

Product Support Bulletin

Circulation:	SmartLyte® Users within Brazil	Notice Date:	04/06/2017
Status:	Mandatory	Bulletin:	3073
		Effective Date:	04/06/2017
Products:	Diamond SmartLyte® ISE Analyzer	Contact:	Kathy Fisher kfisher@diamonddiagnostics.com
Reference:	Non-Diamond Fluid Pack Quality Issues		

SUMMARY

Diamond manufactures fluid packs and reagents for use on its own Diamond SmartLyte® and Roche AVL 9180 systems. There are companies manufacturing inside Brazil or importing products from China into Brazil, and claiming they are functionally equivalent products to that of Diamond. After independent analysis of these products manufactured for use on Diamond SmartLyte® and Roche AVL 9180 systems, it has been concluded that these Brazilian and Chinese reagent products contain contamination and/or will have an immediate negative and adverse impact on the quality of performance of your system and may report false patient results.

COMPARISON

Below is the comparison of the fluid packs from Diamond Diagnostics and 3 companies within Brazil.

Parameters	Diamond	Brazil Mfg 1	Brazil Mfg 2	Brazil Mfg 3
Clear of Micro-Organisms				
Standard A	✓	✓	✓	✗
Standard B	✓	✓	✗	✗
Standard C	✓	✗	✗	✗
Reference	✓	✓	✗	✓
Performance Precision				
Na+	✓	✗	✗	✗
K+	✓	✓	✗	✗
Cl-	✓	✗	✗	✗
Ca++	✓	✓	✗	✗
Li+	✓	✗	✗	✗
Accuracy				
Na+	✓	✗	✗	✗
K+	✓	✓	✗	✗
Cl-	✓	✗	✗	✗
Ca++	✓	✓	✗	✗
Li+	✓	✗	✗	✗
Correlation Slope (0.96-1.04)				
Na+	✓	✗	✗	✗
K+	✓	✓	✗	✗
Cl-	✓	✗	✗	✗
Ca++	✓	✓	✗	✗
Li+	✓	✗	✗	✗
Waste Overflow Protection	✓	✗	✗	✗

CONCLUSION

Diamond warrants its Diamond SmartLyte® analyzer when utilizing its fluid packs and reagent products. Use of unauthorized reagent products or products, known to have adverse effects, shall void the warranty on the Diamond SmartLyte® electrodes and consumables produced by Diamond.