

Evolving State Laboratory Diagnostic Capacity During an HIV Outbreak

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In 2015, an outbreak involving 190 new cases of HIV-1 infection were identified in southeastern Indiana, in an area that reports <5 new cases of HIV infection annually.

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HELP PREVENT HIV
DON'T SHARE THESE.
DON'T ABUSE THESE.

Any drug can be abused. If you or a friend are abusing drugs, get help. Never share needles. It increases your risk of getting HIV.

HIV Services Hotline 1-866-588-4948
Addiction Hotline 1-800-662-HELP(4357)
www.StateHealth.IN.gov

YOU ARE NOT ALONE Indiana State Department of Health



TIME

They're the most powerful painkillers ever invented. And they're creating the worst addiction crisis America has ever seen.

By Massimo Calabresi



In 2015, an outbreak involving 190 new cases of HIV-1 infection were identified in southeastern Indiana, in an area that reports <5 new cases of HIV infection annually.

Rural community

- County pop. 24,000
- City pop. 4,200

Ranked 92/92 for many health and social indicators

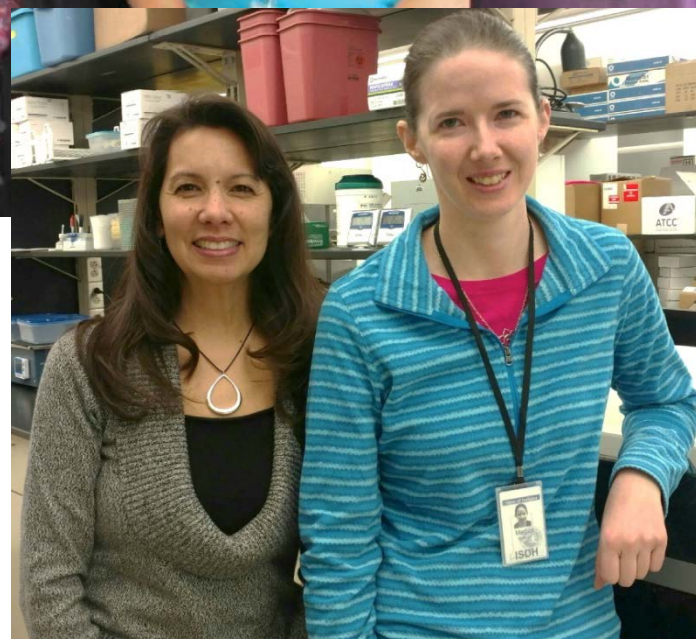
- Life expectancy
- Unemployment
- Poverty
- Lack of high school-level education
- Many uninsured or underinsured



