050	CEFOXITIN (30 µg) - CX	20x50 Discs
8.39.76.0.0250	COLISTIN -CL (10 µg)	5x50 Discs
8.39.77.0.0250	IMIPENEM-IPM (10 µg)	5x50 Discs
8.39.78.0.0250	OXACILLIN -OX (1 µg)	5x50 Discs

ELISA KITS

Features

- The kits feature high sensitivities, simple and robust methods, breakable well strips, quantitative results, ready-to use liquid reagents, and reasonable assay time.
- The assays can be used on most open ELISA manual readers and washers as well as open ELISA auto-analyzers.
- Kits are packed in sizes of 96 tests.

Overview

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect major hormones in the fields of thyroids and fertility in serum.

Item Code	Item Description	Sizes
8.10.01.0.0096	hCG Elisa Kit	96 Tests
8.10.03.0.0096	FSH Elisa Kit	96 Tests
8.10.04.0.0096	LH Elisa Kit	96 Tests
8.10.05.0.0096	Prolactin Elisa Kit	96 Tests
8.12.00.0.0096	T3 Elisa Kit	96 Tests
8.12.01.0.0096	T4 Elisa Kit	96 Tests
8.12.02.0.0096	TSH Elisa Kit	96 Tests
8.12.03.0.0096	Free T4 Elisa Kit	96 Tests
8.12.04.0.0096	Free T3 Elisa Kit	96 Tests
8.11.03.0.0096	Progesterone Elisa kit	96 Tests
8.11.04.0.0096	Testosterone Elisa Kit	96 Tests

CLINICAL CHEMISTRY KITS

Overview

Kits in this group measure concentrations of electrolytes , hormones, proteins, and other metabolic products in human blood , serum,plasma, CSF and urine .
Clincal Chemistry tests are indicated to assess systemic functions such liver function , kidney function , and endocrine and metabolic function .
Methods commonly used are colormetric and kinetic.

Features

- The kits are conveniently packed in different kit sizes of 20, 30, 60, 75,100, 150, 200, 250, 500, and 1000 tests per kit.

Item Code	Item Description	Sizes
8.05.00.0.0250 8.05.00.0.0500	Albumin Bromocresol Green	2x125ml 4x125ml
8.05.01.0.0030 8.05.01.0.0060	Amylase	3x10ml 6x10ml
8.05.04.0.0250 8.05.04.0.0500	Alkaline Phosphatase Kinetic, DGKC Method (Liquid)	5x50ml 5x100ml
8.05.05.0.0250 8.05.05.0.0500	Bilirubin Total (DMSO Method)	2x125ml 4x125ml
8.05.06.0.0250 8.05.06.0.0500	Bilirubin Direct (DMSO Method)	2x125ml 4x125ml
8.05.07.0.0250 8.05.07.0.0500	Bilirubin Total & Direct (DMSO Method)	2x125ml 4x125ml
8.05.08.0.0250 8.05.08.0.0500	Calcium Arsenazo III	2x125ml 4x125ml
8.05.09.0.0250 8.05.09.0.0500	Calcium O-Cresolphthalein	2x125ml 4x125ml
8.05.10.0.0250 8.05.10.0.0500	Chloride Thiocyanate Colorimetric	2x125ml 4x125ml
8.05.11.0.0250 8.05.11.0.0500	Cholesterol Liquid (CHOD-POD)	2x125ml 4x125ml
8.05.13.0.0250 8.05.13.0.0500	CK-MB Kinetic (Liquid)	5x10ml 5x20ml
8.05.15.0.0250 8.05.15.0.0500	CK-NAC Kinetic (Liquid)	5x10ml 5x20ml

Item Code	Item Description	Sizes
8.05.16.0.0250 8.05.16.0.0500	Creatinine Jaffe Color-Kinetic	2x125ml 4x125ml
8.05.17.0.0250 8.05.17.0.0500	Glucose GOD-POD (Liquid)	2x125ml 4x125ml
8.05.19.0.0250 8.05.19.0.0500	GOT (AST) IFCC Kinetic (Liquid)	5x50ml 5x100ml
8.05.20.0.0250 8.05.20.0.0500	GOT (AST) Reitman-Frankel Colorimetric	2x125ml 2x250ml
8.05.22.0.0250 8.05.22.0.0500	GPT (ALT) IFCC Kinetic (Liquid)	5x50ml 5x100ml
8.05.23.0.0250 8.05.23.0.0500	GPT (ALT) Reitman-Frankel Colorimetric	2x100ml 2x125m
8.05.25.0.0250 8.05.25.0.0500	Gamma GT Kinetic, Carboxy Substrate (Liquid)	5x50ml 5x100ml
8.05.26.0.0250 8.05.26.0.0500	HDL Cholesterol Precipitating Reagent	2x50ml 2x100ml
8.05.27.0.0250	Iron Ferrozine Colorimetric	4x50ml
8.05.29.0.0250 8.05.29.0.0500	LDH Pyruvate Kinetic UV DGKC (Liquid)	5x50ml 5x100ml
8.05.30.0.0250	Lipase Kinetic (Liquid)	6x10ml
8.05.31.0.0250 8.05.31.0.0500	Magnesium Calmagite Colorimetric	2x125ml 4x125ml
8.05.32.0.0250 8.05.32.0.0500	Phosphorus Phosphomolybdate UV	2x125ml 4x125ml
8.05.33.0.0250 8.05.33.0.0500	Potassium Colorimetric	50 Tests 100 Tests
8.05.34.0.0250 8.05.34.0.0500	Sodium Colorimetric	50 Tests 100 Tests
8.05.35.0.0250	TIBC (Total Iron Binding Capacity)	100 Tests
8.05.36.0.0250 8.05.36.0.0500	Total Lipids Phosphovainilline Colorimetric	2x125ml 4x125ml
8.05.37.0.0250 8.05.37.0.0500	Total Protein Biuret Colorimetric	2x125ml 4x125ml
8.05.38.0.0250 8.05.38.0.0500	Total Protein in CSF	2x125ml 4x125ml

STAINS FOR HISTOLOGY & MICROBIOLOGY

Overview

Atlas Medical is well known for its range of lab stains for histology and microbiology applications.
Atlas Medical stains are made of the highest quality ingredientsto ensure good quality and vivid staining.

