



Published in final edited form as:

*Sex Transm Dis.* 2021 November 01; 48(11): 895–899. doi:10.1097/OLQ.0000000000001464.

## Costs of Identifying Cases of Syphilis Using Rapid Syphilis Tests in Multiple Non-Clinical Settings in the U.S.

Austin M. Williams, PhD,

Andrés A. Berruti, PhD, MA

Division of STD Prevention, Centers for Disease Control and Prevention

### Abstract

**Background:** Outreach screening is a common strategy for detecting cases of syphilis in high-risk populations. New rapid syphilis tests allow for quicker response times and may alter the costs of detecting and treating syphilis in non-clinical settings.

**Methods:** Between May and October of 2017, we collected detailed retrospective cost data from two outreach screening programs engaging people experiencing homelessness and LGBTQ populations. Comprehensive and retrospective cost information, disaggregated by cost category, programmatic activity, and source of support, was collected during and after the testing period.

**Results:** Across all sites, rapid syphilis tests were conducted on 595 people at an average cost of \$213 per person. Twenty-three cases of syphilis were confirmed and treated for an average cost of \$5,517 per case, ranging from \$3,604 at a rehabilitation facility to \$13,140 at LGBTQ venues served by a mobile clinic. Personnel contributed the most to total costs (56.4%), followed by supplies (12.8%) and the use of buildings (10.4%). Expenditures by programmatic activity varied substantially across sites.

**Conclusions:** Testing costs varied between venues, reflecting differences in the models used and intensity of services provided. While staff costs are the major driver, buildings and supplies costs are also significant. Our findings suggest that outreach screenings using rapid syphilis tests may be a feasible and cost-effective tool for health departments when targeting known high-prevalence areas and hard to reach populations.

### Short Summary:

A cost study of outreach syphilis screening found that rapid syphilis testing can be a cost-effective tool when serving high-prevalence populations.

### Keywords

rapid syphilis test; mobile clinics; LGBTQ; people experiencing homelessness

## Introduction

Rates of primary and secondary syphilis in the U.S. have been increasing for the past two decades, and the increase has primarily occurred in men who have sex with men (MSM).<sup>1</sup> The rate of congenital syphilis has also risen recently, with 1,306 cases reported in 2018.<sup>1</sup> Screening for syphilis has been found to be cost-effective in prenatal care, where testing costs are relatively low and the risk of serious and costly complications of untreated syphilis are high.<sup>2,3</sup> Less is known about the cost and effectiveness of screening nonpregnant populations in non-clinical settings, though the US Preventive Service Task Force recommends screening persons at increased risk for infection, such as MSM, people living with HIV, and people with a history of incarceration.<sup>4</sup> The goal of outreach screening is to reach high risk populations that would not otherwise be tested and treated. Outreach screening is likely to be more cost-effective within high prevalence populations, since the additional costs of testing in nontraditional environments are expected to be balanced by identifying more cases and weakening disease transmission.<sup>5</sup> Of course, outreach screening is only effective if patients that have initial positive test results are ultimately connected to confirmatory testing and treatment.

We evaluated the use of RST in two populations: people experiencing homelessness located at a shelter, rehabilitation facility, and an encampment in San Joaquin County, CA; and participants found at 16 LGBTQ (lesbian, gay, bisexual, transgender, queer) venues such as gay bars and pride events in Pima County, AZ. San Joaquin County, CA, has experienced a steady increase in primary and secondary syphilis cases over the past decade, and local epidemiology suggests that people experiencing homelessness are disproportionately affected by syphilis in the county.<sup>6</sup> Pima County, AZ, has experienced a dramatic increase in primary and secondary syphilis cases since 2014. The groups most at risk have been those under age 40 years, MSM, and Hispanic populations.<sup>7</sup>

In each location Syphilis Health Check (Trinity Biotech) tests, the first RST with FDA approval, were used to acquire initial results. In non-clinical settings, RSTs may have advantages over other treponemal tests because they are low cost, user friendly, produce rapid results (within 10 minutes), are easily storable, and have similar sensitivity (98.5%) and specificity (95.9%) as traditional tests.<sup>8</sup>

Collecting cost data is an important aspect of evaluating a public health program or intervention. Cost components include labor hours, supplies, and facilities, among others. Standardized collection of detailed cost data allows for comparisons across sites, programs, and places, so that data collection efforts from one locale may inform programs in other settings. Understanding program costs helps public health departments prioritize resources and plan future budgets and spending. In this paper, we evaluate the costs of using rapid syphilis tests (RSTs) to screen for syphilis in high prevalence populations across multiple non-clinical settings. Costs are measured from the perspective of the health department conducting the programs. We identify factors that influence overall costs, component costs, and variation in costs across the different settings.

