

Quality Assurance Monitoring of Pima CD4 Testing: Operator Errors Attributing to Higher Invalid Test Rates

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Introduction:

Pima CD4 is a point-of-care test for HIV/AIDS care



- ❑ Important to monitor the quality of POCT
- ❑ QA activity of monitoring invalid test rates
- ❑ Pima CD4 Invalid tests due to:
 - Failures of Pima Analyzer or cartridges
 - Suboptimal specimen
 - Incorrect testing procedure

Field Evaluation of Point-of-Care CD4 Assay in Tanzania: Phase II

Goal:

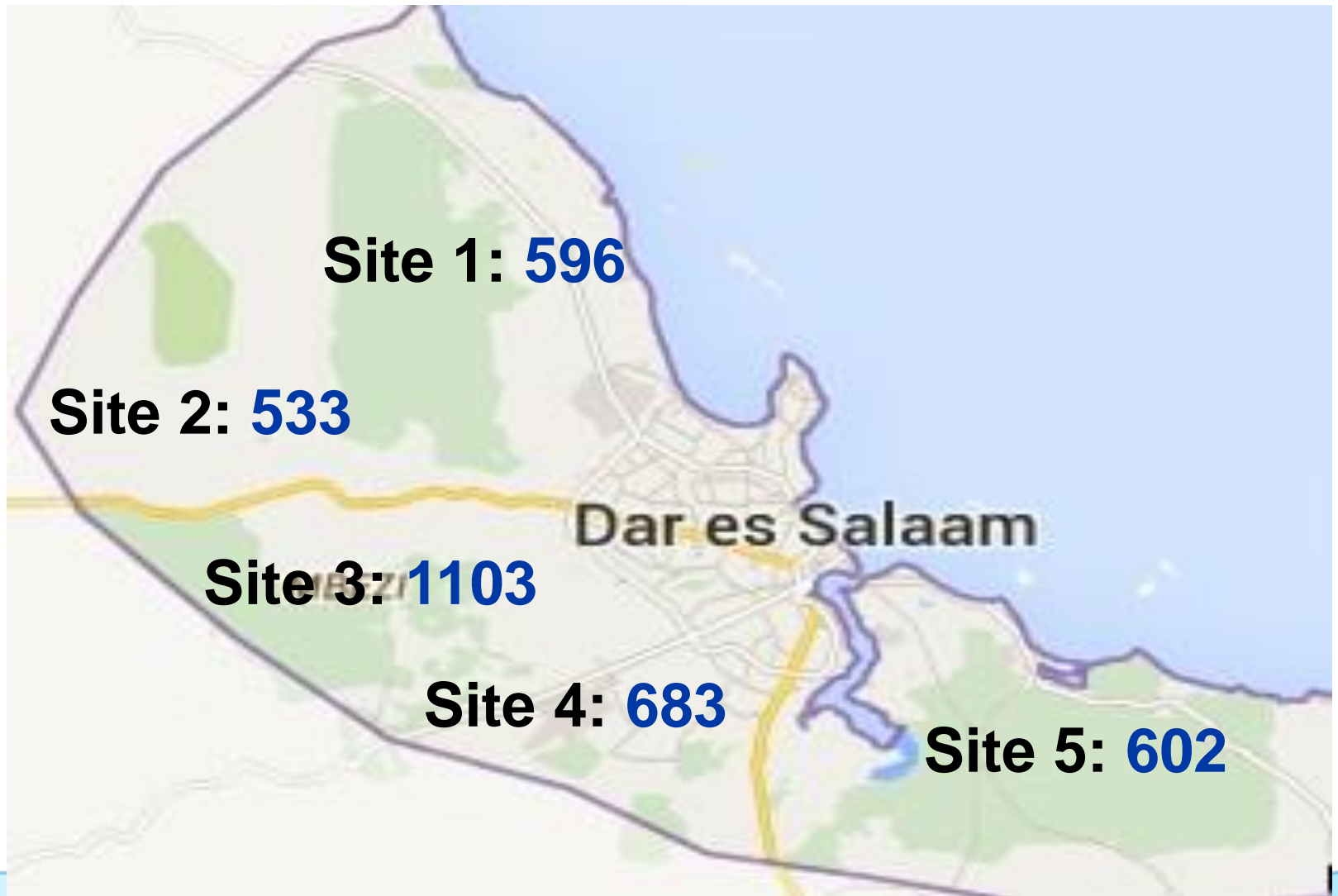
To validate and assess point-of-care CD4 testing using Pima Analyzer in clinical settings.

