

Michigan Statewide Rollout of the 4th Generation Alere Determine HIV 1/2 Ag/Ab Combo

Dawn Lukomski, MA & Kenneth Borkowski, MPH, CHES

Background

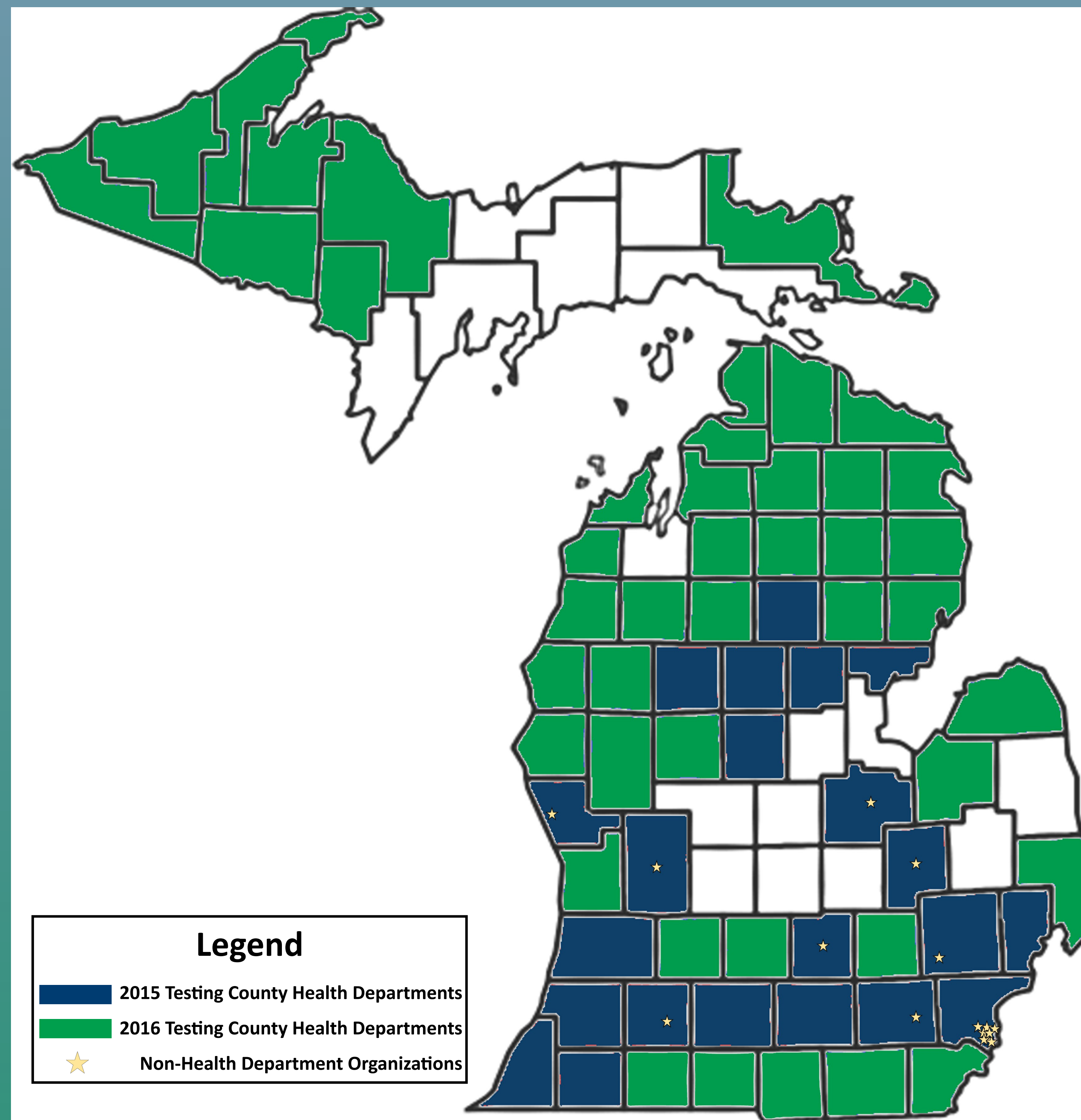
In 2015, Michigan Department of Health and Human Services (MDHHS) funded 17 local health departments, 14 community based organizations, 2 emergency rooms, a jail services program, and a federally qualified health center to conduct rapid HIV testing. Approximately 59,000 HIV tests are conducted annually at MDHHS funded sites and 89% of those are rapid tests. With the CDC's recommendation for offering the most sensitive tests to allow for detection of acute HIV, MDHHS decided it would be beneficial to consider transitioning testing devices to best serve the people of Michigan.

