The High Positive Immunoassay Confirms HIV-1 Infection and Avoids the Need of Confirmatory Tests

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Background

- HIV IAs are traditionally interpreted in a qualitative manner
  - Reactive (positive) or non-reactive (negative
  - A quantitative result is generated and expressed as a signal-to-cutoff ratio (reactivity index) of each individual sample
  - **The S/CO ratio is directly related to the antibodies concentration**
- Previous studies
  - A high S/CO of HIV IA was associated with true positive results

Objectives of the study

"To assess whether a high S/CO ratio of an HIV third-generation enzymatic IA is an accurate predictor of confirmatory results in patients with positive HIV antibodies test"

Materials & Methods

- Public Health Laboratory of Colima
- Diagnostic test design (retrolective)
- Eligible
  - Positive HIV IA (2)
  - ≥ 13 years
  - Not pregnant
  - **Patients setting (High prevalence)**

Laboratory Tests

- Vironostika 1 Microelisa System
  - Automated equipment
  - S/CO ratio recorded from the analyzer
- Cobas Amplicor HIV-1 Monitor, v 1.5
  - Quantitative HIV-1 RNA test
  - Reverse transcription–polymerase chain reaction
- Cambridge Biotech HIV-l, Western Blot Kit

Gold Standard

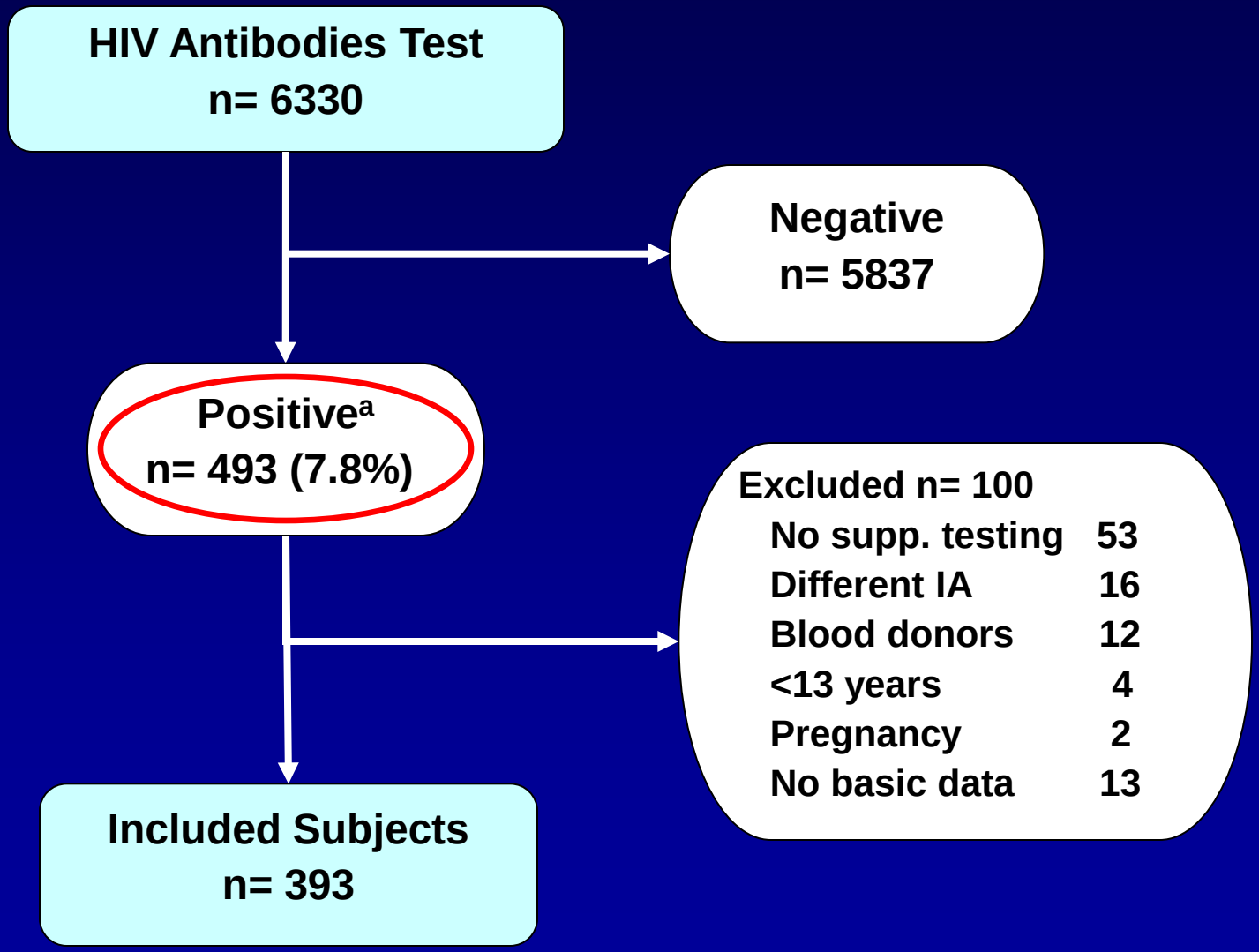
- A positive WB test by CDC´s criteria

  or

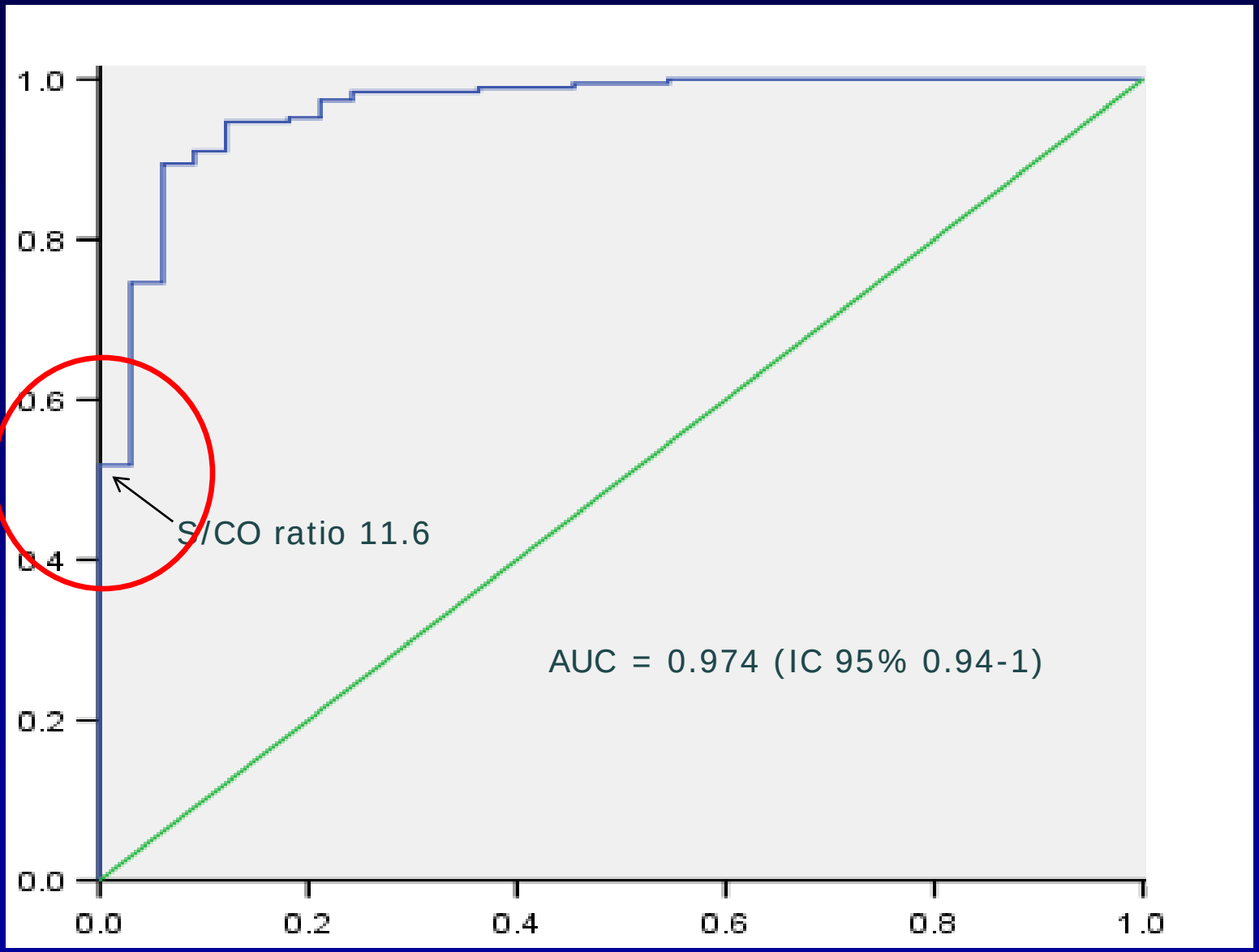
- HIV-1 RNA ≥ 2000 copies/ml

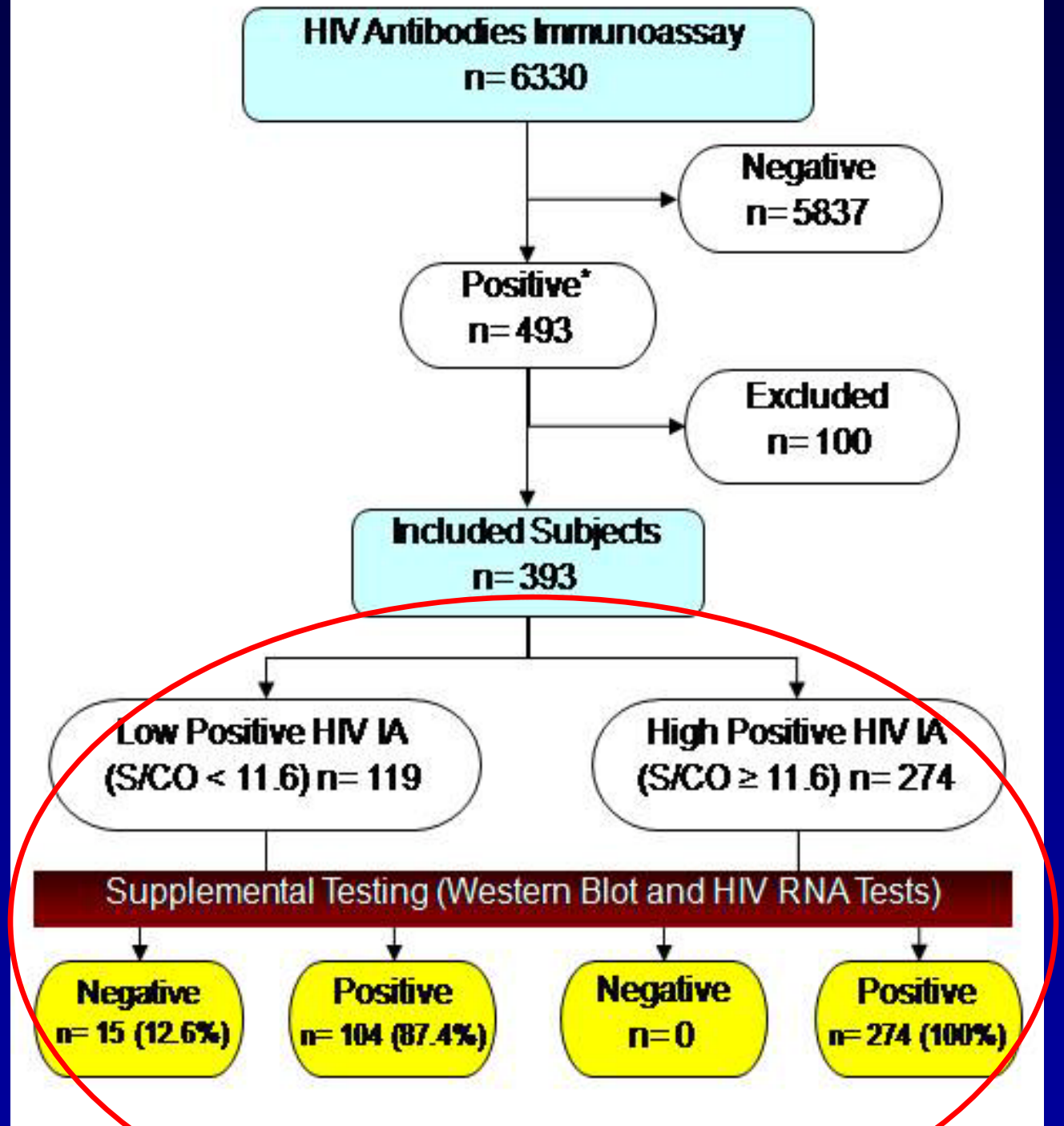
- Indeterminate WB result without HIV RNA test were considered as false-positive (or non confirmed)

Results


HIV Antibodies Test
n= 6330
Negative
n= 5837
Positive[a]
n= 493 (7.8%)
Excluded n= 100
No supp. testing 53
Different IA 16
Blood donors 12
<13 years 4
Pregnancy 2
No basic data 13
Included Subjects
n= 393