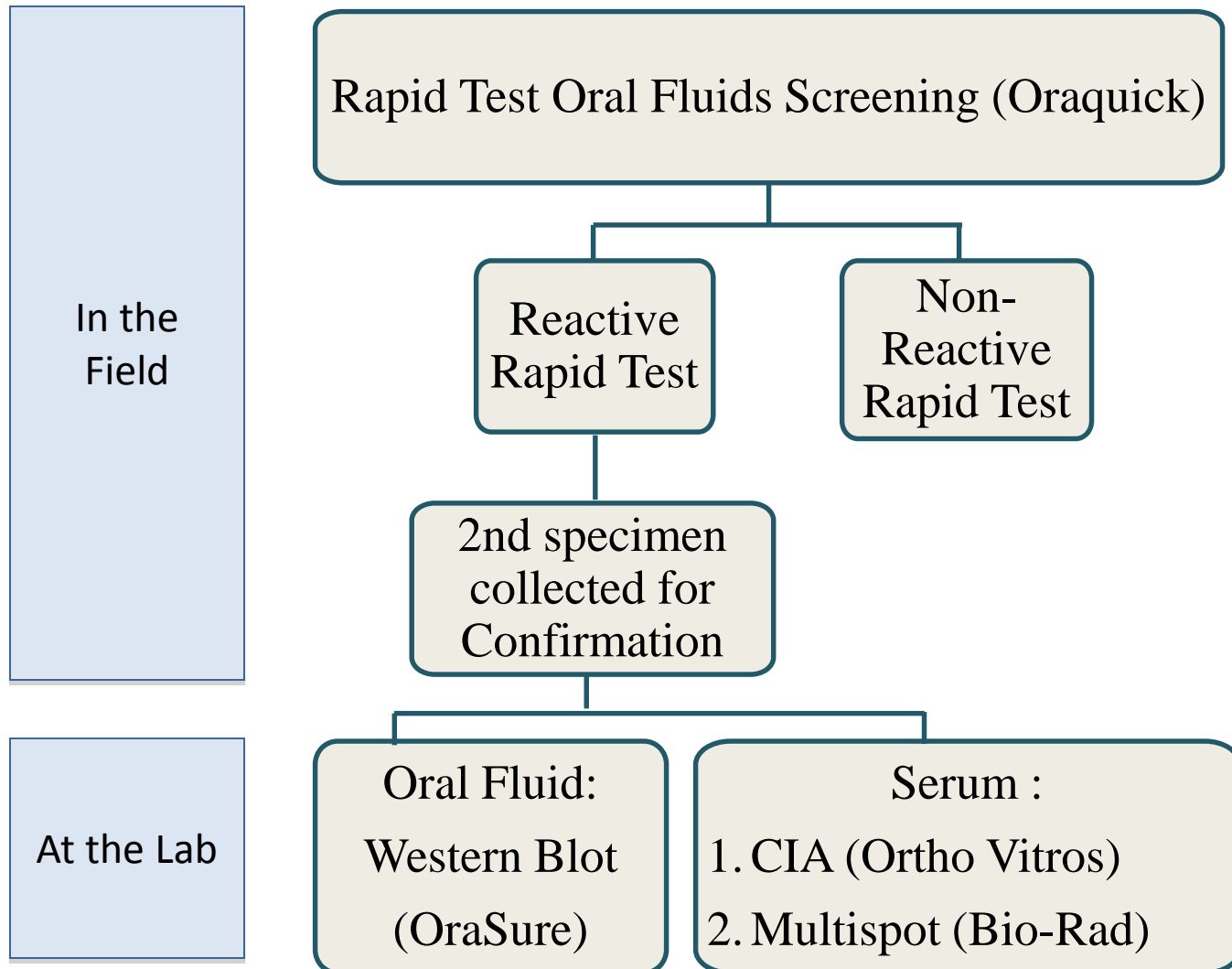


Above: Ed Hartle (Tech), Jessica Gentry (Supervisor), Marta Cruz (Analyst), Erica Vecchio (Analyst), Kathy Backfish (Analyst), Mike Cross (Analyst)

Right – Stephanie Dalenberg (Supervisor), Megan Rinehart (Analyst)



ISDH HIV Testing Algorithm, Prior to Outbreak



Phase One:

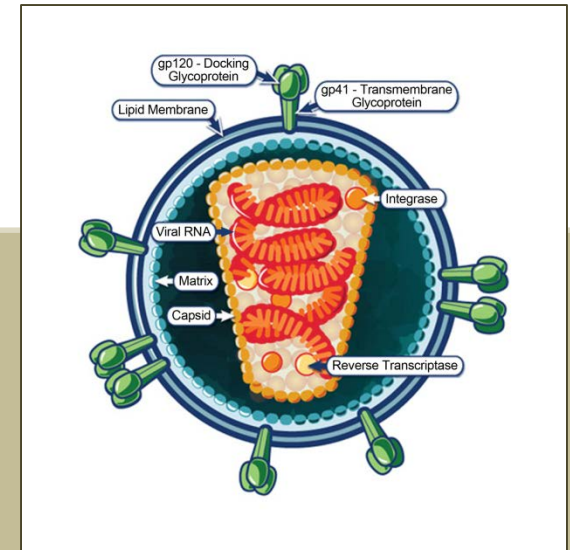
In March 2015, the ISDHL began testing anti-HIV negative specimens for HIV-1 RNA, using a pooled NAAT (nucleic acid amplification test) as a strategy for the early detection of HIV.

The ISDHL had previously evaluated the use of NAAT over a 2-year period in 2011-2013. Although ~45,000 specimens were screened in this pilot period, zero (0) HIV NAAT positive, antibody negative cases were detected.

The pilot project was terminated in 2013 due to the lack of acute detections.