Features

- The stains come in convenient sizes, but custom sizes are also available.

STAINS FOR HISTOLOGY

Item Code	Item Description	Sizes
8.15.017.0250	Carbol Fuchsin (Gram)	250ml/Bottle
8.15.019.0250	Carbol Fuchsin (Ziehl-Neelsen)	250ml/Bottle
8.15.032.0250	Crystal Violet (for Gram Stain)	250ml/Bottle
8.15.037.0250	Eosin Y (1% Aqueous)	250ml/Bottle
8.15.038.0250	Eosin Y (5% Aqueous)	250ml/Bottle
8.15.039.0250	Eosin Stain (diff 3)	250ml/Bottle
8.15.041.0250	Field Stain (Solution A)	250ml/Bottle
8.15.042.0250	Field Stain (Solution B)	250ml/Bottle
8.15.043.0750	Field Stain (Fixing Reagent, Eosin Reagent, Methylene Blue Reagent	3x250ml
8.15.044.0500	Field Stain (Solution A+B)	2x250ml
8.15.047.0250	Giemsa Stain (Modified-Glycerol/Methanol)	250ml/Bottle
8.15.049.0250	Gram's Iodine	250ml/Bottle
8.15.051.0250	Gram's Decolouriser	250ml/Bottle
8.15.059.0250	Haematoxylin Harris (no Acetic Acid)	250ml/Bottle
8.15.069.0250	Leishman Stain	250ml/Bottle
8.15.074.0250	Lugol's Iodine	250ml/Bottle
8.15.076.0250	Malachite Green (Aqueous)	250ml/Bottle
8.15.078.0250	May Grunwald Stain (Modified)	250ml/Bottle
8.15.105.0250	New Methylene Blue for Reticulocytes	250ml/Bottle
8.15.110.0250	Papanicolaou Stain EA35	250ml/Bottle
8.15.111.0250	Papanicolaou Stain EA36	250ml/Bottle
8.15.112.0250	Papanicolaou Stain EA65	250ml/Bottle
8.15.114.0250	Papanicolaou Stain EA50	250ml/Bottle
8.15.115.0250	Papanicolaou Stain OG6	250ml/Bottle
8.15.126.0250	Safranin (1% Aqueous)	250ml/Bottle
8.15.143.0250	Wright's Stain (Modified)	250ml/Bottle
8.15.144.0250	ZN Decolouriser	250ml/Bottle
8.15.146.0100	Immersion Oil	100ml/Bottle
8.15.150.0250	Mayers haematoxylin	250ml/Bottle

STAIN PACKS FOR HISTOLOGY

Item Code	Item Description	Sizes
8.17.009.1000	Gram Stain Pack	4x250ml
8.17.010.0750	Cold ZN - Kinyoun Stain Pack	3x250ml
8.17.011.0750	ZN Pack Standard	3x250ml
8.17.015.0500	Diff-3 Stain Pack	4x125ml

MICROBIOLOGY

Item Code	Item Description	Sizes
8.38.00.0.0025	Blood Culture Bottles, Pediatric Size	25ml/Bottle
8.38.00.0.0050	Blood Culture Bottles, Adult Size	50ml/Bottle

HOME TESTS

CE 0459

Overview

Atlas Medical provides a range of home tests that have been specifically CE marked for OTC use. The range includes fertility tests (Pregnancy, Ovulation and Menopause). The home tests range also includes other medical conditions such as liver function, kidney function, diabetes and urine tract infection. These tests are based on urine reagent strips.

Screening Kits

Item Code	Item Description	Sizes
70004001	Atlas Home Diabetes Test	2 Tests/Box
70021001	Atlas Home Urinary Tract Infection Test	2 Tests/Box
70022001	Atlas Home Kidney Function Test	2 Tests/Box
70023001	Atlas Home Liver Function Test	2 Tests/Box

Features

- These tests come in cassette, midstream and strip formats.
- The screening kits come with 2 individually pouched strips and easy to read instructions for use.
- All kits are packed in attractively designed boxes with various languages.
- Atlas Medical also supplies these kits under OEM arrangements.
- Screening bundle including (UTI, Kidney, Liver, Diabetes) is available , Family planning kit (Pregnancy and Ovulation) is also available .

CE 0459

Fertility Kits

Item Code	Item Description	Sizes
70171001	Atlas Home Pregnancy Test Cassette	1 Test/Box
70172001	Atlas Home Pregnancy Test Midstream	1 Tests/Box
70174001	Atlas Home Ovulation Test Cassette	5 Tests/Box
70175001	Atlas Home Ovulation Test Midstream	3 Tests/Box
70177001	Atlas Home Menopause Test Cassette	1 Test/Box
70178001	Atlas Home Menopause Test Midstream	1 Test/Box
70180001	Atlas Home Pregnancy Test Strip (With Handle)	1 Test/Box
70170001	Atlas Home Pregnancy Test Strip	1 Test/Box

BLOOD GLUCOSE MONITORING SYSTEMS

Overview

Testing your blood glucose regularly helps you better manage your diabetes. Reliance ™ by Atlas Medical, uses the latest blood glucose sensor technologies to offer you the most accurate and reliable results for the peace of mind you need. Atlas Medical offers these systems in strips which includes Gold Electrodes.