## Methods

Rapid syphilis testing was conducted at three centers engaging people experiencing homelessness (a men's shelter, an encampment, and a rehabilitation facility) in San Joaquin County and in 16 LGBTQ venues in Pima County. Patients with reactive RST results were linked to the local health department clinic for confirmatory testing and treatment, and transportation was provided for people experiencing homelessness. Each participant in both counties received a small token (i.e., backpacks, snacks, bottled water, bar coasters, beer glasses, etc.) for their participation.

We conducted a cost analysis from a programmatic perspective by collecting data on the total costs incurred by RST programs and considering all sources of financial or in-kind support.<sup>9</sup> We included all funding sources (e.g., local site, U.S. government, etc.) in the evaluation to provide complete information on financial support for the RST program and to allow for accurate projections of program costs to other settings or with program scale-up. The cost methodology combined an ingredients-based approach, whereby a unit cost is multiplied by a resource quantity to generate a total cost. We used a step-down cost accounting approach for program level data in which joint costs are allocated to activities through cost categories. A variety of sources were used for data on inputs, outputs and costs, including inspection of program records and registers, mobile clinic observation, expert interviews with clinic and project staff, and review of project financial accounts. We collected information in 7 cost categories: personnel (e.g. staff labor), travel, contracted services, utilities (e.g. electricity, phone, internet), equipment (e.g. van, folding tables, tents, centrifuge), buildings, and rapid syphilis test kits. Costs were also allocated across 6 programmatic activities: program-related training and mentoring, screening and testing, counseling (e.g. STI prevention education), referral (e.g. connecting patients with follow-up care), monitoring and evaluation, and general administration. These three dimensions (cost-categories, programmatic activities, and source of support) provide a detailed description of each expenditure included in the economic evaluation of the RST program (e.g. the cost of personnel dedicated to screening and testing, funded by the federal government).

Personnel costs included all staff members involved in operating the RST program. This included full-time equivalent (FTE) staff hired directly by the grantee as well as external contractors hired to support the project. Capital costs (i.e., equipment) were included as investments and were annuitized over their useful life span. Donated items were valued at market prices,<sup>10</sup> overhead and shared costs were assigned by direct allocation,<sup>11</sup> and the opportunity cost of existing infrastructure was estimated as the equivalent rental cost. All costs were converted to 2019 U.S. dollars adjusted the all items component of the consumer price index for all urban consumers. A cost collection tool based in Microsoft Excel (version 16.0) was used to collect the cost information, which was then cleaned and analyzed in Stata (version 14).

We collected information from the health departments in San Joaquin County and Pima County. Due to the relatively low testing volume at each of the LGBTQ venues, we aggregated all expenditures from the mobile clinic. Separate costs were calculated for each venue in San Joaquin County as well as overall costs across all venues. We divided total

costs by (1) the number of tests administered to calculate costs per patient tested and (2) the number of confirmed positives to estimate the cost of identifying a syphilis case. Confirmed positives were defined as those with positive confirmatory tests following a positive rapid test result.

Finally, we conducted one-way sensitivity analyses that varied personnel costs, number of tests, and target population positivity. Personnel costs were varied  $\pm 20\%$  of the estimated baseline value. This approximately aligns with the interquartile range for wages of similar occupations as documented by the Bureau of Labor Statistics.<sup>12</sup> Positivity ranged from the overall county incidence to the highest positivity found among racial/ethnic subpopulations in the RST pilot for each county. The number of tests was varied  $\pm 20\%$  the actual number given. We assumed costs of supplies and test kits increased proportionately with the number of tests, but no other costs were impacted. Total costs, number of positives, and cost per positive were then calculated for each scenario. For the one-way analyses, data from the three San Joaquin County sites were combined. This exercise calculates a range of possible outcomes under realistic changes in input costs, patient flow, and the positivity of patients reached.