Receiver Operator Characteristics

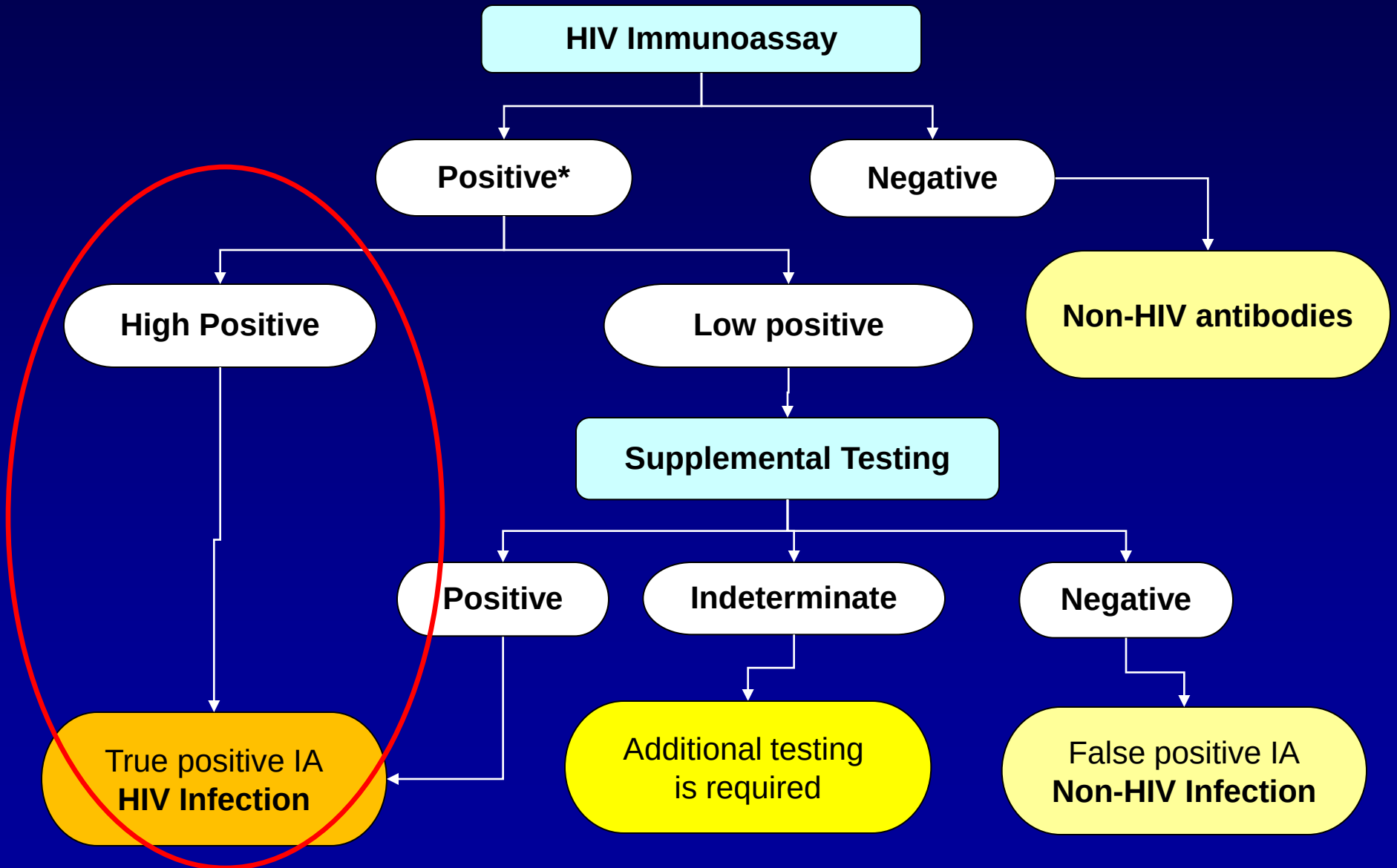



HIV Antibodies Immunoassay
n= 6330
Negative
n= 5837
Positive*
n= 493
Excluded
n= 100
Included Subjects
n= 393
Low Positive HIV IA
(S/CO < 11.6) n= 119
High Positive HIV IA
(S/CO ≥ 11.6) n= 274
Supplemental Testing (Western Blot and HIV RNA Tests)
Negative
n= 15 (12.6%)
Positive
n= 104 (87.4%)
Negative
n= 0
Positive
n= 274 (100%)

Comparison of Two Different cutoffs of HIV IA

	S/CO ratio > 3.0	S/CO ratio ≥ 11.6
Sensitivity, % (95%CI)	99.7 (99.2-100)	72.5 (68.1-76.9)
Specificity, % (95%CI)	46.7 (41.8- 51.6)	100.0 (98.9-100)
PPV, % (95%CI)	97.9 (96.5-99.3)	100.0 (98.9-100)
NPV, % (95%CI)	87.5 (84.3-90.7)	12.6 (9.8-15.3)
+ Likelihood Ratio	1.9	72.5
- Likelihood Ratio	0.06	0.27

Proposal of a Diagnostic Algorithm Including the High Positive HIV IA Result



Conclusions

- A high positive HIV IA may confirm HIV-1 Infection (high prevalence population)
- Quantitative assessment of HIV IA
  - No additional efforts
  - May shortens required time for HIV confirmation
  - Avoids the need of unnecessary supplemental tests
- These findings warrant further research
  - Others HIV immunoassays
  - Other populations


Seguridad?