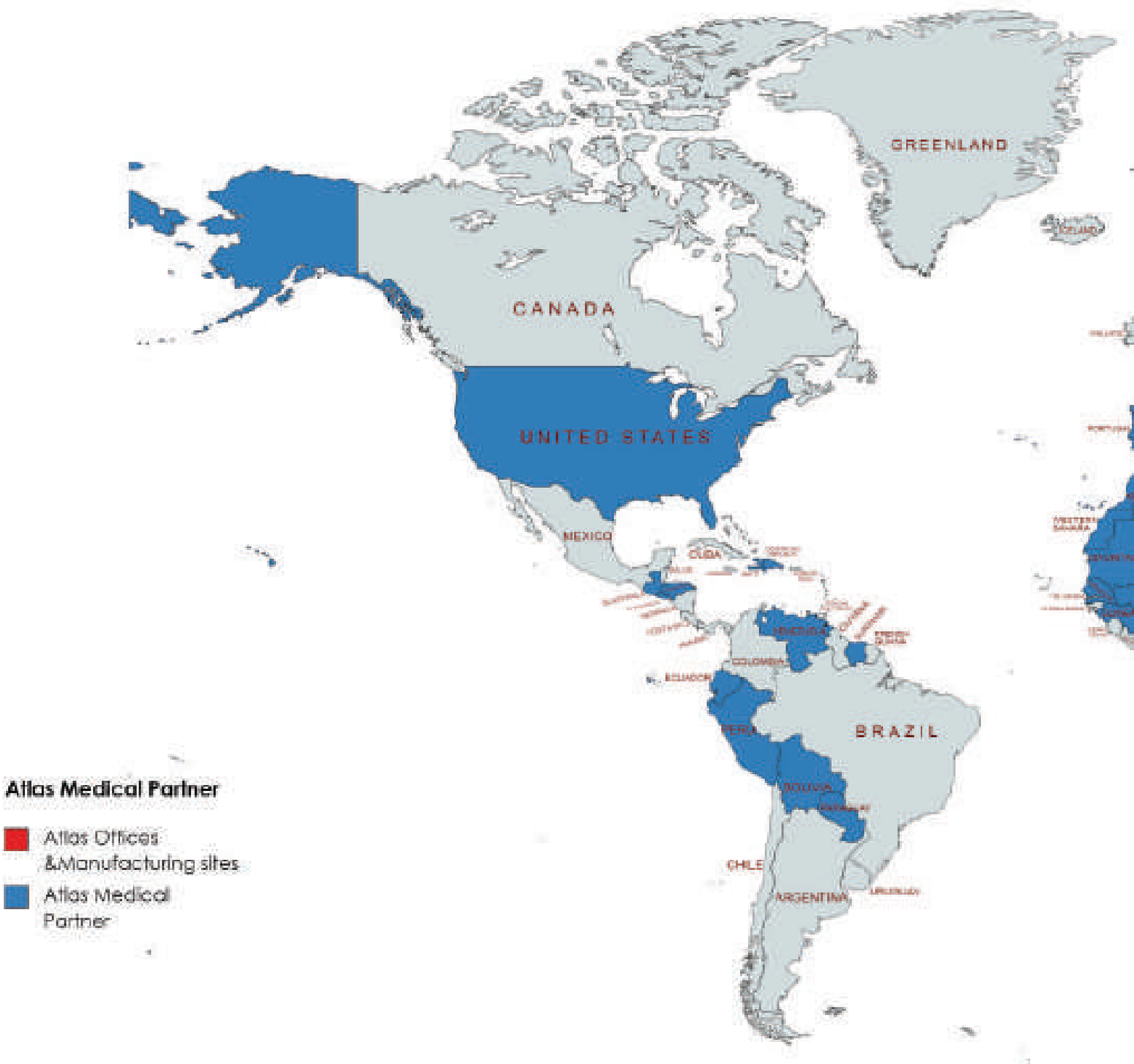
Features

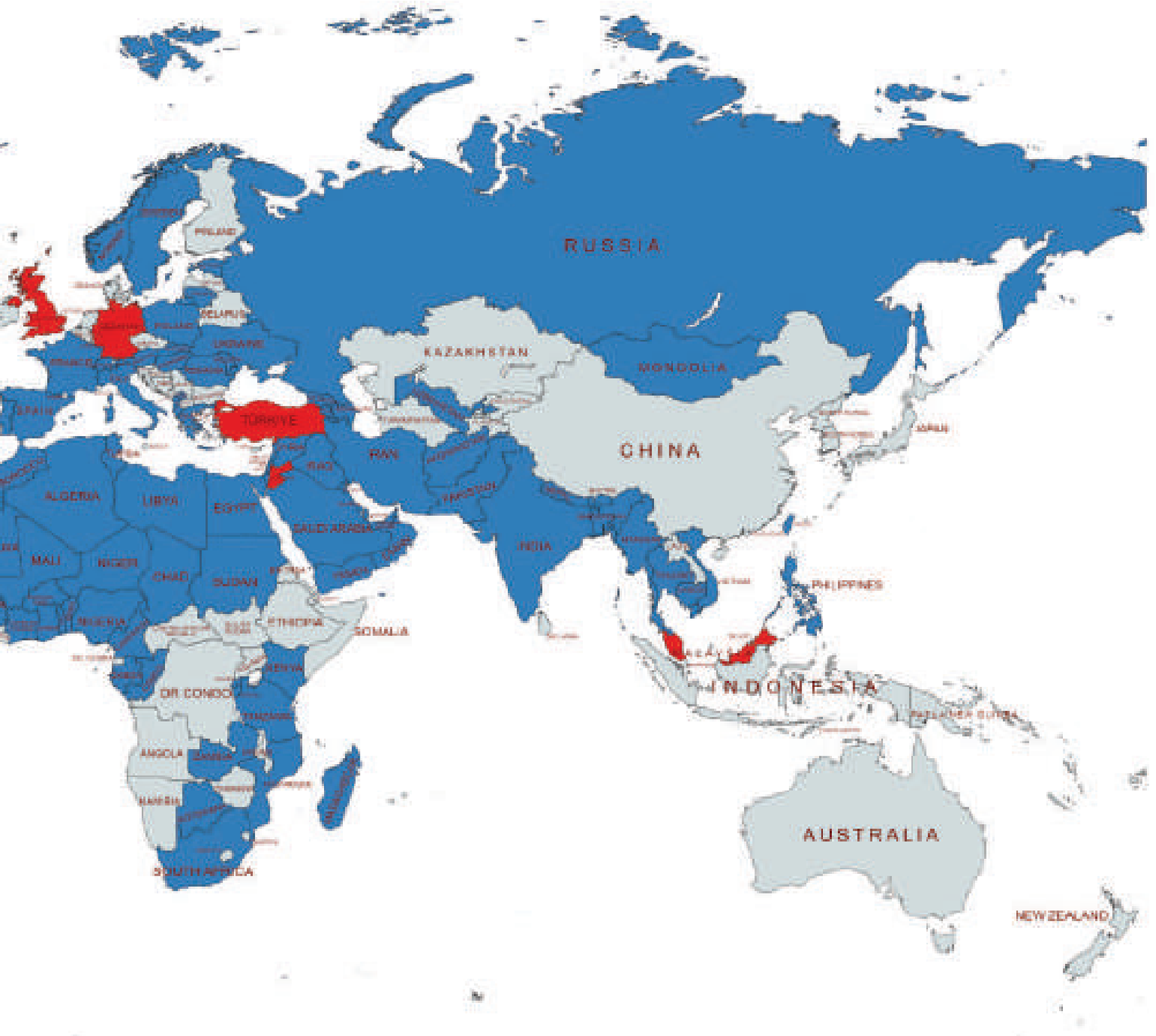
- Reliance Gold ™ by Atlas Medical, uses the latest blood glucose gold sensor technology to offer the most accurate and reliable results.
- Test time required is 5 Seconds.
- Required sample volume is 0.9µl
- Test result range is between 10 - 600 mg/dl (0.6 -33.3 mmol/L)

Reliance Gold

Item Code	Item Description	Sizes
8.52.00.0.0001	Reliance Gold Glucometer Pack	1 Pack
8.52.00.0.0025 8.52.00.0.0050	Strips for Reliance Gold Glucometer	25 Strips/Bottle 50 Strips/Bottle
8.52.00.1.0001	Reliance Gold Glucometer (Divce only)	1 Divce only

INTERNATIONAL PRESENCE




RUSSIA
KAZAKHSTAN
MONGOLIA
CHINA
INDIA
IRAN
IRAQ
TÜRKIYE
SAUDI ARABIA
EGYPT
LIBYA
ALGERIA
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NIGER
CHAD
SUDAN
ETHIOPIA
SOMALIA
DR CONGO
ANGOLA
NAMIBIA
SOUTH AFRICA
PHILIPPINES
INDONESIA
AUSTRALIA
NEW ZEALAND

CERTIFICATES

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.2

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum
See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

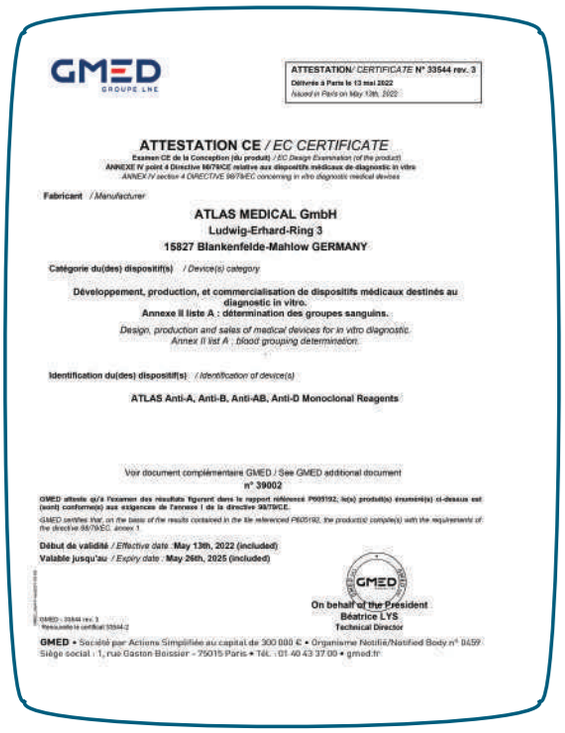
Début de validité / *Effective date* : October 9th, 2023 (included)
Valable jusqu'au / *Expiry date* : October 8th, 2026 (included)
Etabli le / *Issued on* : October 9th, 2023

On behalf of the President
Béatrice LYS
Technical Director

GMED N° 36655-2
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification
Remplace le certificat 36655-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

ISO 13485



ATTESTATION / *CERTIFICATE* N° 33544 rev. 3
Délivrée à Paris le 13 mai 2022
Issued in Paris on May 13th, 2022

ATTESTATION CE / *EC CERTIFICATE*
Examen CE de la Conception (du produit) / *EC Design Examination (of the product)*
ANNEXE IV point 4 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro
ANNEX IV section 4 DIRECTIVE 98/79/EC concerning in vitro diagnostic medical devices

Fabricant / *Manufacturer*

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

Catégorie du(des) dispositif(s) / *Device(s) category*

Développement, production, et commercialisation de dispositifs médicaux destinés au diagnostic in vitro.
Annexe II liste A : détermination des groupes sanguins.
Design, production and sales of medical devices for in vitro diagnostic.
Annex II list A : blood grouping determination.

Identification du(des) dispositif(s) / *Identification of device(s)*

ATLAS Anti-A, Anti-B, Anti-AB, Anti-D Monoclonal Reagents

Voir document complémentaire GMED / See GMED additional document
n° 39002

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P605192, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 98/79/CE.
GMED certifies that, on the basis of the results contained in the file referenced P605192, the product(s) complies with the requirements of the directive 98/79/EC, annex I.