## Results

Among those tested at the outreach sites in San Joaquin County, 74.3% lacked a permanent residence, 74.6% had used drugs in the past year, 43% had been in jail or prison, and 1.3% were HIV positive.<sup>6, 13</sup> Out of 401 tests conducted across the three sites, 58 were reactive and 20 confirmed syphilis cases were identified. Forty-one percent of those receiving tests and 48% of patients treated were females. People belonging to racial and ethnic minority groups were more less likely to complete a confirmatory test after a positive RST result. Positive RST results were more common among those identifying as Hispanic, females, and people who had been previously diagnosed with a sexually transmitted disease. Across the LGBTQ venues reached via a mobile clinic in Pima County, 194 RSTs were performed, resulting in 8 reactive tests and 3 confirmed syphilis cases. Thirty percent of patients tested, and 1 out of 3 confirmed positives, were among females. The median age of those tested in Pima County, 36 years, was lower than the population tested in San Joaquin (47). 31.5% of patients at the Pima County sites reported having sex while intoxicated or high on drugs, 73.4% reported sometimes or always engaging in condomless sex, and 5.1% recalled having a previous diagnosis of syphilis.<sup>7, 13</sup> Positive RST results were more common among those that reported not using condoms.

Table 1 reports the number of tests conducted, number of confirmed cases identified, and costs across the sites. Estimated total costs were \$87,480 across the San Joaquin County sites and \$39,420 across all LGBTQ venues. The mean cost per test performed was \$213 and ranged from \$187 to \$288. Costs per confirmed syphilis case identified ranged from \$3,604 to \$13,140. Overall, personnel represented the largest cost category, contributing to 56.4% of all expenditures. The second largest category was supplies (12.8%), which included gloves, needles, biohazard bins, and incentives such as food and gift cards for people experiencing homelessness. Supply costs differed significantly between the sites engaging people experiencing homelessness and the LGBTQ venues. Specifically, for the

LGBTQ sites that utilized a mobile clinic for screening and provided limited incentives to some patients (i.e., promotional coaster, beer glasses), equipment and utilities were much larger expenditure categories than supplies (see Table 2). On the other hand, supplies and buildings made up much larger percentages of costs at the sites engaging people experiencing homelessness. Costs by category of expenditure are presented at the top of Figure 1.

We also evaluated costs by programmatic activity (See Figure 1, bottom). General administration, which included office space and personnel time used for planning and organizing outreach events, was the costliest activity with 34.6% of total spending. Screening & testing and monitoring & evaluation were the next most costly with about 23% of expenditures each. Referral costs were notably different between the sites engaging people experiencing homelessness and the LGBTQ sites. They accounted for 4.9% of spending at the sites engaging people experiencing homelessness, but 0% of spending at the LGBTQ venues. Conversely, counseling costs were much higher at the LGBTQ venues: 34.7% versus 1.7% at the sites engaging people experiencing homelessness (see Table 3).

Eighty-two percent of funding for the outreach screening activities was provided from federal sources including the Centers for Disease Control and Prevention and the National Association of County and City Health Officials. Seventeen percent of costs were funded by the county, and approximately 1% of costs were directly paid for by staff out-of-pocket.

In our sensitivity analysis, we demonstrated that costs per positive can vary substantially as parameter inputs change, with positivity having the most significant impact (see appendix Table A1 and Figure A3). In San Joaquin County, the 10<sup>th</sup> percentile of simulated cost per positive outcomes was \$2,414 and the 90<sup>th</sup> percentile was \$18,970. For Pima County, these same percentiles yielded costs per positive of \$7,662 and \$71,499. The number of positives identified in San Joaquin County ranged from 5 (10<sup>th</sup> percentile) to 36 (90<sup>th</sup> percentile), and in Pima County the number of positives ranged from 1 (10<sup>th</sup> percentile) to 5 (90<sup>th</sup> percentile).

## Discussion

Our estimates of the costs of rapid syphilis testing in non-clinical settings are comprehensive and include all component costs. Previous estimates of syphilis outreach screening were often limited by missing cost elements.<sup>14, 15</sup> Across all sites, we estimated an average cost per patient tested of \$213. Since fixed costs (e.g. staff trainings, buildings, utilities) do not increase with the number of tests performed, we would expect to see lower costs per patient tested as the number of tests administered at a venue increase. This is a particular problem in outreach screening. In order to increase the patient volume, the sites in the study used different non-monetary incentives to lure the patients into the program. There is some evidence to support the relation between cost per patient tested and number of tests in our data; the venue with the fewest tests given, the rehabilitation facility (75 tests), resulted in a cost per patient tested of \$288, while the cost per patient tested at the venue with the most tests administered, the men's shelter (200 tests), was \$212. For comparison, when adjusted for inflation, Lewis et al. found an average cost of \$130 per patient tested over

294 tests given by community-based organizations in Philadelphia in 2007. Ciesielski et al. estimated the costs of outreach screening at bathhouses and bars using a mobile clinic in Chicago in 2002. Including only personnel costs, they found costs per patient tested of \$50 at bathhouses and \$38 at bars, adjusted for inflation. If we assume personnel costs are only 56% of total costs, as we found across all sites, then the total costs per patient tested at these locations would be \$90 and \$67, respectively. Appendix Figure 2 maps the relation between the quantity of tests performed and the average cost per patient tested.