NAAT Assay Parameters

- Qualitative Assay for HIV-1 RNA
- “Pooled HIV-1 NAT increased the yield of new HIV diagnoses by 2.2% in specimens with a nonreactive 3rd generation immunoassay...”
- Specificity = 99.6-99.9% (study dependent)
- Most cost effective with larger test volumes.
- Previous Baseline: 0.00%

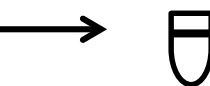
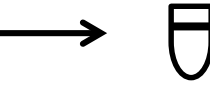
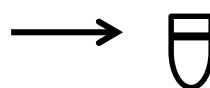
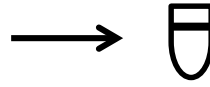
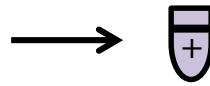


phil.cdc.gov

Individual Specimens
(n = 256)



Intermediate
Pools (n = 16)



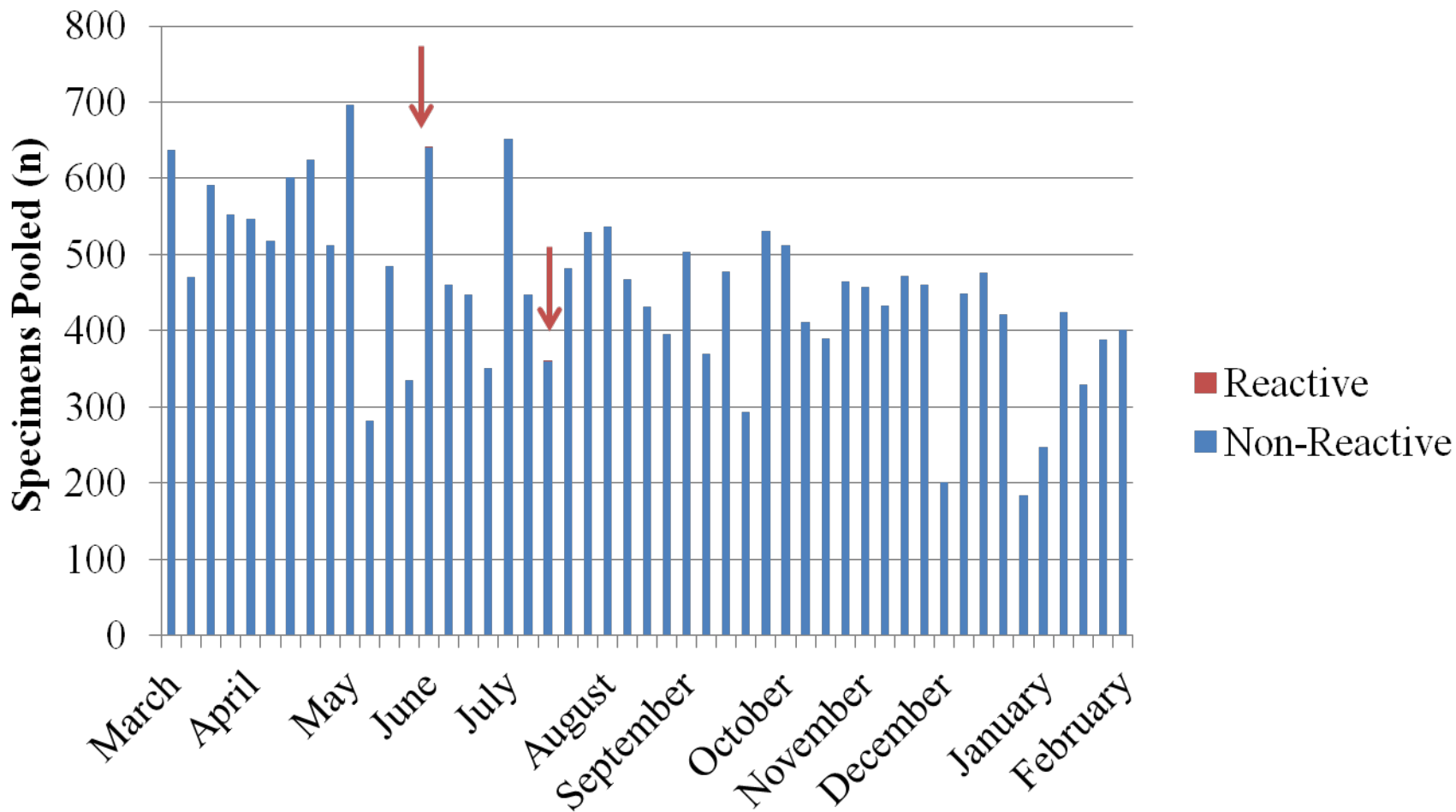
Master Pool



NAAT
Pooling
Strategy

HIV Pooled NAAT

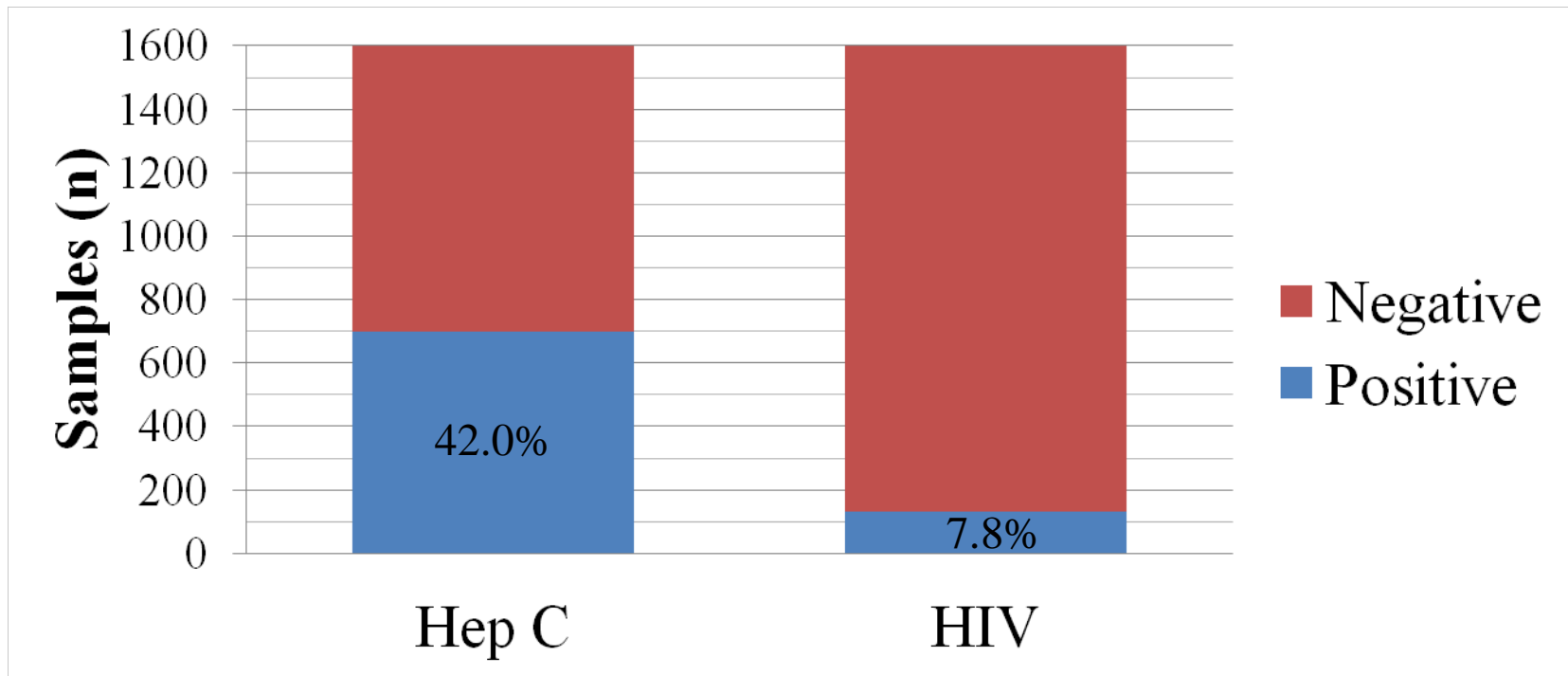
22,357 tested, 3 reactive
= 0.01% positivity



Phase 2:

Due to the high risk and high prevalence of Hepatitis C in this IDU population, Hepatitis C was automatically added to all serum-testing requests beginning in March 2015. A pooled NAAT protocol for HCV was revived and adapted for outbreak testing in May of 2015.

