8th HTAI Annual Meeting 2011

WHAT WOULD BE THE OPTIMAL SALIVARY COLLECTION DEVICE TO SELECT SUSCEPTIBLE GROUPS FOR VACCINATION AND TO EVALUATE VACCINE-INDUCED HUMORAL RESPONSE AGAINST HEPATITIS A VIRUS (HAV)?

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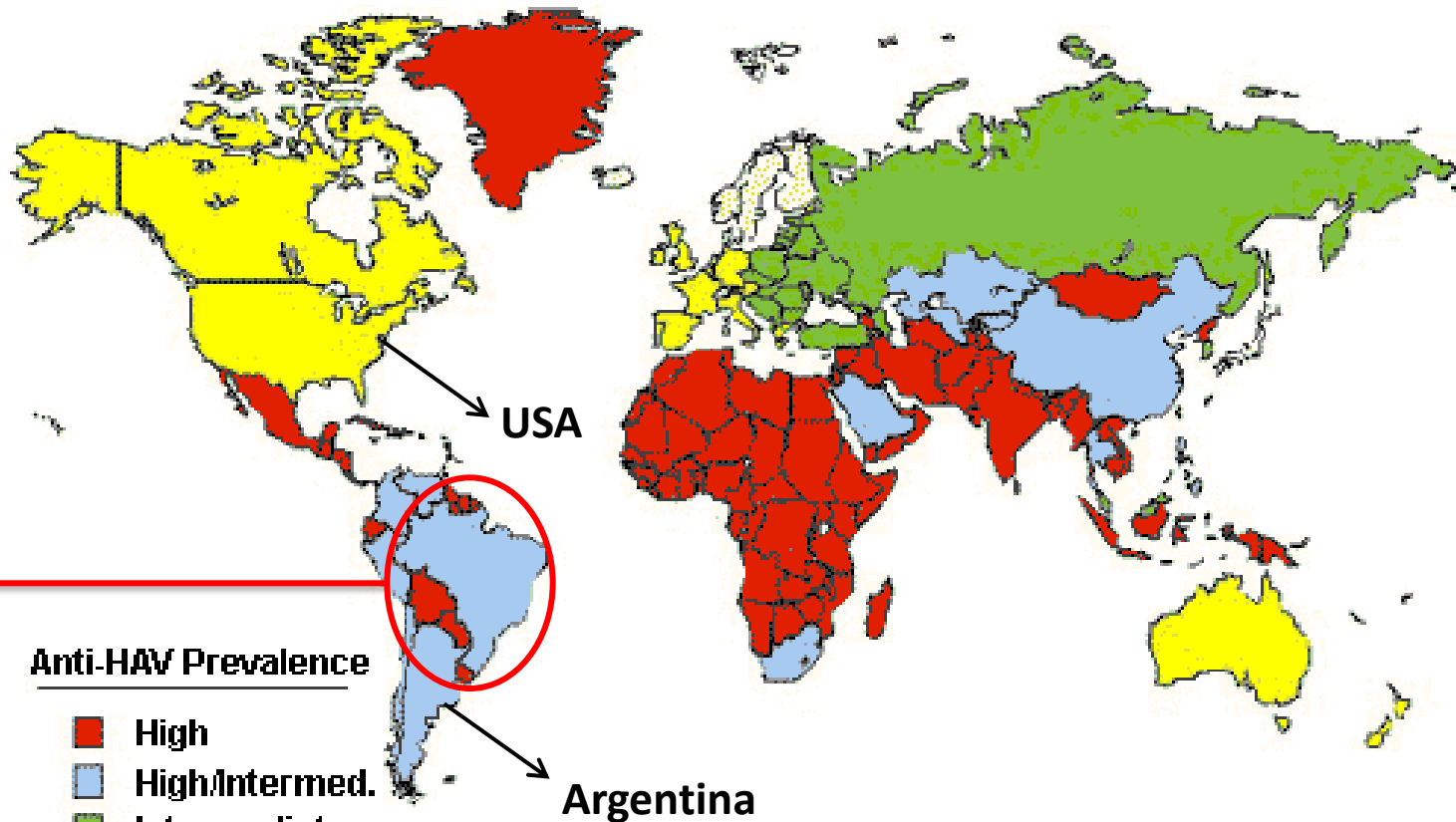Lab. of Thechnological Development in Virology IOC/FIOCRUZ