Understanding how different components contribute to total costs may allow health departments to plan and budget for their own tailored outreach screening programs. For example, when examining costs by programmatic activity, we found that general administration costs were much higher for the sites engaging people experiencing homelessness than for the mobile clinic. This may reflect more difficulty in planning for and reaching people experiencing homelessness. Referral costs were also higher for this population, because connecting the patients with follow-up confirmatory treatment and care is difficult in a population that often lacks permanent housing, transportation, or contact information. Health departments should consider whether these additional referral costs could be replaced with onsite confirmatory testing or presumptive treatment. On the other hand, referral costs were zero for the mobile clinic, because patients from the LGBTQ venues were responsible for transporting themselves to any necessary follow-up care. When breaking down costs by category, we found that personnel contributed to the majority of costs. Thus, programs should consider the mix of staff salaries when assigning activities, so that labor hours are used efficiently. Other cost categories depend on the mode of reaching patients. Programs investing in high cost equipment, such as vans for mobile clinics, should have enough testing events planned to justify the large fixed cost.

The average cost per confirmed syphilis positive identified and treated was \$5,517 (range, \$3,604 - \$13,140). Treating an infectious case has value beyond its direct benefit to the patient, through reduction in transmission to others, reduced cases of congenital syphilis, and reduced probability of acquiring STI-attributable HIV infections.<sup>16</sup> Chesson et al. (2008) estimated the direct medical costs and indirect productivity costs saved by treating one case of syphilis to be \$7,298 when adjusted for inflation. Thus, even when treatment costs are considered, the program in San Joaquin County is likely to be cost-effective. This threshold omits some benefits to averting syphilis, such as patient quality of life. Thus, some programs may decide to engage in outreach screening even if the expected cost per positive exceeds this threshold. Increasing patient flow, i.e. the number of patients tested during a particular screening event, can better utilize personnel resources and improve cost per test/positive metrics. Further, the cost-per-positive outcome is very sensitive to the number of confirmed cases; even one additional case found will have a significant impact on the measure. In our simulation analysis, county-level rates were used as lower bounds on positivity. Figure A3 and Table A1 demonstrate that cost-per-positive at low levels are quite high, indicating that outreach screening is only likely to be cost-effective in populations that are known to have significantly higher syphilis burden than the general population (though prenatal syphilis screening, where the benefits of identifying a positive case are much higher, has been found to be cost effective<sup>2, 17</sup>). In the United States in 2015, the rate of primary and secondary syphilis among MSM was found to be 309 per 100,000.<sup>18</sup> This rate is similar

to the upper bound used in the sensitivity analysis and suggests that outreach testing of this population will often prove to be cost effective.

There are potential cost implications when using a reverse testing algorithm (a treponemal test followed by a confirmatory nontreponemal test) rather than the traditional algorithm for diagnosing syphilis. An initial treponemal test is more sensitive for detecting primary and latent syphilis, but costs may be higher using a reverse algorithm because more confirmatory tests are required<sup>19</sup>. In populations at high risk for cases of early syphilis, the benefits of identifying additional cases likely outweigh the costs of additional confirmatory tests.

Our analysis comes with some limitations. The benefits of identifying cases of syphilis are only realized if infectious patients are ultimately treated. Only 34 confirmatory tests were given out of 58 reactive tests across the sites engaging people experiencing homelessness, highlighting the potential for attrition in this population. Further, outreach screening is not as beneficial if patients would otherwise have sought testing on their own. However, in Pima County 50% of patients surveyed indicated they had not sought health department services within the past three years, suggesting that they may not have received any health care in the absence of the outreach program, and may have been especially unlikely to have been screened for syphilis. Next, disease prevalence impacts the cost-effectiveness of any outreach screening program. A solid understanding of the local epidemiology is crucial for determining the suitability and value of such a program. Finally, cost estimates can change significantly in different settings. Changes to inputs like personnel costs can alter the cost effectiveness of outreach screening. Our sensitivity analysis demonstrates how cost, patient volume, and positivity can influence the cost of identifying positive syphilis cases.

