

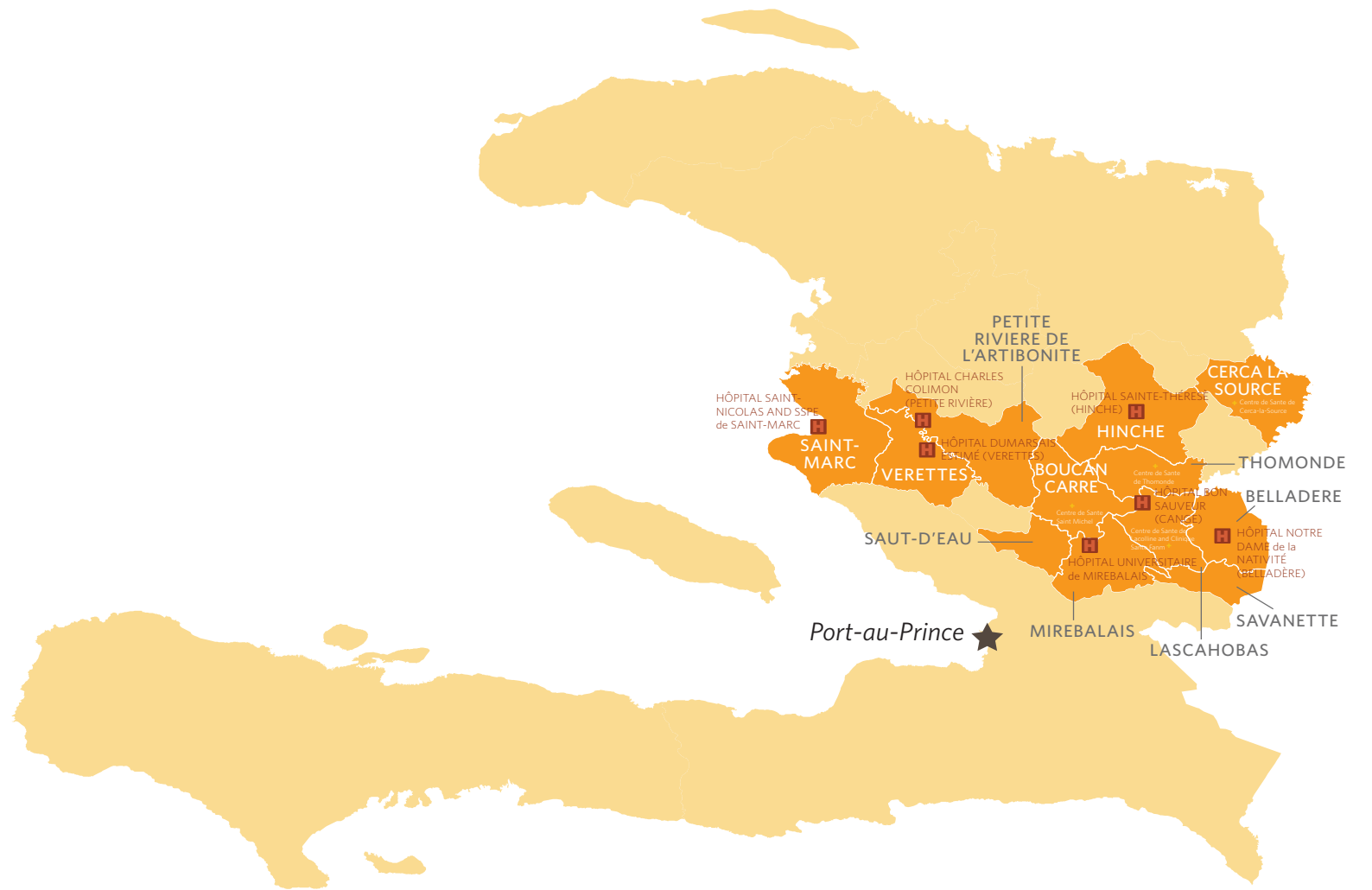
# Laboratory evaluation of immunochromatographic rapid diagnostic tests for cholera in Haiti