Timeline

- Summer 2014—Counseling, Testing, and Referrals (CTR) Coordinator met with HIV rapid test representatives to analyze current testing technologies.
- Fall 2014—CTR Coordinator visited funded agencies to create buy-in for transition to a new HIV rapid test.
- Dec 2014—Alere receives CLIA waiver for the Determine HIV 1/2 Ag/Ab Combo Rapid Test.
- Jan 2015—Two highest testing volume sites begin using the new rapid test (an emergency room & health department).
- Feb 2015—Grantees meeting with presentation and hands-on training on the Alere Determine Combo.
- Mar 2015—14 small group trainings occurred around southern Michigan with no more than three agencies present at one time to allow for a more personalized training experience.
- May 2015—2 individuals received Ag only rapid test results. Both were confirmed to be infected upon supplemental testing.
- Jul 2015—65% of sites have switched over to the Alere Determine for rapid testing.
- Oct 2015— Another individual received an Ag only rapid test result and was confirmed to be infected upon supplemental testing.

Challenges

- Interpretations of test device results can be difficult as the lines are not as crisp as with previous test devices which occurs due to larger sample sizes and detecting additional markers.
- Collection of a larger sample using a different method (e.g. 5 vs 50 µL and loop vs pipette).



Location Type	STAT-PAK Tests 2014 ¹	Positivity 2014 ¹	Determine Tests 2015 ¹	Positivity 2015 ¹
Emergency Room ²	5,460	0.238	4,139	0.314
Health Department 1 ²	4,797	0.375	4,801	0.312
Health Department 2 ²	1,440	0.278	1,748	0.172
Health Department 3 ²	863	0.000	912	0.219
Community Based Organization 1 ²	489	1.227	290	0.345
Community Based Organization 2 ²	121	0.000	108	1.852
Community Based Organization 3 ²	85	3.529	37	8.108

¹ Testing data from July to December of listed year

² Change in positivity was not statistically significant (p > 0.10)

Successes

- 100% of funded sites were using the Alere Determine at the end of 2015.
- 3 antigen positives were identified using the Alere Determine and were confirmed to be infected with HIV.
- There have been no reports of any problems or need for additional training for the past several months at sites funded in 2015.
- In 2015 the MDHHS Bureau of Laboratories implemented the 4th generation HIV testing algorithm to allow for detection of acute HIV cases through conventional testing methods.

Limitations

- Due to constraints of the previous data system, MDHHS was unable to collect specific rapid test results (e.g. Ag, Ab, Ag/Ab) and relied on self-reporting from funded sites.
- Although no significant change in positivity was seen, though an accurate conclusion may not be drawn as the test devices were used during different years of testing.

Recommendations

- Community buy-in is required when large scale changes occur (e.g. changes in rapid testing technologies) or resistance and push back is likely to occur.
- Progressive roll-outs can decrease the burden on a program and allow for individual sites to transition when it best fits them.
- Initial roll-out at largest sites allows problems to be identified and alleviated before others would encounter them.
- Continual training and technical support is required and will remove barriers to using this test device.

Future Directions

- Starting in January 2016, MDHHS funded sites began using Evaluation-Web for data collection. With this transition, a policy has been included to allow for the collection of specific rapid test results in the system so self reporting issues will no longer occur.
- Testing capacity will increase as MDHHS has allocated funding to an additional 10 health departments that cover an additional 45 counties.