Our study demonstrates that outreach screening using RSTs has the potential to be a cost-effective tool for mitigating outbreaks. Given the importance of connecting patients to confirmatory testing and treatment, RSTs have an advantage over traditional tests because plans for follow-up care can be arranged during the first contact with a patient. The ease of use of RSTs is an additional benefit when targeting hard to reach populations. Health departments must consider their own unique circumstances when making the decision to engage in outreach testing; the evidence from this study can help guide this decision-making process.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgement:

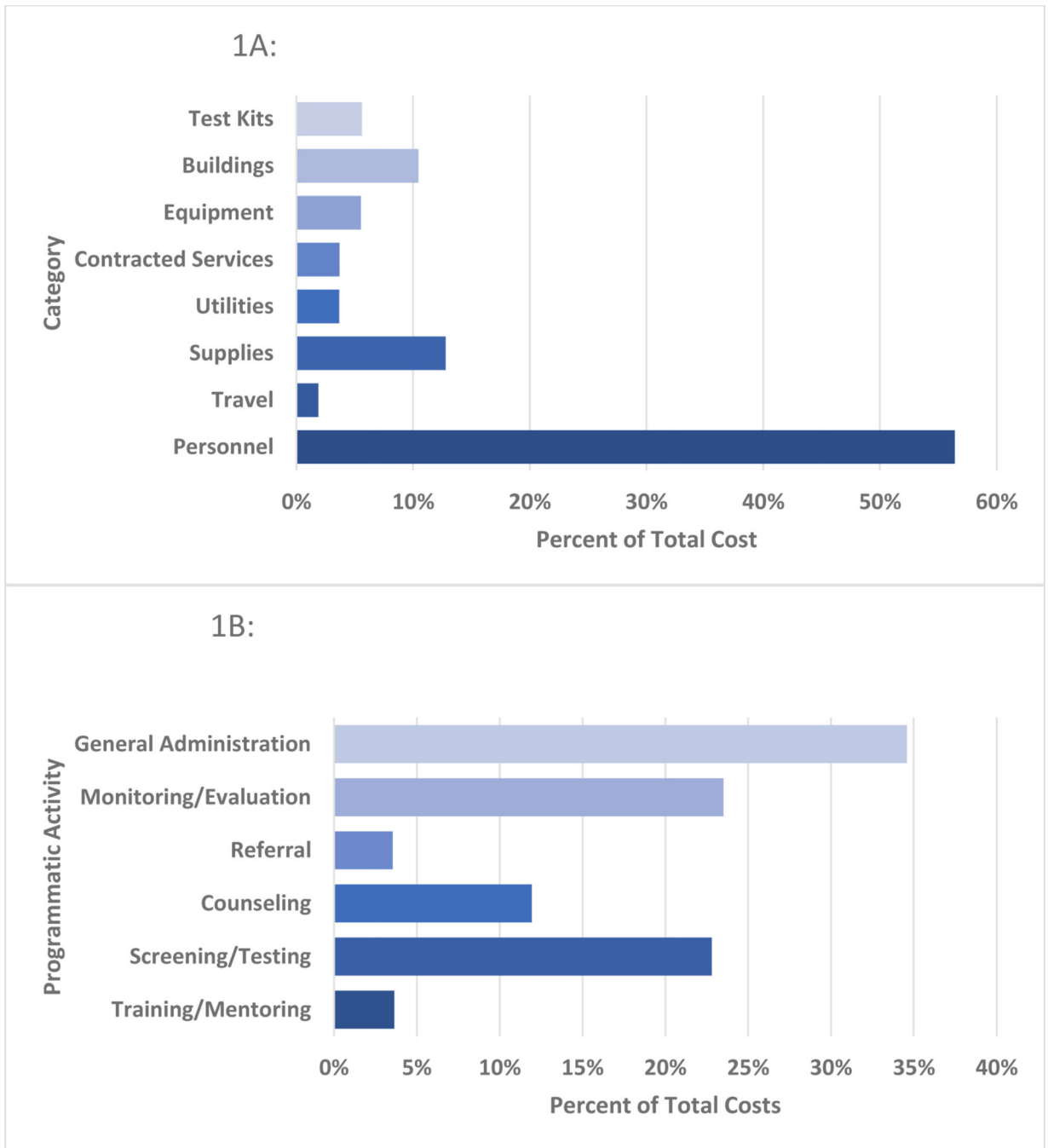
San Joaquin County, CA and Pima County, AZ.