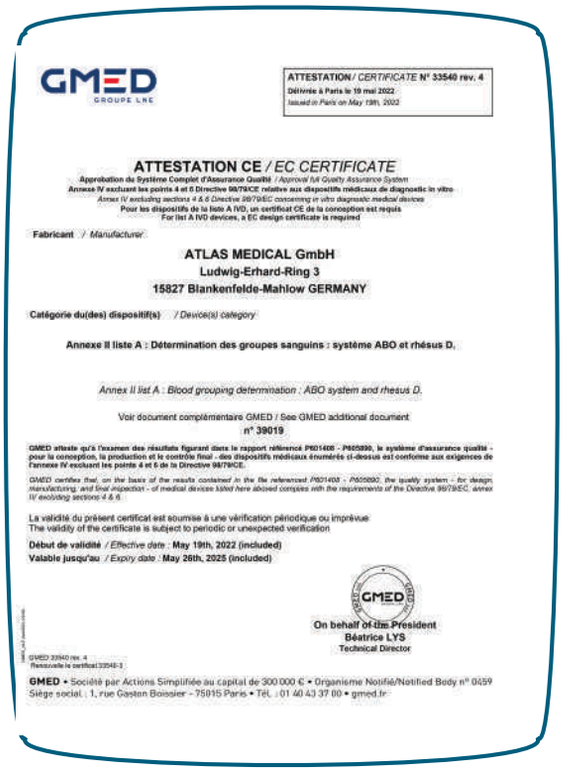
Début de validité / *Effective date* : May 13th, 2022 (included)
Valable jusqu'au / *Expiry date* : May 26th, 2025 (included)

On behalf of the President
Béatrice LYS
Technical Director

GMED - 33544 rev. 3
Remplace le certificat 33544-2

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Blood Grouping CE Certificate



ATTESTATION / *CERTIFICATE* N° 33540 rev. 4
Délivrée à Paris le 19 mai 2022
Issued in Paris on May 19th, 2022

ATTESTATION CE / *EC CERTIFICATE*
Approbation du Système Complet d'Assurance Qualité / *Approval full Quality Assurance System*
Annexe IV excluant les points 4 et 6 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro
Annex IV excluding sections 4 & 6 Directive 98/79/EC concerning in vitro diagnostic medical devices
Pour les dispositifs de la liste A IVD, un certificat CE de la conception est requis
For list A IVD devices, a EC design certificate is required

Fabricant / *Manufacturer*

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

Catégorie du(des) dispositif(s) / *Device(s) category*

Annexe II liste A : Détermination des groupes sanguins : système ABO et rhésus D.

Annex II list A : Blood grouping determination : ABO system and rhesus D.

Voir document complémentaire GMED / See GMED additional document
n° 39019

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P601408 - P605890, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe IV excluant les points 4 et 6 de la Directive 98/79/CE.
GMED certifies that, on the basis of the results contained in the file referenced P601408 - P605890, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 98/79/EC, annex IV excluding sections 4 & 6.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date* : May 19th, 2022 (included)
Valable jusqu'au / *Expiry date* : May 26th, 2025 (included)

On behalf of the President
Béatrice LYS
Technical Director

GMED 33540 rev. 4
Remplace le certificat 33540-3

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Full Quality Assurance Certificate.

OTHER CERTIFICATES

- FDA 510k Atlas Drug of Abuse Tests (Cup & Panel Format)
- GMP Certificate
- FDA 510k Atlas Home Pregnancy Test (Midstream Format)
- FDA 510k Atlas Home Ovulation Test (Midstream Format)
- hCG Test Strip CE certificate
- hCG Test Cassette CE certificate
- hCG Midstream Test CE certificate
- Ovulation Test Midstream CE certificate
- Ovulation Test Cassette CE certificate
- Menopause Test Midstream CE certificate
- Menopause Test Cassette CE certificate
- Liver Function Test CE certificate
- Diabetes Test CE certificate
- UTI Test CE certificate
- Kidney function Test CE certificate

FIND US ON:

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Amazon.co.uk/Atlas Medical

Atlas Medical CE 0459

Blood Grouping Reagents:
Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent, Anti-AB Monoclonal Reagent, Anti-D IgG/IgM blend Reagent, & Their variants
SLIDE AND TUBE TESTS

IVD **For *In-Vitro* and professional use only**

2℃ 8℃ **Store at 2- 8°C**

INTENDED USE

The blood grouping reagents are used to detect the presence or absence of A, B or Rhesus Antigens on the surface of human red blood cells based on hemaglutination using slide or tube test techniques in whole blood samples or anticoagulant blood samples collected in EDTA , citrate or heparin tubes.

INTRODUCTION & PRINCIPLES

Blood grouping reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines. The reagents are diluted with phosphate buffer containing sodium chloride, EDTA and bovine albumin to give reagents that are optimized for use in tube and slide procedures. **Anti-A monoclonal reagent is colored with acid blue (patent blue) dye, Anti-B monoclonal reagent is colored with acid yellow (tartrazine) dye, and Anti-AB monoclonal reagent is not colored.** The test procedure is based on hemaglutination principle, where red cells possessing the antigen agglutinate in the presence of the corresponding antibody indicating that the result is positive. The test is considered negative when no agglutination appears.

Anti-D IgG/IgM blend reagent is prepared from carefully blended human monoclonal IgM and IgG. Anti-D IgG/IgM blend reagent is suitable for slide and tube test procedures. The reagent will directly agglutinate Rh D positive cells, including majority of variants (but not D^{VI}) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D^{VI} and low grade weak D (D^{u}) phenotypes by the indirect anti-globulin techniques.