INTRODUCTION

1. EPIDEMIOLOGY

Anti-HAV Prevalence

- ■ High
- ■ High/Intermed.
- ■ Intermediate
- ■ Low
- ▫ Very Low

USA

Argentina

Changing in the epidemiological profile of hepatitis A and high cost of vaccine: conducting of epidemiological studies to select susceptible individuals to be vaccinated

1. INVESTIGATION OF THE IMMUNITY STATUS

➡ **Diagnosis of hepatitis A → SERUM OR PLASMA → INVASIVE and potencially PAINFUL.**

➡ **Search for alternative fluids that are non-invasive and easy to collect, such as ORAL FLUID.**

➡ **Concentration of immunoglobulin (mg/L) in plasma and in different salivary components**

Specimen	IgG	IgM	IgA
Plasma	14730	1280	2860
Parotid saliva	0.36	0.43	39.5
Crevicular fluid	3500	250	1110
Whole saliva	14.4	2.1	194

(reference: Roir e Lehner, 1983).

1. ORAL FLUID COLLECTION DEVICES

➡️ **There are several methods available for collecting oral fluid. Although, there have been few studies investigating which one is optimal for low titers antibody detection and community use.**
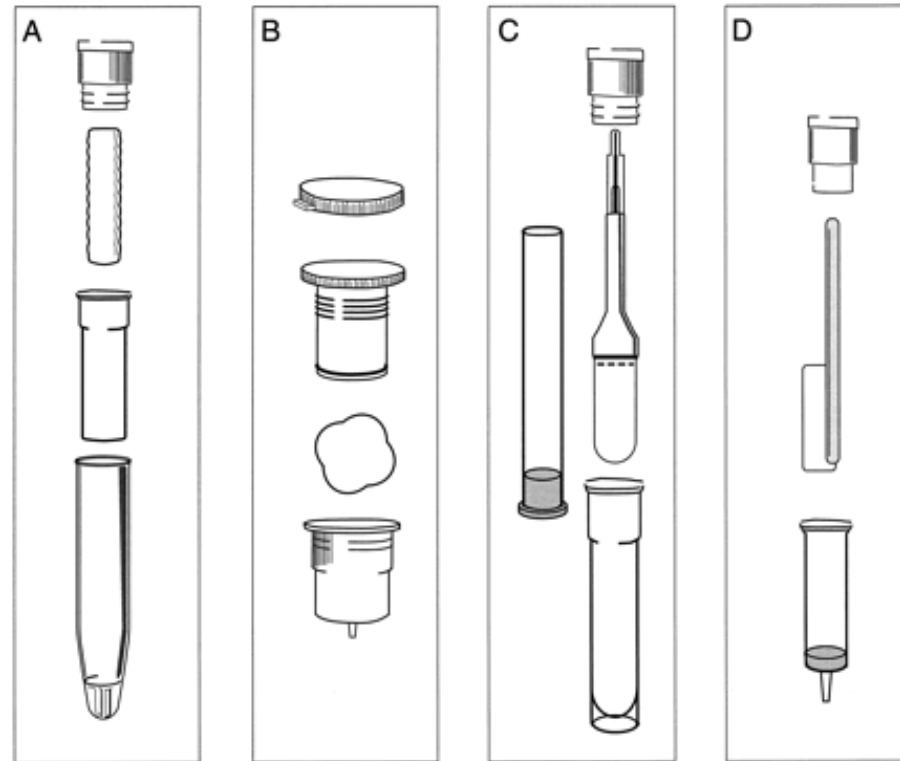
Some oral fluid collection devices: (A) Salivette; (B) Orapette; (C) Omni-SAL; (D) OraSure (reference: Hodinka *et al.*, 1998).

OBJECTIVE

2. OBJECTIVE

WHAT WOULD BE THE OPTIMAL SALIVARY COLLECTION DEVICE TO DETECT ANTI-HAV ANTIBODIES?