ISDH-Tested HIV and HCV Results, Outbreak Counties

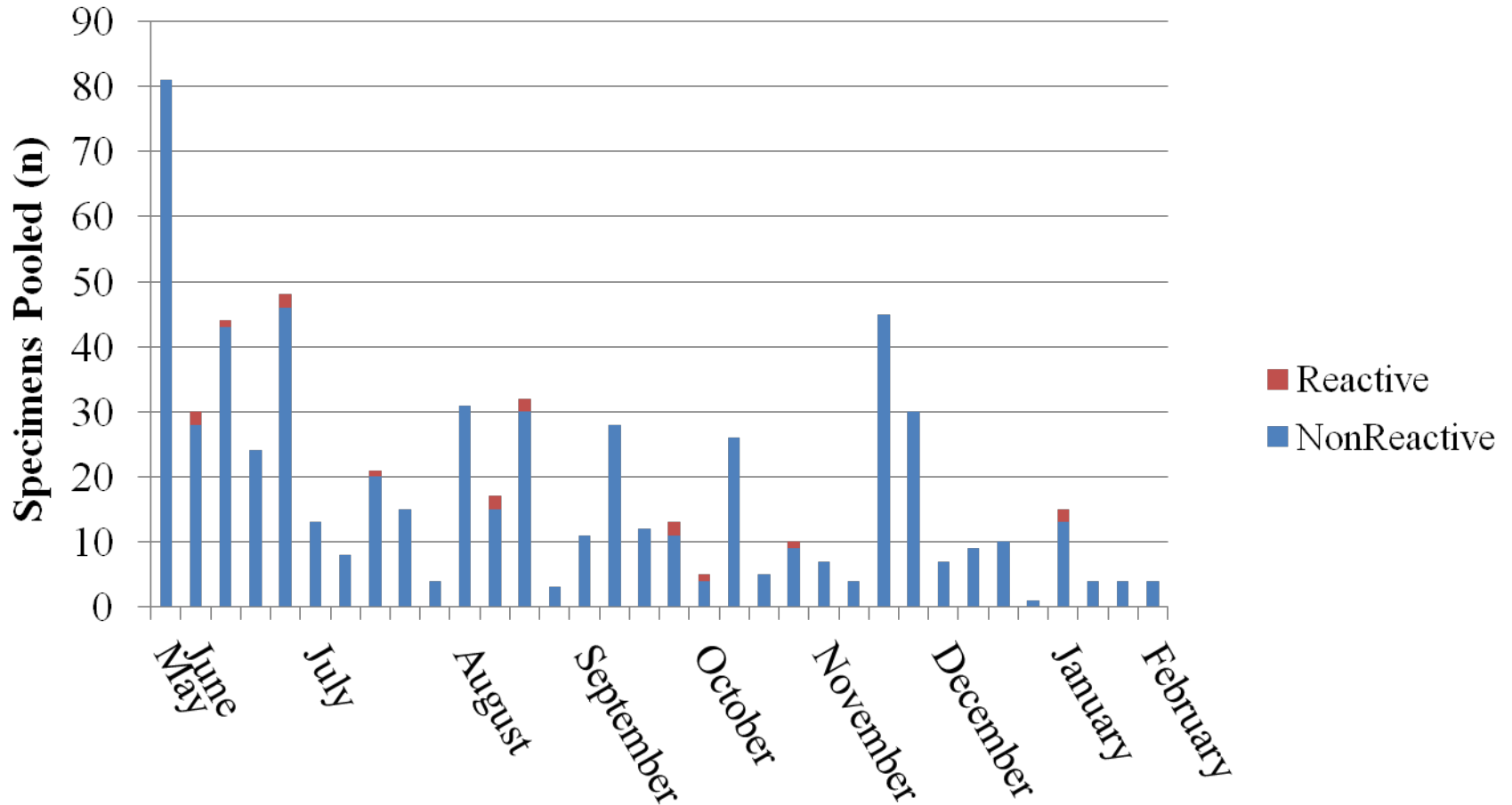


Data set: Persons tested for both HCV and HIV at the ISDH Laboratories, residing in Scott or surrounding Counties,

- $n = 1,662$
- 91.5% of HIV-positive persons were also HCV positive

HCV Pooled NAAT

621 tested, 16 reactive
= 2.6% positivity



Phase 3:

Concerns regarding the sensitivity and specificity of the rapid screening test remained.

In May 2015, ISDH requested that all HIV-tested persons in Scott Co. submit a blood specimen, regardless of rapid test result.

Which test is the best?