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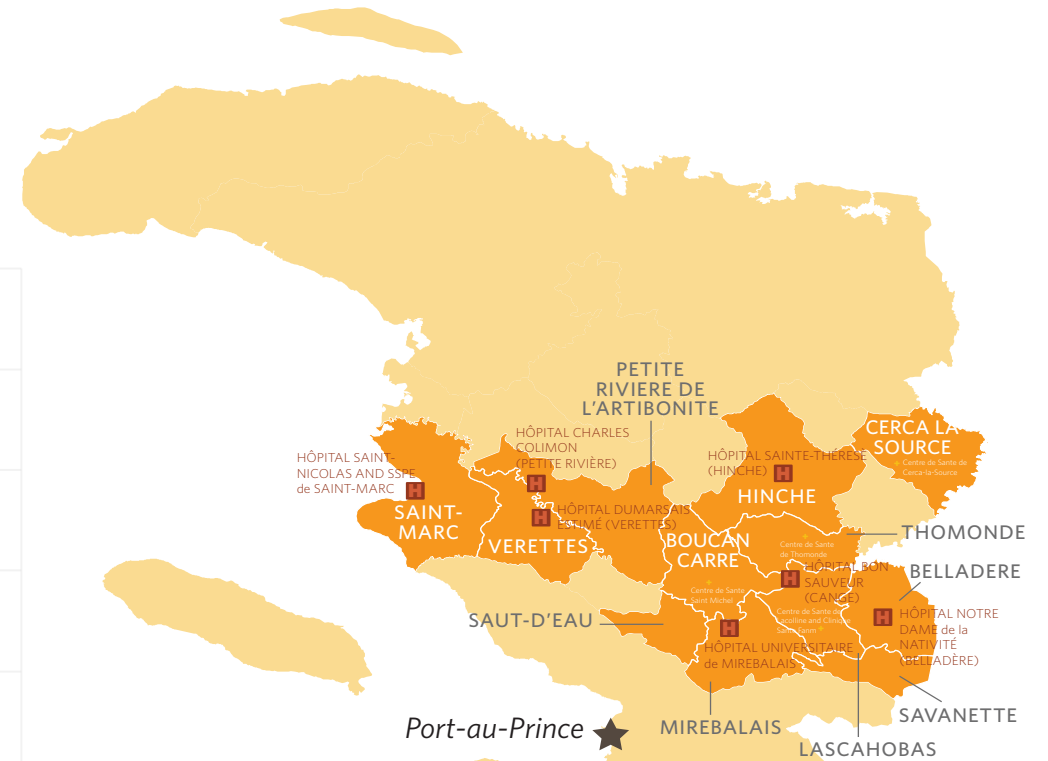
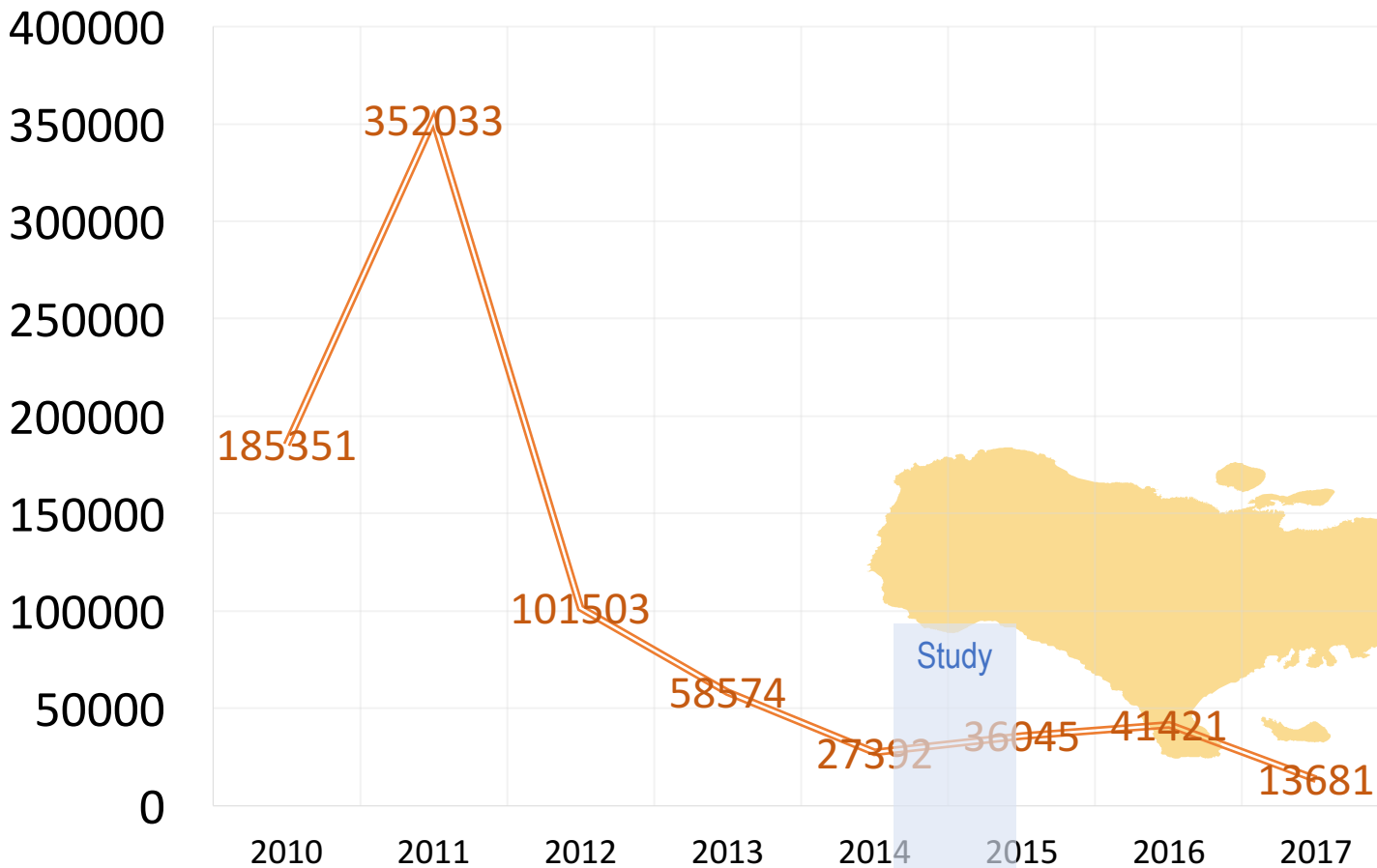