➡ The aim of this study was to evaluate different oral fluid collection devices in order to identify which one is more suitable for distinguishing between susceptible and immune individuals with improved sensitivity and/or specificity in community survey studies.
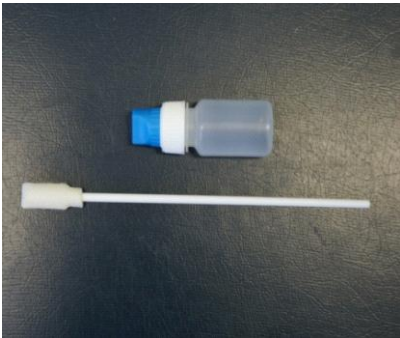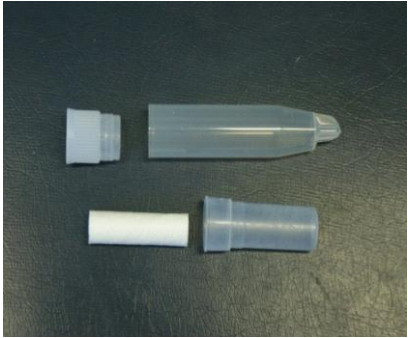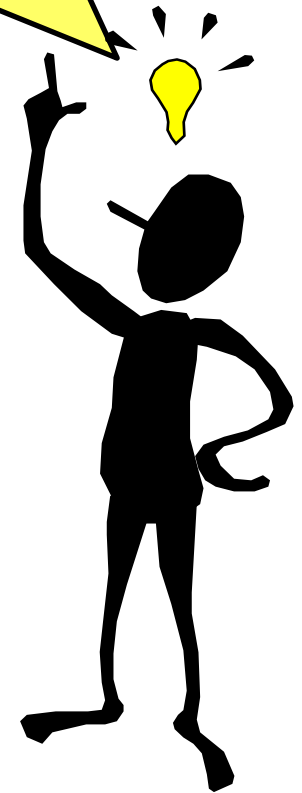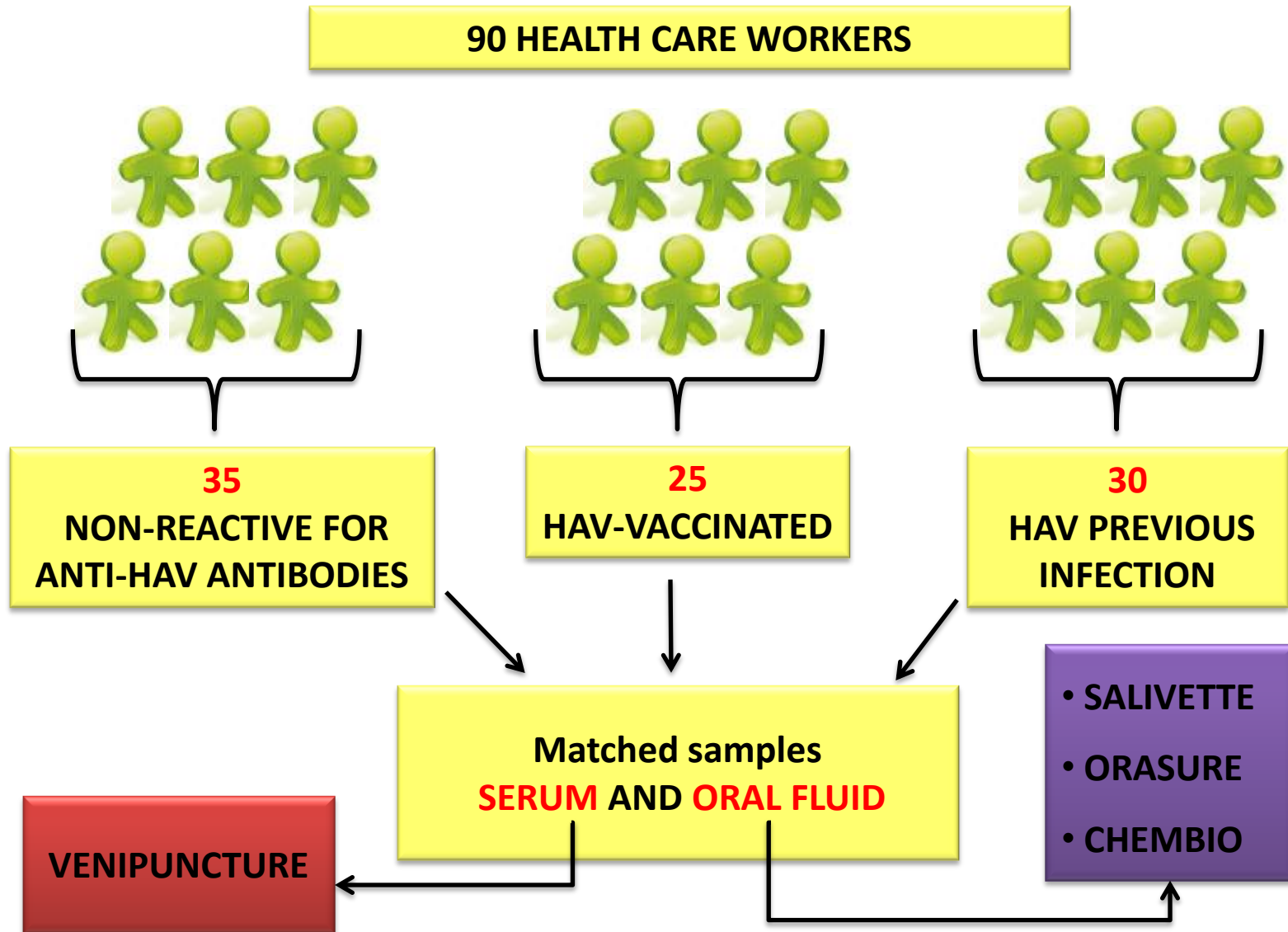
# MATERIALS AND METHODS