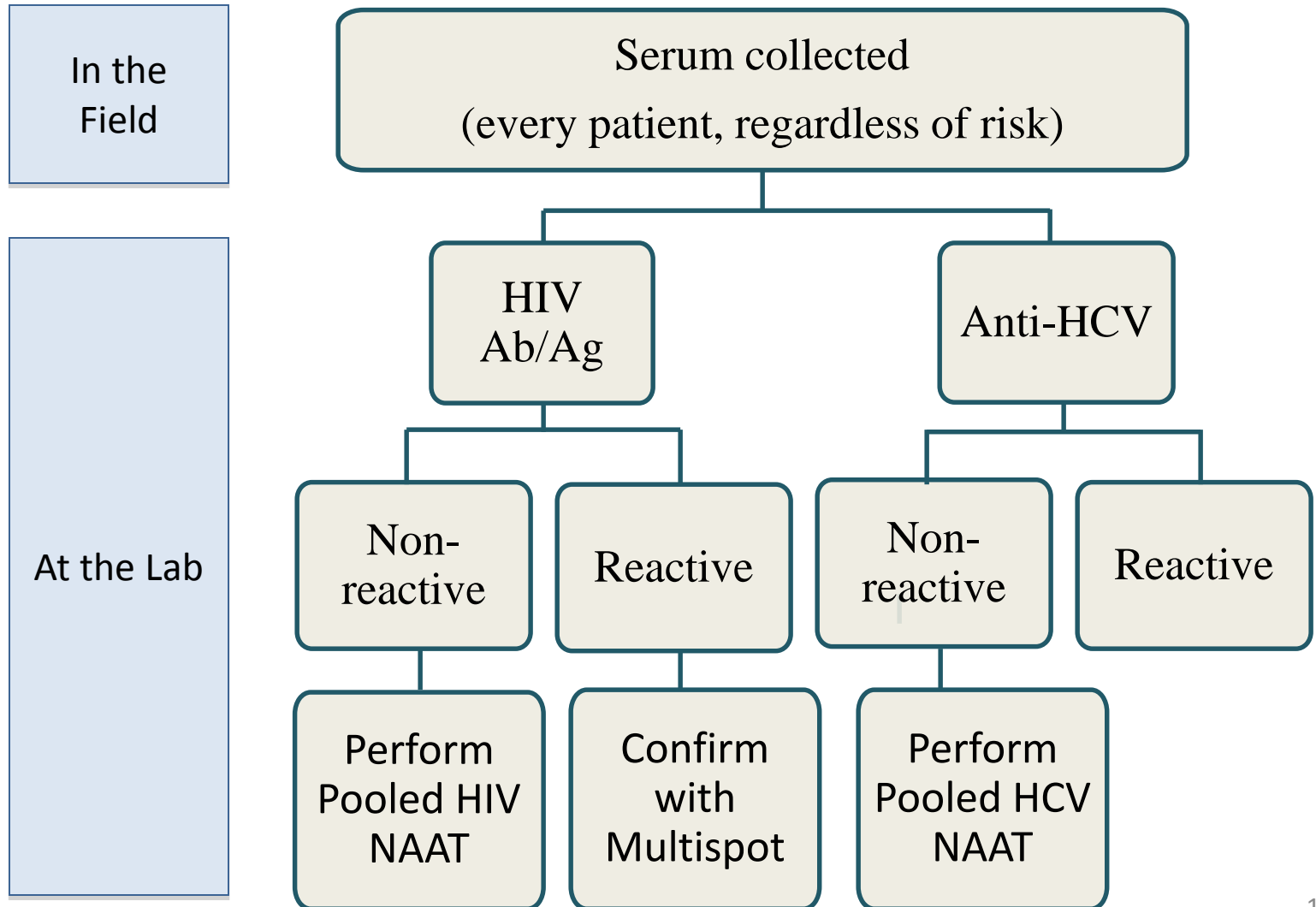


ISDHL Opinion: Instead of changing brands of test, consider transitioning the specimen type requested from oral fluids to finger-stick blood. This transition is estimated to enhance sensitivity by 4-8% according to a review of the scientific literature.

Phase 4:

As of December 2015, the ISDH Laboratories have transitioned to the Abbott Architect for the detection of HIV, Hepatitis C, and Hepatitis B.

Final ISDH Outbreak Testing Algorithm



Lessons Learned



- Maintaining a scientific curiosity about our population led to the development of useful tools/resources.
- Pilot testing, even if testing is never expanded, is of public health benefit!
- Make use of funding opportunities & collaboration.
- Never say never ... outbreaks can occur in every testing area.

Thank you!

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