Anti-D IgG/IgM blend reagent is diluted with a sodium chloride solution, sodium phosphate solution and bovine albumin (sodium caprylate free). Anti-D IgG/IgM blend reagent is not colored. The procedure is based on hemaglutination principle, where red cells' possessing the antigen agglutinates in the presence of the corresponding antibody in the reagent indicating that the result is positive. The test is considered negative when no agglutination appears.

MATERIALS

MATERIALS PROVIDED

Blood Grouping Reagents:

- Anti-A monoclonal reagent (10 ml/vial), Clone: (9113D10).
- Anti-B monoclonal reagent (10 ml/vial), Clone: (9621A8).
- Anti-AB monoclonal reagent (10ml/vial), Clone: (152D12+9113D10).
- Anti-D IgG/IgM Blend reagent (10 ml/vial), Clone: (P3X61 + P3X21223B10 + P3X290 + P3X35).

MATERIALS NEEDED BUT NOT PROVIDED

- Plastic test tube or glass.
- Isotonic saline solution (% 0.9) NaCl).
- Applicator sticks.
- Centrifuge (100-1200 (g) for tube test).
- Timer.
- Incubator
- Anti-Human Globulin Reagent (can be ordered from Atlas Medical).
- White or transparent glass slide.

PRECAUTIONS

- The reagents are intended for in vitro diagnostic use only.
- The test is for well trained professional healthy user not for lay user.
- These reagents are derived from animal and human sources, thus, appropriate care must be taken in the use and disposal of these reagents, as there are no known test methods that can guarantee absence of infectious agents.
- Do not use reagents if it is turbid or contain particles as this may indicate reagent deterioration or contamination.
- Protective clothing should be worn when handling the reagents.
- **The reagents contain (0.1-0.2%) Sodium Azide and 0.02% sodium arseniate which is toxic and can be absorbed through the skin. When drained, the drains should be thoroughly flushed with water.**
- The reagents should be used as supplied and in accordance to the procedure mentioned below. Don't use beyond expiration date.
- Avoid cross contamination of reagents or specimens.
- Visible signs of microbial growth in any reagent may indicate degradation and the use of such reagent should be discontinued.
- Don't use these reagents if the label is not available or damaged.
- Do not use dark glass slide.
- Don't use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and the test table top with water and soap once the testing is done.
- Heamolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well let area with very good visibility.
- Failure to follow the procedure in this package insert may give false results or safety hazard.
- Close the vial tightly after each test.
- The reagent is considered toxic, so don't drink or eat beside it.
- If spillage of reagent occurs clean with disinfectant (disinfectant used could be irritable so handle with care).

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 - 8°C.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

REAGENT PREPRATION

- The reagents are intended for use as supplied, no prior preparation or dilution of the reagent is required.
- All reagents should be brought to room temperature before use.

SPECIMEN COLLECTION AND PREPARATION

- Blood collected with or without anticoagulant (EDTA, Heparin or Citrate) can be used for Antigen typing.

Note: Blood collected without anticoagulant should be tested immediately.

- The specimens should be tested as soon as possible after collection. If testing is delayed, the specimens should be stored at 2- 8 ºC, Sample must be retained to room temperature prior to analysis. (Testing should be carried out within five days of collections).
- Insure that there is no sign of hemolysis.
- At the time of the test, centrifuge the blood sample at 1200 RCF for 3 minutes.
- Blood collection is to be done with great care.

PROCEDURES

A. DIRECT TUBE METHOD AT ROOM TEMPERATURE

1. Prepare a 5% suspension of red blood cells in isotonic solution.
2. Using the vial dropper, transfer a drop (40±10µl) of each reagent into a separate and appropriately marked tube.
3. Add 50 µl of red blood cell suspension prepared in step 1.
4. Shake to homogenize the mixture, then centrifuge at 500g for **1 minute.**
5. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
6. Read the reaction immediately.
7. For Anti-D tube, if the reaction is weak or negative, shake the tubes and incubate at 37°C for **15 minutes.**
8. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
9. Add one drop (50µl) of the AHG reagent into the tube. Mix and centrifuge at 120g for **1 minute.**
10. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
11. Read the reaction immediately.

B. ANTIGLOBULIN INDIRECT METHOD for ANTI-D

1. After immediately centrifuging and reading as above, if the reaction is weak or negative, shake the tubes and incubate at 37°C for 15 minutes.
2. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
3. Add one drop (40 µl ± 10 µl) of ANTI-HUMAN GLOBULIN to the tube. Mix and centrifuge at 120 (g) for **1 minute**.
4. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
5. Read the reaction immediately.

C. DIRECT SLIDE METHOD AT ROOM TEMPERATURE

1. Bring reagents and samples to room temperature (18-25°C).
2. Using the wax pen divide the slide into appropriate numbers of divisions.
3. Using the provided dropper, place one drop (40 µl ± 10 µl) of each reagent onto its correspondent division on the slide.
4. Add 25µl of the precipitated cells next to each drop of reagents.
5. Mix the reagent and the cells using a clean stirring stick over an area with a diameter of approximately 20-40mm.
6. Incubate the slide at room temperature (18-25°C) without stirring for **30 seconds**.
7. Hold the slide and gently rock the slide for **3 minutes** and observe macroscopically for any agglutination.
8. Read the reaction immediately.

READING THE RESULT

POSITIVE: If Agglutination appears.

NEGATIVE: If no agglutination is observed.

Use the below table to determine the blood group:

Result of each reaction				ABO Group
Anti-A monoclonal reagent	Anti-B monoclonal reagent	Anti-AB monoclonal reagent	Anti-D IgG/IgM blend reagent	
+	-	+	+	**A+**
+	-	+	-	**A-**
-	+	+	+	**B+**
-	+	+	-	**B-**
+	+	+	+	**AB+**
+	+	+	-	**AB-**
-	-	-	+	**O+**
-	-	-	-	**O-**

STABILITY OF THE REACTIONS

- ABO Blood Grouping Tube tests should be read immediately following centrifugation.
- Slide tests should be interpreted within three minutes to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of reagents.
- Delay in reading and interpreting results may result in weekly positive or falsely negative reactions. Slide tests should be interpreted at the end of the three minutes.