3. Optimization panel of oral fluid samples

3. Optimization panel of oral fluid samples

Characteristics of the three commercially available oral fluid devices used in the present study.

|	*ChemBio®*	*OraSure®*	*Salivette®*
Buffer volume	500μL	800μL	1mL of PBS
Time of collection	1 min	2 min	2 min
Temperature of Storage	4-8°C	-20°C	-20°C
Target specimen	Crevicular fluid	Whole Saliva	Whole Saliva
Collection device			

3. Sample screening

➡️ **Commercially available dot-blot based on an immunocapture principle → ImmunoComb®II HAV Ab**

➡️ **The test was adapted for oral fluid samples, so oral fluid was added without sample diluents.**
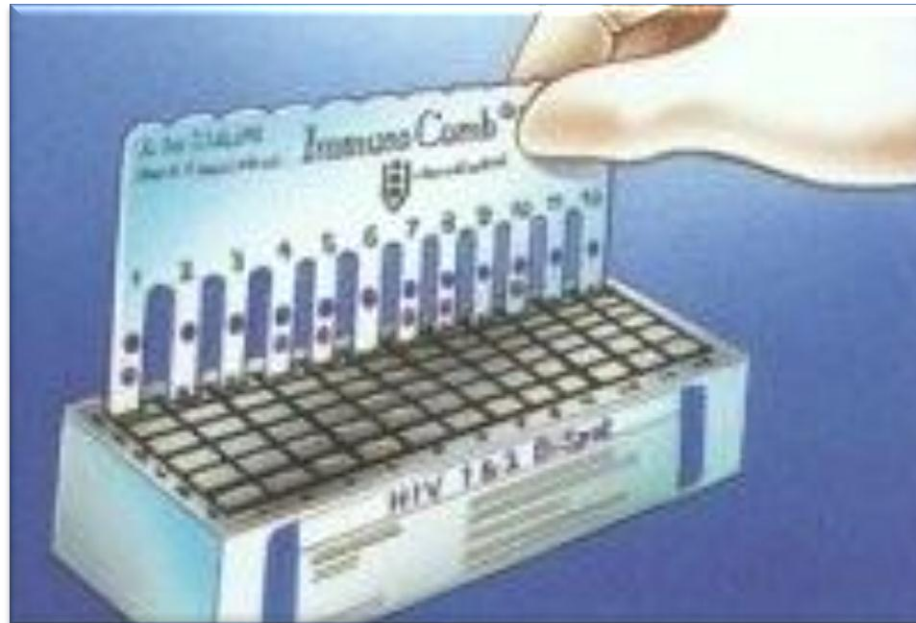
3. Applicability of the optimal salivary collection device in surveillance settings

➡️ **The study was carried out in four isolated communities living in South Pantanal, Brazil, in difficult-to-access areas.**

