

# External Quality Assessment Program for serology of Hepatitis B and Hepatitis C from the National Reference Laboratory for Viral Hepatitis in Argentina : 21 years in the field

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## DESCRIPTION

The National Reference Laboratory (Lab) for Viral Hepatitis in Argentina has been carrying on an External Quality Assessment Program for Hepatitis B and Hepatitis C serology, since 1996 (Pro).

This Pro was created for the Sentinel Units Labs of a National Network and then extended, by spontaneous requests, to other public Hospitals and Blood Banks Labs.

Today it comprises a minimum of 80 Labs around the country, at least one in each province.

The Pro is free of charge for all the participants, this include small to medium complexity Labs.

Twice yearly, April and October, we send a Panel (Pan) composed by three blind samples set, that must be analyzed for HBsAg, antiHBc and antiHCV marker.

The participants have maximum 15 days to return the results.

The samples are obtained from recalcified plasma from infected blood donors.

Both False Negative (FN) and False Positive (FP) results are then analyzed for each marker, Lab type and Techniques used.

Access and SPSS softs are used for statistical analysis.

## PUBLIC HEALTH IMPACT

This work serves to alert that in the era of high technologies, an External Quality Assessment Program is very useful mostly in the context of small to medium complexity Labs of our country

### Global results by marker

Results	antiHBc	HBsAg	antiHCV
<b>NEGATIVE SAMPLES</b>			
TOTAL	3944	4718	4630
FALSE POSITIVES	99	149	142
FALSE POSITIVES %	2.5	3.2	3.1
<b>POSITIVE SAMPLES</b>			
TOTAL	2666	2544	2532
FALSE NEGATIVES	76	23	96
FALSE NEGATIVES %	2.9	0.9	3.8
<b>TOTAL SAMPLES</b>			
TOTAL SAMPLES	6610	7262	7162
TOTAL ERRORS	175	172	238
% ERRORES	2.6	2.4	3.3

Along the 40 Pan distributed,

\*in 2500 results for a Positive marker, we found 2.6% FN for antiHBc, 3.8% for antiHCV and 0.9% for HBsAg.

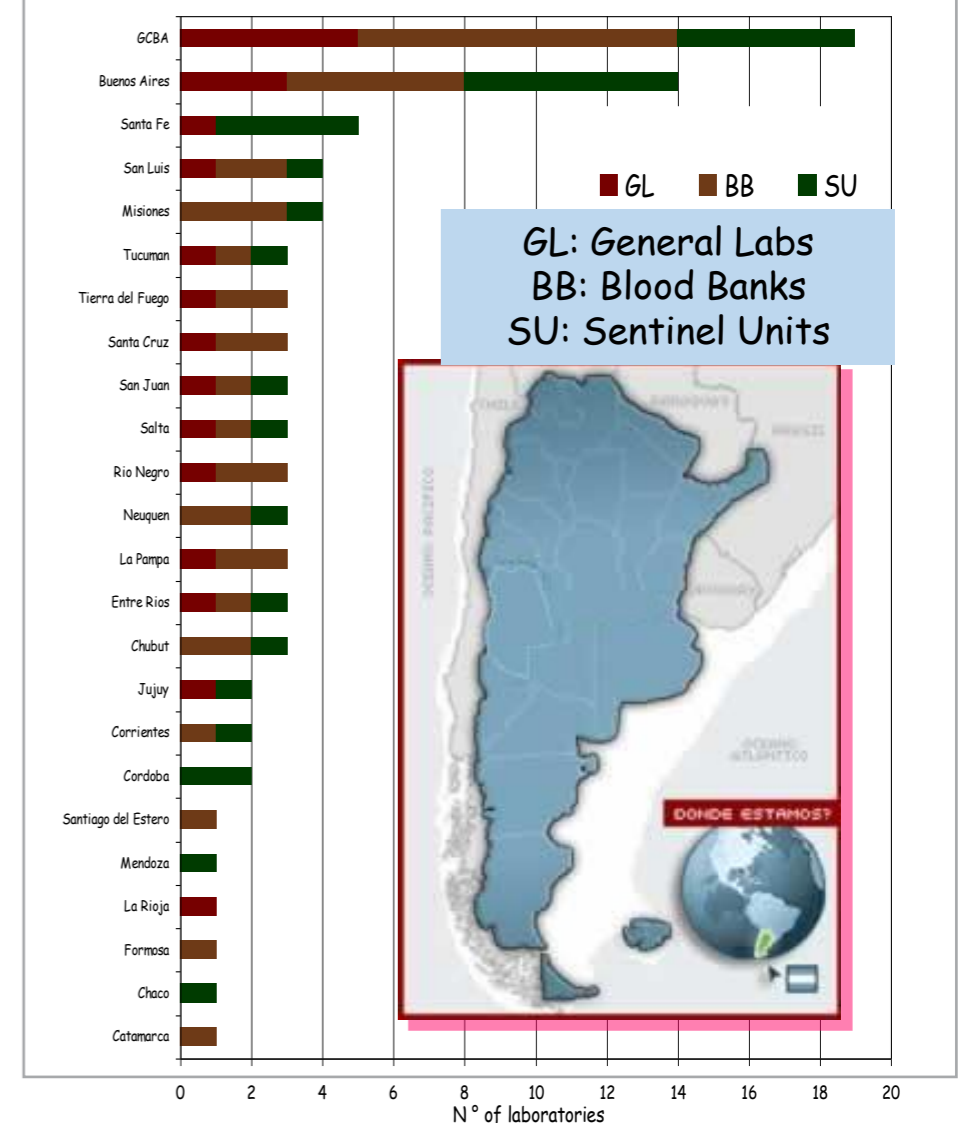
\*in 3900 results for a Negative marker, we found 2.5% FP for antiHBc, 3.1% for antiHCV and 3.2% for HBsAg