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**Figure 1A:** Expenditure Shares by Category, All Locations **Figure 1B:** Expenditure Shares by Programmatic Activity, All Locations

**Table 1:**

## Tests, Positives, and Costs by Site

	Men's Shelter	Encampments	Rehabilitation Facility	Mobile Clinic	Total
<b>Total Cost</b>	\$42,318	\$23,540	\$21,622	\$39,420	\$126,900
<b>Number tested</b>	200	126	75	194	595
<i>Cost per patient tested</i>	\$212	\$187	\$288	\$203	\$213
<b>Syphilis (confirmed positives)</b>	8	6	6	3	23
<i>Cost per positive</i>	\$5,290	\$3,923	\$3,604	\$13,140	\$5,517

Testing at the men's shelter, encampments, and rehabilitation facility all focused on the people experiencing homelessness in San Joaquin County. The mobile clinic engaged the LGBTQ community at various venues in Pima County. Costs inflated to 2019 USD.

**Table 2:**

Costs by Category and Testing Location

Category	Personnel	Travel	Supplies	Utilities	Contracted Services	Equipment	Buildings	Test Kits	All Categories (100%)
<b>Total Costs (\$)</b>	71,594 (56.4%)	2,378 (1.9%)	16,221 (12.8%)	4,651 (3.7%)	4,672 (3.7%)	7,012 (5.5%)	13,253 (10.4%)	7,118 (5.6%)	126,900
<b>Men's Shelter</b>	21,541 (50.9%)	781 (1.8%)	7,903 (18.7%)	0 (0.0%)	2,332 (5.5%)	963 (2.3%)	6,139 (14.5%)	2,661 (6.3%)	42,318
<b>Encampment</b>	11,151 (47.4%)	491 (2.1%)	4,973 (21.1%)	0 (0.0%)	1,467 (6.2%)	606 (2.6%)	3,178 (13.5%)	1,674 (7.1%)	23,540
<b>Rehabilitation Facility</b>	12,580 (58.2%)	293 (1.4%)	2,962 (13.7%)	0 (0.0%)	874 (4.0%)	361 (1.7%)	3,557 (16.4%)	997 (4.6%)	21,622
<b>Mobile Clinic</b>	26,323 (66.8%)	814 (2.1%)	384 (1.0%)	4,651 (11.8%)	0 (0.0%)	5,083 (12.9%)	379 (1.0%)	1,786 (4.5%)	39,420

Testing at the men's shelter, encampments, and rehabilitation facility all focused on the people experiencing homelessness in San Joaquin County. The mobile clinic engaged the LGBTQ community at various venues in Pima County. Costs inflated to 2019 USD.

Costs by Programmatic Activity and Testing Location

Table 3:

Programmatic Activity	Training/Mentoring	Screening/Testing	Counseling	Referral	Monitoring/Evaluation	General Administration	All Activities (100%)
<b>Total Costs (\$)</b>	4,609 (3.6%)	28,939 (22.8%)	15,143 (11.9%)	4,489 (3.5%)	29,830 (23.5%)	43,890 (34.6%)	126,900
<b>Men's Shelter</b>	3,011 (7.1%)	9,173 (21.7%)	587 (1.4%)	1,902 (4.5%)	10,689 (25.3%)	16,956 (40.1%)	42,318
<b>Encampment</b>	941 (4.0%)	5,602 (23.8%)	354 (1.5%)	1,517 (6.4%)	2,663 (11.3%)	12,463 (52.9%)	23,540
<b>Rehabilitation Facility</b>	489 (2.3%)	3,459 (16.0%)	539 (2.5%)	1,070 (4.9%)	6,607 (30.6%)	9,458 (43.7%)	21,622
<b>Mobile Clinic</b>	167 (0.4%)	10,705 (27.2%)	13,662 (34.7%)	0 (0.0%)	9,871 (25.0%)	5,014 (12.7%)	39,420

Testing at the men's shelter, encampments, and rehabilitation facility all focused on the people experiencing homelessness in San Joaquin County. The mobile clinic engaged the LGBTQ community at various venues in Pima County. Costs inflated to 2019 USD.