224 matched serum and oral fluid samples
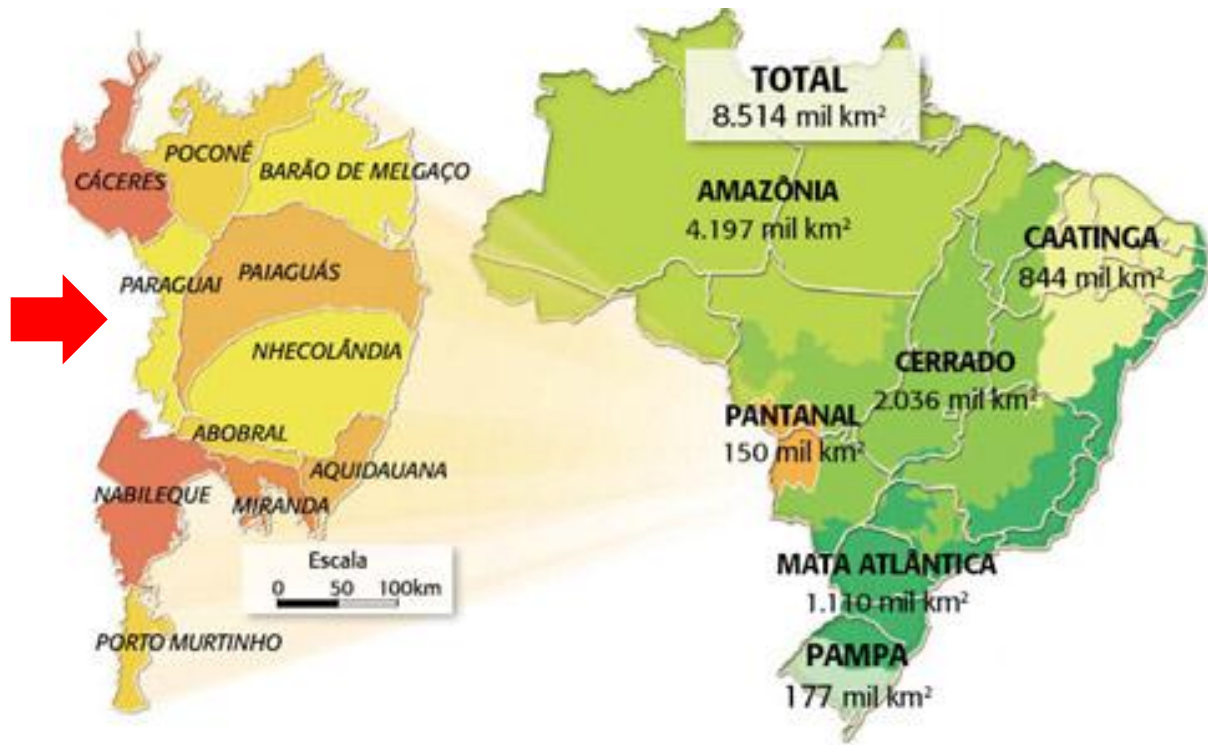
Subregions of the brazilian Pantanal (reference: Globo Rural - 288 edition – October, 2009).