PROCEDURE LIMITATION

1. False positive/ negative results may occur due to:
   - Contamination from test materials.
   - Improper storage, cells concentration, incubation time or temperature.
   - Improper or excessive centrifugation.
   - Deviation from the recommended technique.
   - Blood samples of weak A or B subgroups may give rise to false negative results or weak reactions when tested using slide test method. It is advisable to re-test weak subgroups using tube test method.
2. Weaker reactions may be observed with stored blood than with fresh blood.
3. ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
4. ABO blood grouping interpretation on individuals greater than 6 months old should be confirmed by testing serum or plasma of the individual against group A and group B red cells (reverse grouping). If the results obtained with the serum do not correlate with the red cell test, further investigation is required.
5. Return the kit to the agent if it does not function properly.
6. Anti-D IgG/IgM blend Reagent tests conducted on particular weak-D phenotypes, while satisfactory, cannot ensure recognition of all weak variants, due to the variability of antigen patterns.

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

The following tables compare the results in slide and tube techniques of 3 lots of Atlas Medical reagents and the results of a CE marked device.

Slide Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
232	232	232	232	100%
Tube Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
212	212	212	212	100%

Slide Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%
Tube Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%

Slide Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
241	241	241	241	100%
Tube Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
243	243	243	243	100%

Slide Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
33	33	33	33	100%
Tube Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
24	24	24	24	100%

No inversion in diagnosis has been shown: from a qualitative point of view we have observed 100% compliance in direct group testing in slide and tube techniques for determination of A, B, AB and O groups for the three lots of Atlas Medical.

QUALITY CONTROL

The reactivity of all blood grouping reagents should be confirmed by testing known positive and negative red blood cells on each day of use.

To confirm the specificity and sensitivity, Blood grouping reagents should be tested with antigen-positive and antigen-negative red blood cells.

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PPI861A01
Rev.L (19.02.2022)

CE 0459

LIST OF VARIENTS:

Product Code	Product Name
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/Carton Box
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial. 10 vials / Plastic Pack
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial. 18 vials / Carton Box
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, / Carton Box
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials / Plastic Pack
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials / Carton Box
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/ Carton Box
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials/Plastic Pack
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials/Carton Box
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 1 vial/ Carton Box
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 10 vials / Plastic Pack
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 18 vials / Carton Box
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1 Vial/Carton Box
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials / Plastic Pack
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials /Plastic Pack
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1 /256), Anti-D (1/64)),3x10ml / plastic Pack
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1 /256), 2x10ml /Plastic Pack
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,10 vials /Plastic Pack
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,18 vials / Carton Box
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 1Vial/ Carton Box
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 10 vials / Plastic Pack
8.02.47.0.0030	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-D (1 /128)),3x10ml/Plastic Pack
8.02.47.1.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Carton Box.
8.02.47.3.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Plastic Pack
8.02.47.5.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /128)), 3x10ml/Plastic Pack
8.02.49.0.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /64)), 4x10ml/Carton Box
8.02.49.2.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /128)), 4 x 10ml, 4 vials/Plastic Pack
8.02.53.0.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml/Plastic Pack
8.02.53.1.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml, 4vials/Plastic Pack
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial ,1Vial/ Carton Box
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial , 1Vial/ Carton Box
8.02.85.0.0010	Anti-D IgG/IgM Blend reagent (Titer 1 /256), 10ml/vial, 1Vial/ Carton Box

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

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IZ NOE-Sued, Hondastrasse, Objekt M55 A – 2351 Wiener Neudorf, Austria,
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Anti-k, monoclonal

HUMAN BLOOD GROUPING REAGENTS

For Indirect Antiglobulin Techniques

REF Cont.

B18908 **1x 2 mL** **Anti-k, monoclonal**

For professional in vitro diagnostic use only.

SUMMARY

The k (Cellano) antigens were reported in 1949. Anti-k has been implicated in Haemolytic Transfusion Reactions and Haemolytic Disease of the Newborn.

Anti-K	Anti-k	Phenotype	Percentage
+	0	**K+k-**	0.2
+	+	**K+k+**	8.8
0	+	**K-k+**	91.0

PRINCIPLE

The reagent will cause indirect agglutination (clumping) of test red cells, that carries the corresponding specific antigen, in the antiglobulin phase of testing. No agglutination generally indicates the absence of the corresponding specific antigen (see Limitations).

REAGENTS

This Monoclonal IgG blood grouping reagent contains human monoclonal antibodies diluted in a phosphate buffer containing sodium chloride and bovine albumin. The reagent is supplied at optimal dilution for use with all the recommended techniques stated below without the need for further dilution or addition. For lot reference number and expiry date see Vial Label.

Product	Cell Line/Clone
Anti-k (Cellano)	P3A118OL67

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. The reagent has undergone transportation stability studies at 37°C and -25°C as described in EN23640:2011.

SAMPLE COLLECTION AND PREPARATION

Blood samples can be collected into EDTA, citrate, CPDA anticoagulants or as a clotted sample. The samples should be tested as soon as possible following collection. If a delay in testing should occur, store the samples at 2-8°C. Samples displaying gross haemolysis or microbial contamination should not be used for testing. Blood samples showing evidence of lysis may give unreliable results. It is preferable to wash all blood samples with PBS or Isotonic saline before being tested.