# Haiti



# Haiti

## SUSPECT CHOLERA CASES, HAITI 2010-2017



# Rapid tests in Haiti

## Crystal VC Dipstick

Span Diagnostics, Ltd., India

Sensitivity: 88 – 100%  
Specificity : 61 – 87.3%



## Artron Vibrio Cholerae O139 and O1 Combo Test

Artron Laboratories. Inc., Canada

Sensitivity: 99%  
Specificity : 99%  
Never field tested



## SD Bioline Cholera Ag O1/O139

RDT Standard Diagnostics Inc.,  
South Korea

Sensitivity : 95.4%  
Specificity: 94.1%  
Never field tested



# Study Design

- Retrospective review of ordinarily collected laboratory surveillance records
- May 2014 to October 2015
- Cases - acute watery diarrhea
- Rapid diagnostic testing
- Bacterial culture
  - processed immediately, or
  - stored in Cary Blair (Becton, Dickinson and Co., Maryland, USA) transport medium at 2-8C and processed within a week.
- Trained laboratory technicians

Alkaline Peptone Water (APW)

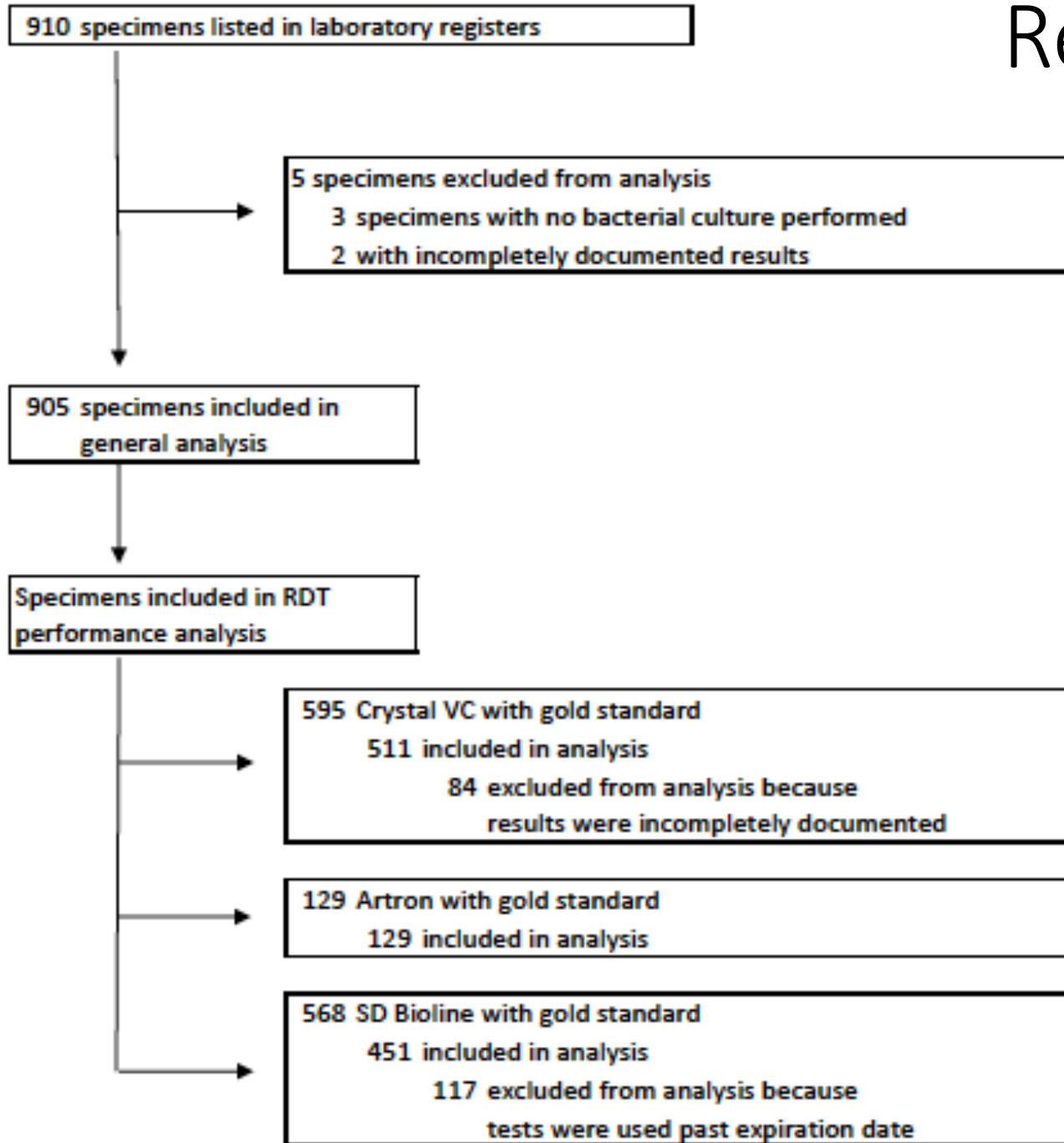
May, 2014 - May, 2015

- plated directly onto TCBS without enrichment in APW.