3. Effect of time exposure and temperature for the detection of anti-HAV antibodies in oral fluid

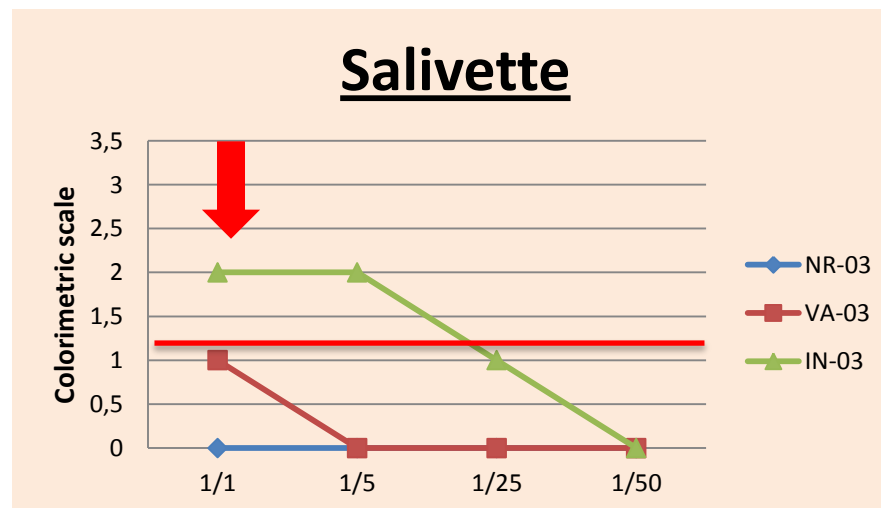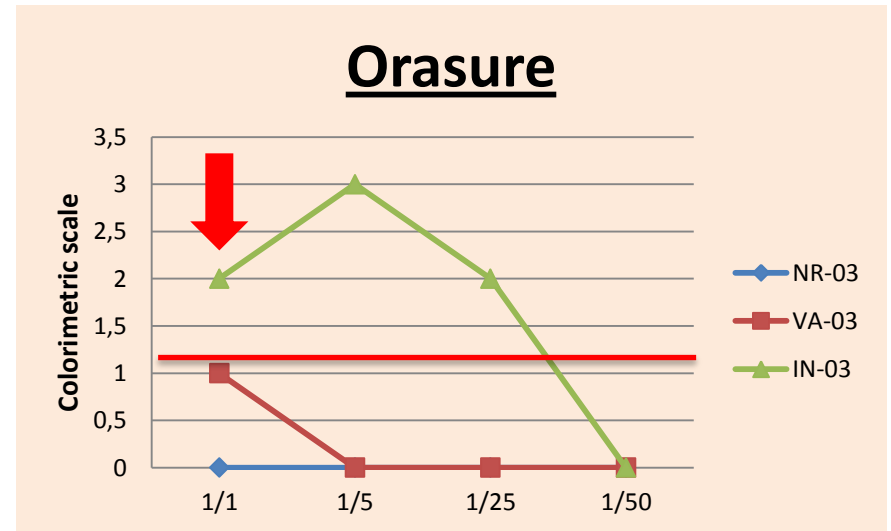➡️ **This analysis aimed to demonstrate the suitability of such specimen to surveillance settings.**
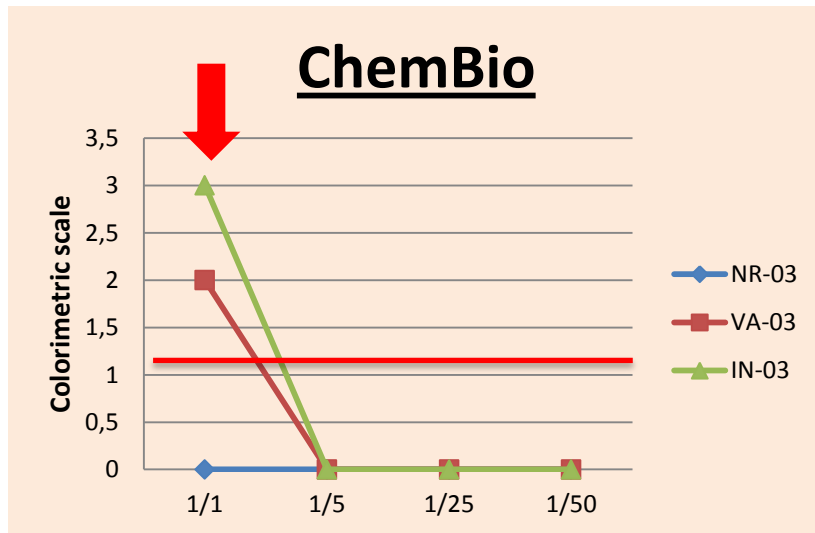

