

INTRODUCTION

Serological diagnosis in prenatal screening is crucial for preventing diseases. Detecting various types of antibodies against infectious diseases helps avoid infants developing long-lasting and hidden illnesses that can reduce their lifespan and overall well-being. Advances in disease screening have led to the use of new technologies, like the xMAP® multiplex platform from Luminex Corporation. This multiplex assay enables efficient sample utilization and reduces result turnaround time by testing multiple factors simultaneously.

OBJECTIVE: to evaluate the performance of the NeoMAP® 4plex AT multiplex kit for prenatal screening of total antibodies against Syphilis, Chagas, HTLV 1/2 and Hepatitis C (HCV).

METHODS

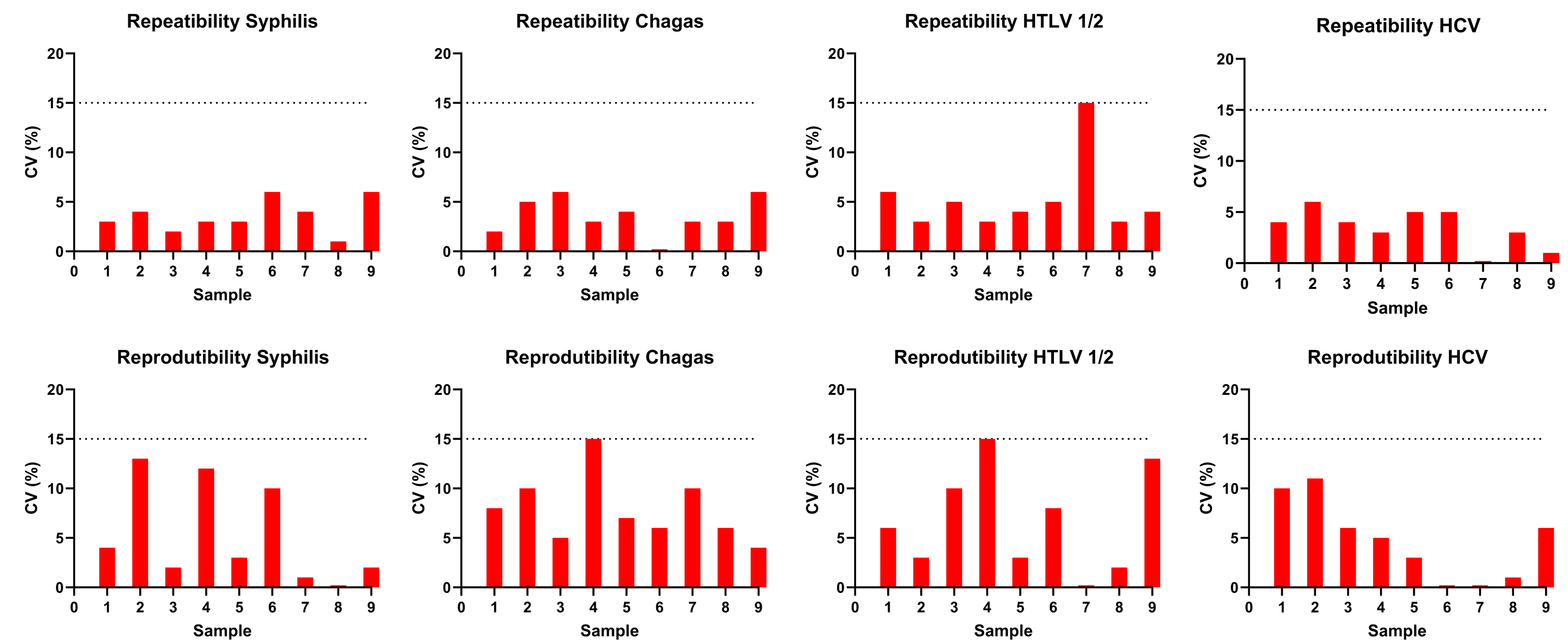
- Samples in dried blood spot (DBS) with previous characterization was used from a reference method, on presence or absence of the antibodies against the studied conditions.
- The samples were tested with a multiplex kit that uses a bead-based technology (Luminex corporation) and the resulting data is expressed in Medium Fluorescence Intensity (MFI) produced in the MAGPIX® equipment.
- ROC analysis was performed in the R software to obtain sensitivity, specificity, AUC, cutoff, and confidence interval (95% CI) values.
- Precision (repeatability and reproducibility) was verified with the formula $CV = \text{Std.dev}/\text{mediam} * 100$.

RESULTS

Figure 1: ROC Analysis.

ROC	SYPHILIS	CHAGAS	HTLV 1/2	HCV
Specificity	98	98	94	98
Sensitivity	95	100	100	100
Cutoff	652	6447	1100	871
AUC	98.7%	100.0%	98.4%	99.8%
95% IC	97.9%-99.4%	99.9%-100%	96.5%-100%	99.2%-100%

Figure 2: Precision.



CONCLUSION

The fundamental criteria for assessing the performance of the NeoMAP® 4PLEX AT multiplex kit in prenatal screening using DBS, demonstrated strong sensitivity and specificity in detecting total antibodies related to the four specified parameters (Syphilis, Chagas, HTLV 1/2 and HCV), while maintaining low levels of imprecision.

REFERENCES

- YUFENYUY, Ernest L. et al. Development of a Bead-Based Multiplex Assay for Use in Multianalyte Screening and Surveillance of HIV, Viral Hepatitis, Syphilis, and Herpes. *Journal of Clinical Microbiology*, v. 60, n. 5, p. e02348-21, 2022.
- NAEEM, Faheel et al. Multiplexed technologies for sexually transmitted infections: global evidence on patient-centered and clinical health outcomes. *BMJ Global Health*, v. 6, n. 7, p. e005670, 2021.