Operational Procedure Manual			
Doc no	PRL-OPM- F001	Revision 0.0	Effective Date: 1 Sept 2020
Written By;Gugu Ditshego		Reviewed by: Gugu Ditshego	Approved by: Jabulani Kubheka
Date: Aug 2020		Date: Aug 2020	Date: 31 Aug 2020

18069 Ngungunyane Street
Kwa Thema
1575

Tel: 011 737 1045/2518
Fax: 086 604 3815
Email: info@proteuslab.co.za

Verification reports for ABO & Rh Grouping, Methods and Equipment

Equipment / Method	***ABO & Rh Manual***
Performed by	**Gugu Ditshego**
Date of Verification	**20 February 2021**
Date of Report	**20February 2021**
Reviewed by	**Gugu Ditshego**
Approved by	**Jabulani Kubheka**
Date Approved	**28 February 2021**

Introduction

Validation was done using PRL-OPM-001. Samples used were fresh whole blood drawn in EDTA tubes. Samples were analysed within sample stability. A comparability study was done using10 samples. 100 % correlation was achieved. Raw data available to verify traceability & validity of the report.

Results: acceptance criteria are based on 100% correlation. These was achieved.
Statistical analysis: 10 samples were obtained for ABO & Rh grouping
Limitations of the method: The amount of sample volume can limit ABO & Rh typing. Weak positives result due to reagent/cell strength can cause limitation of method.
Conclusion: A 100% correlation was achieved. Therefore, the ABO Method used in the lab is fit for purpose.
Literature: The ABO and Rh **blood grouping** system is based on agglutination reaction. When red **blood** cells carrying one or both the antigens are exposed to the corresponding antibodies, they interact with each other to form visible agglutination or clumping.

ABO and Rh Data

Proteus Lab	**Results**	**Comparative method**	**Results**
148927	O POSITIVE	35420824	O POSITIVE
995601	A POSITIVE	35420825	A POSITIVE
148795	AB POSITIVE	35420826	AB POSITIVE
995597	B POSITIVE	35420823	B POSITIVE
104936	A POSITIVE	93174434	A POSITIVE
149538	B POSITIVE	35421568	B POSITIVE
995761	O NEGATIVE	35421567	O NEGATIVE
995720	A POSITIVE	35421566	A POSITIVE
149508	O POSITIVE	35421565	O POSITIVE
149560	A NEGATIVE	35421564	A NEGATIVE
Achieved outcome was 100% Correlation.			

Statistical processing

Malaria field staining technique	Diagnostic accuracy criteria		Total
	Known Positive	Known Negative	
Positive	# true positive – TP	#false positive – FP	TP+FP
Negative	#false negative – FN	# true negative - TN	FN+TN
Total	TP+FN	FP+TN	N

$$\text{Sensitivity} = \frac{no\ of\ true\ positives}{no\ of\ true\ positives + no\ of\ false\ negatives} \times 100$$

$$\text{Specificity} = \frac{no\ of\ true\ negatives}{no\ of\ true\ negatives + no\ of\ false\ positives} \times 100$$

$\text{Sensitivity} = \frac{TP}{(TP+FN)} \times 100$ $= \frac{10}{(10+0)} \times 100$ $= \frac{10}{10} \times 100$ $= 100\%$	$\text{Specificity} = \frac{TN}{(TN+FP)} \times 100$ $= \frac{10}{(10+0)} \times 100$ $= \frac{10}{10} \times 100$ $= 100\%$

		Gold standard			
		Positive	Negative	Total	
The Test Result	Positive	True Positive (TP)	False Positive (FP)		**Sensitivity**
		10	0	10	100%
	Negative	False Negative (FN)	True Negative (TN)		**Specificity**
		0	10	10	100%
	Total	10	10	20	