NR

PI

ChemBio

15   90   120   150   180   210

Days after collection at 2-8°C
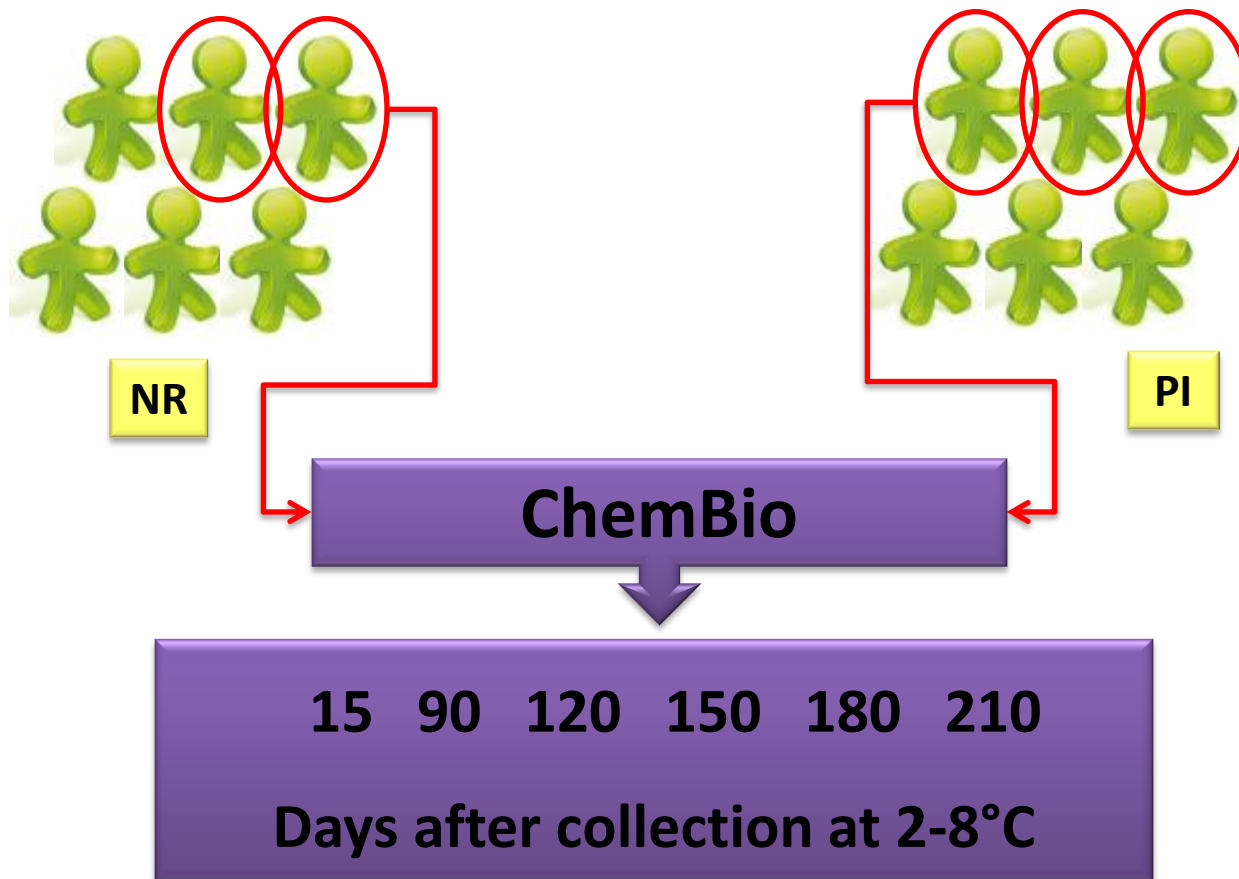
RESULTS

4. Determination of the optimal dilution of oral fluid samples for detection of anti-HAV antibodies

4. Performance of oral fluid collection devices for detection of anti-HAV antibodies

Parameters	Oral fluid colletion device		
	ChemBio®	Orasure®	Salivette®
Sensitivity (95% CI)*	100.0 (0.9351 – 1.000)	96.36 (0.8748 – 0.9956)	92.73 (0.8242 – 0.9798)
Specificity (95% CI)*	100.0 (0.9001 – 1.000)	100.0 (0.9001 – 1.000)	100.0 (0.9001 – 1.000)
Positive predictive value (95% CI)*	100.0 (0.9351 – 1.000)	100.0 (0.9328 – 1.000)	100.0 (0.9302 – 1.000)
Negative predictive value (95% CI)*	100.0 (0.9001 – 1.000)	94.5 (0.8179 – 0.9934)	89.74 (0.7577 – 0.9714)
Spearman's correlation coefficient (p-value) [†]	0.987 (**< 0.0001**)	0.969 (**< 0.0001**)	0.948 (**< 0.0001**)
Kappa statistic	100.0	95.4	90.8

*95% CI, 95% confidence interval.

[†]$P < 0.05$ (in bold) are statistically significant.