End May - Oct, 2015

- enriched in APW for 6 hours prior to plating on TCBS

# Results



Test	Total	Positive	Negative	Positivity Rate
Culture	905	477*	428	52.7%
Crystal VC	511	347	164	67.9%
Artron	129	90	39	69.8%
SD Bioline	451	212	239	47.0%

\*345 Ogawa (72.3%); 132 Inaba (27.7%)

# RDT Performance Characteristics for *V. cholerae* O1

<b>Test</b>	<b>Sensitivity</b> <b>[95% CI]</b>	<b>Specificity</b> <b>[95% CI]</b>
Crystal VC	98.6% (96.5 – 99.6%)	71.1% (64.7 – 76.9%)
Artron	98.6% (92.7 – 100.0%)	69.1% (55.2 – 80.9%)
SD Bioline	81.1% (75.6 – 85.8%)	92.8% (88.4 – 95.9%)

# RDT Performance Characteristics for *V. cholerae* O1

<b>Test</b>	<b>Sensitivity</b> [95% CI]	<b>Specificity</b> [95% CI]	<b>Positive Predictive Value</b> [95% CI]	<b>Negative Predictive Value</b> [95% CI]
Crystal VC	98.6% (96.5 – 99.6%)	71.1% (64.7 – 76.9%)	81.3% (76.8 – 85.2%)	97.6% (93.9 – 99.3%)
Artron	98.6% (92.7 – 100.0%)	69.1% (55.2 – 80.9%)	81.1% (71.5 – 88.6%)	97.4% (86.5 – 99.9%)
SD Bioline	81.1% (75.6 – 85.8%)	92.8% (88.4 – 95.9%)	92.9% (88.6 – 96.0%)	80.8% (75.2 – 85.6%)



# O139 False Positives Crystal VC and Artron RDTs

- Crystal VC RDT
  - **511** total tests
  - **129** O1, O139 (25.2%)
  - **26** O139 (5.1%)
- Artron RDT
  - **129** total tests
  - **9** O1, O139 (7.0%)
  - **3** O139 (2.3%)
- No O139 Positive bands were detected with SD Bioline RDT
- Only 1 *Vibrio cholerae* O139 had been isolated in Haiti



# Conclusions

- Limitations
  - Retrospective
  - Culture as gold standard
- Performance characteristics of Crystal VC, Artron, and SDBioline RDTs are suboptimal
  - Use in outbreak identification
  - Use in formal surveillance activities
- Frequent false O139 positives with Crystal VC and Artron RDTs

# Thank you

- Partners In Health (PIH)
- Zanmi Lasante (ZL)
- Ministère de la Santé Publique et de la Population
- l'Hôpital Saint Nicolas de Saint Marc
- Massachusetts General Hospital
- Harvard Medical School Department of Global Health and Social Medicine
- The Doris Duke Foundation
- National Institutes of Health
- Madison Family Fund
- The Bill and Melinda Gates Foundation



**Supporting Table 1. Positivity Rates for Bacterial Culture and 3 RDTs for detection of *V. cholerae* O1.**

	Without APW enrichment				With APW enrichment				Grouped			
Test	Total	Positive	Negative	Positivity Rate (%)	Total	Positive	Negative	Positivity Rate (%)	Total	Positive	Negative	Positivity Rate (%)
Culture	450	234	216	52.0	455	243	212	53.4	905	477	428	52.7
VC	349	239	110	68.5	162	108	54	66.7	511	347	164	67.9
Art	9	5	4	55.6	120	85	35	70.8	129	90	39	69.8
SD	428	204	224	47.7	23	8	15	34.8	451	212	239	47.0

**Supporting Table 2. Number of Specimens tested by different combinations of RDTs.**

\*VC = Crystal VC; SD = SD Bioline; Art = Artron

VC	VC + SD	VC + Art	VC + SD + Art	SD	SD + Art	Art
19	363	120	9	79	0	0

- Isolation on TCBS, biochemical testing with oxidase and string test, serological confirmation with O1/O139 and Ogawa/Inaba antisera