## CONCLUSIONS

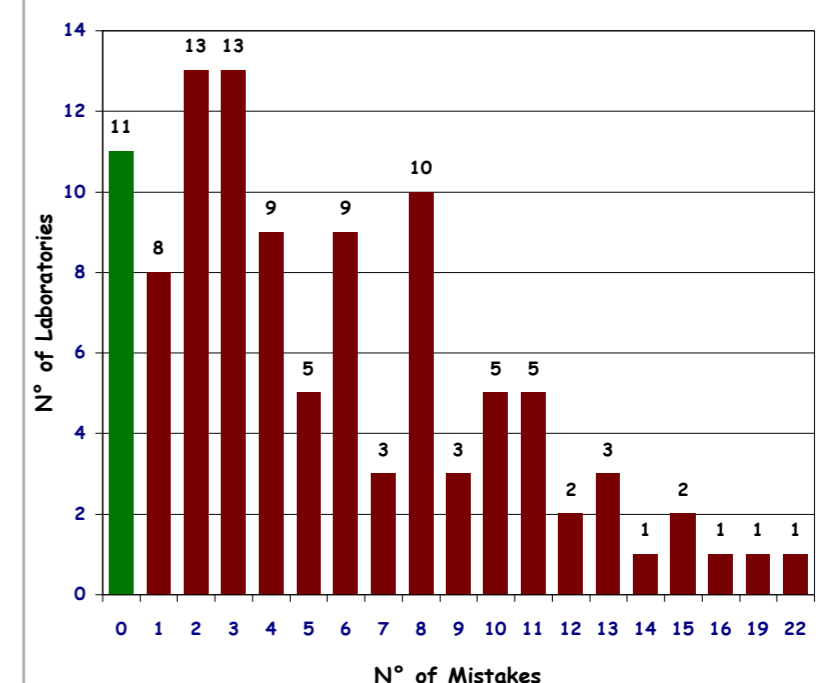
- ✓ We also must take into account other non-measurable variables that are under the user control, for example : equipment and facilities maintenance, personnel training, internal control system, Pan transport and conservation conditions, etc, that maybe also cause of mistakes but we cannot considered it in the analysis.
- ✓ We, as National Reference Lab, always offer our help, to all participants, in order to contribute to the mistakes correction and analyze its performance.

## WHY IS THIS INNOVATIVE?

This is a free Pro, distributed along all the country Participants by Province



## N° laboratories / N° Mistakes



Only 11 out of 105 Lab responding between 1 and 40 Pan had no errors.

## CONCLUSIONS

- ✓ The errors have multi-factorial causes.
- ✓ We can not establish causal associations between brands and error -although same statistical association were found during the evaluations- given the high number of results with incomplete data, the large number of brands used, the rotation of brand used by Lab along the Pr, the brand appearance - disappearance in the market, the reports with clearly clerical errors, etc.
- ✓ These variables can be analyzed with the information registered in the Pro database.

## CONFLICTS OF INTEREST

None

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