# 4. Applicability of oral fluid specimen for community use

Total anti-HAV prevalence of matched serum and oral fluid samples collected from communities of South Pantanal, Brazil.
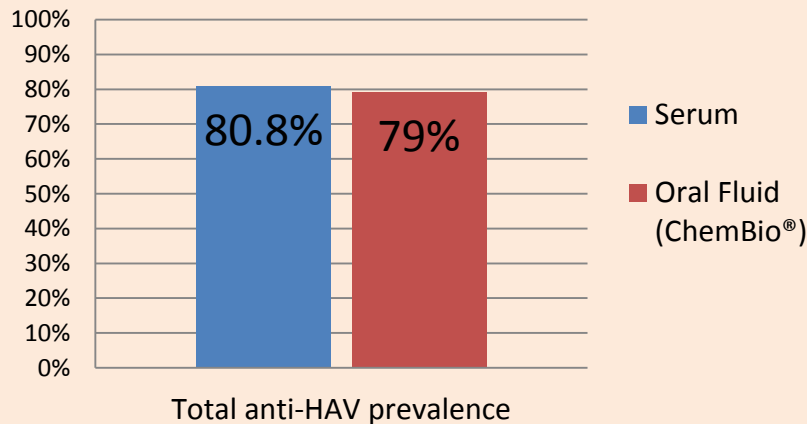
➡️ **SENSITIVITY AND SPECIFICITY values of the test, using oral fluid samples , were similar to the optimization panel = 98%**

4. Effect of time exposure and temperature for detecting anti-HAV antibodies in oral fluid

➡ **Antibodies against hepatitis A remained stable in oral fluid samples for more than 210 days.**

➡ **The storage caused no significant change during the 180 first days after collection. On the 210th day, there was a decrease in antibody titers for reactive samples.**
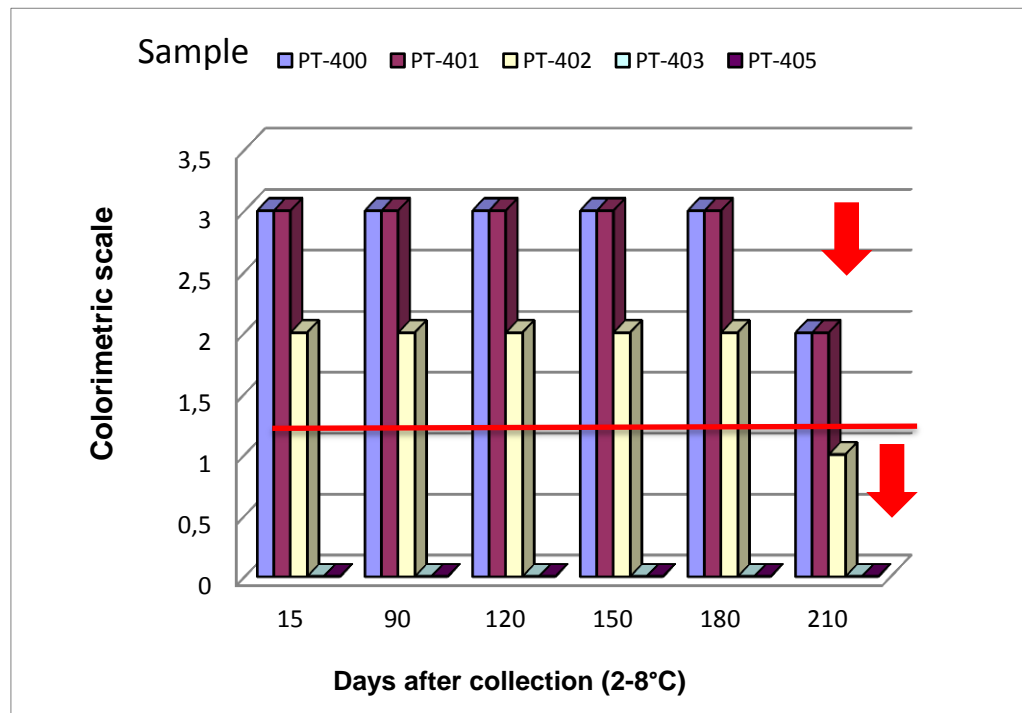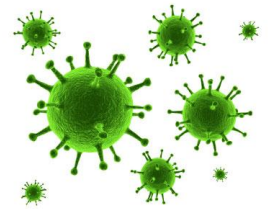
CONCLUSION

5. CONCLUSION

➡️ **Chembio® was the oral fluid collection device which better distinguished between susceptible and immune individuals.**

➡️ **This collection device could be used to facilitate the screening of age groups to receive HAV vaccine and the implementation of a program to control the disease in Brazil.**

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