CONTROLS AND ADVICE

1. It is recommended a positive control (ideally heterozygous cells) and a negative control be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. The antiglobulin techniques can only be considered valid if all negative tests react positively with IgG sensitised red cells.
3. The reagents contain macromolecular potentiators which may cause false positive reactions with IgG sensitised cells, it is recommended that patient's cells are tested with patient's plasma to test for false positive reactions.
4. In the **Tube Technique** one volume is approximately 50 µL when using the vial dropper provided.
5. The use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
6. User must determine suitability of the reagents for use in other techniques.

REAGENTS AND MATERIALS REQUIRED

- Anti-Human Globulin (e.g. DIALAB Anti-HG polyspecific/monoclonal, REF: B05181) or anti-IgG
- Coombs cell washer
- Bio-Rad / DiaMed ID-Cards (LISS/Coombs or Coombs Anti-IgG).
- Bio-Rad / DiaMed ID-Centrifuge
- Bio-Rad / DiaMed ID-CellStab or ID-Diluent 2.
- Bio-Rad / DiaMed ID-Incubator equilibrated to 37ºC ± 2ºC
- Glass test tubes (10 x 75 mm or 12 x 75 mm)
- IgG sensitised red cells
- Ortho BioVue System Cassettes (AHG/Coombs)
- Ortho BioVue System Centrifuge
- Ortho BioVue System Heat Block equilibrated to 37°C ± 2ºC
- Ortho 0.8% Red Cell Diluent
- PBS solution (pH 6.8 – 7.2) or Isotonic saline solution (pH 6.5 – 7.5)
- Positive (ideally heterozygous) and negative control red cells
- Volumetric pipettes
- Water bath or dry heat incubator equilibrated to 37ºC ± 2ºC

RECOMMENDED TECHNIQUES

A. Indirect Antiglobulin Technique (IAT)

1. Prepare a 2-3% suspension of washed test red cells in PBS or Isotonic Saline.
2. Place in a labelled test tube: 1 volume of DIALAB Anti-k, monoclonal reagent and 1 volume of test red cell suspension.
3. Mix thoroughly and incubate at 37ºC for 15 minutes.
4. Wash test red cells 4 times with PBS or Isotonic saline, taking care to decant saline between washes and resuspend each red cell button after each wash. Completely decant saline after last wash.
5. Add 2 volumes of anti-human globulin or anti-IgG to each dry cell button.
6. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
7. Gently resuspend red cell button and read macroscopically for agglutination
8. Confirm validity of all negative reactions with IgG sensitised red cells.

B. Bio-Rad/DiaMed-ID Micro Typing Technique

1. Prepare a 0.8% suspension of washed test red cells in ID-CellStab or ID-Diluent 2.
2. Remove aluminium foil from as many microtubes as needed on either LISS/Coombs or Coombs Anti-IgG ID cards.
3. Place in appropriate microtube: 50 µL of test red cell suspension and 25 µL of DIALAB Anti-k, monoclonal reagent.
4. Incubate the LISS/Coombs ID-Card(s) for 15 minutes at 37ºC.
5. Centrifuge the LISS/Coombs ID-Card(s) in a Bio-Rad/Diamed ID-Card centrifuge.
6. Read macroscopically for agglutination.

C. Ortho BioVue Typing Technique

1. Prepare a 0.8% suspension of washed test red cells in 0.8% Ortho Red Cell Diluent.
2. Remove aluminium foil from as many reaction chambers as needed on either AHG Polyspecific or AHG Anti-IgG cassettes.
3. Place in appropriate reaction chamber: 50 µL of test red cell suspension and 40 µL of DIALAB Anti-k, monoclonal reagent.
4. Incubate cassette(s) 15 minutes at 37ºC.
5. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
6. Read macroscopically for agglutination.

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of the test red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the presence of the k- antigen on the test red cells.
2. **Negative:** No agglutination of the test red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of the k-antigen on the test red cells.

STABILITY OF THE REACTIONS

1. Washing steps should be completed without interruption and tests centrifuged and read immediately after addition of the reagent. Delays may result in dissociation of antigen-antibody complexes, causing false negative or weak positive results.
2. Caution should be exercised in the interpretation of results of tests at temperatures other than those **recommended**.

LIMITATIONS

1. Red cells that have a positive DAT due to a coating of IgG cannot be typed by the **Indirect Antiglobulin Technique.**
2. Suppressed or diminished expression of certain blood group antigens may conversely give rise to false negative reactions and so caution should always be exercised when assigning genotypes on the basis of test results.
3. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper storage, cell concentration, incubation time or temperature
   - Improper or excessive centrifugation
   - Deviation from the recommended techniques

PERFORMANCE CHARACTERISTICS

1. The reagents have been characterised by the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of DIALAB Anti-k, monoclonal reagent is tested by the **Recommended Techniques** against a panel of antigen-positive red cells to ensure suitable reactivity.
3. Specificity of source monoclonal antibodies is demonstrated using a panel of antigen-negative cells.
4. The Quality Control of the reagents was performed using red cells that had been washed twice with PBS or Isotonic saline prior to use.
5. The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services

DISCLAIMER

1. The user is responsible for the performance of the reagents by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations from the **Recommended Techniques** should be validated prior to use.

PRECAUTIONS

1. The reagents are intended for in vitro diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagents past the expiration date (see **Vial Label**).
4. Do not use the reagents if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagents have been filtered through a 0.2 µm capsule to reduce the bioburden. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.

7. The reagents contain 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal, flush away with large volumes of water.
8. Materials used to produce the reagents were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

For information on disposal of the reagents and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

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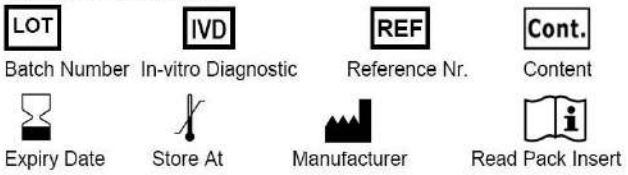
TABLE OF SYMBOLS



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