Objectives:

- To evaluate the level of agreement between Pima used at the point-of-care level and FACSCalibur at the reference laboratory
- To evaluate three different blood collection methods.
 - Fingerstick capillary blood directly applied to Pima CD4 cartridge
 - Fingerstick capillary blood collected into an EDTA micro-tube
 - Venous blood collection
- To evaluate the acceptability of the use of the Pima CD4 Assay in PMTCT and CTC settings
- To evaluate acceptability of various blood collection methods.
- To evaluate the elements for implementing a QA program for Pima CD4 POCT

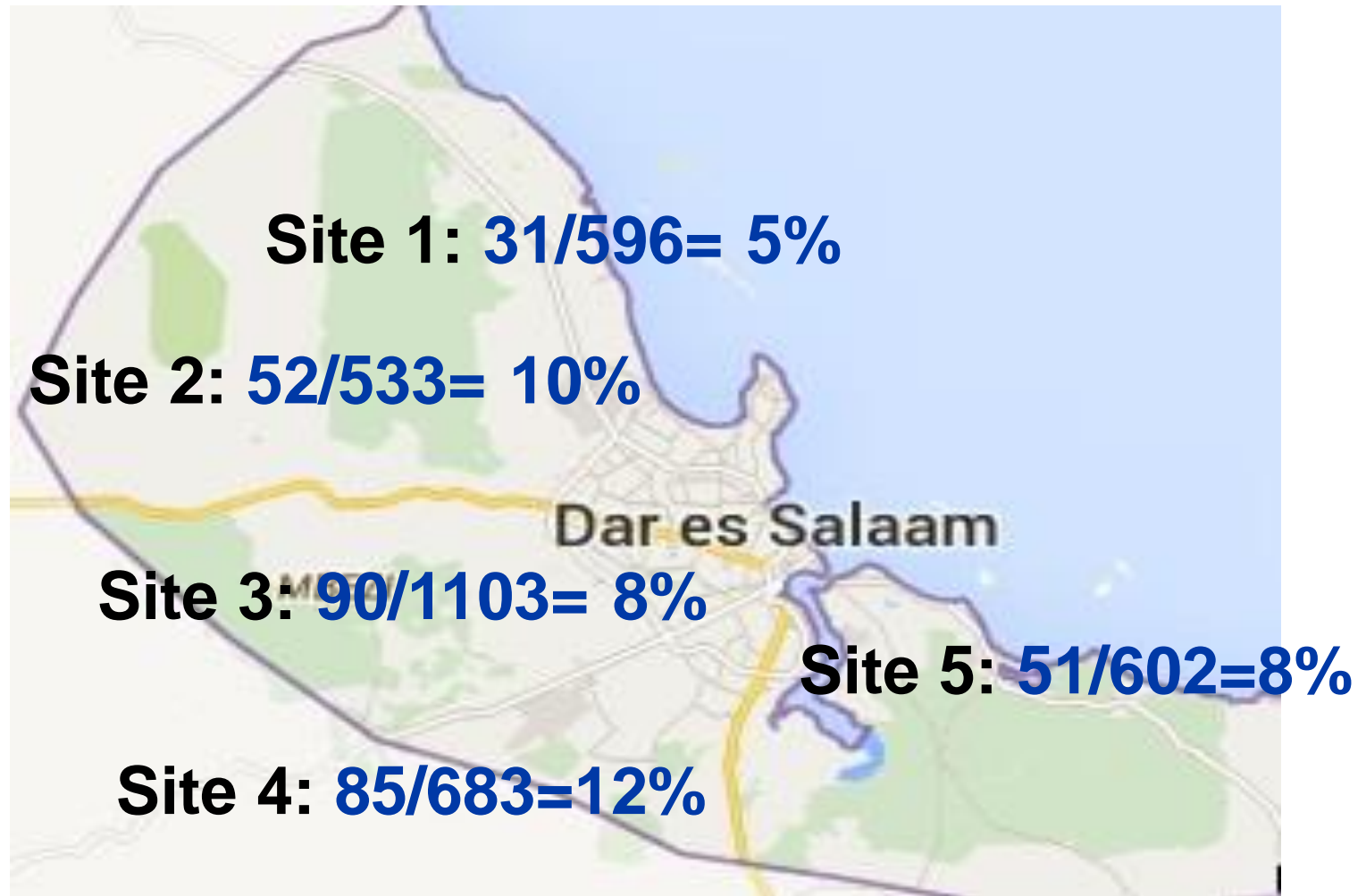
Number of Pima CD4 Test

Total: 3517 Pima CD4 Test



Invalid Test Rates of Pima CD4 Test

Invalid Tests: 309 /3517 = 9%



Invalid Test Rates of Pima CD4 Test: Health Care Worker

Site 1:

	Number	#Invalid	% Rate
HCW#1	407	25	6%
HCW#2	133	2	2%
HCW#3	56	4	7%
Total	596	31	5%

Site 2:

	Number	#Invalid	% Rate
HCW#4	185	12	6%
HCW#5	181	21	12%
HCW#6	102	9	9%
HCW#7	65	10	15%
Total	533	52	10%

Site 3:

	Number	#Invalid	% Rate
HCW#8	500	62	12%
HCW#9	603	28	5%
Total	1103	90	8%

Site 4:

	Number	#Invalid	% Rate
HCW#10	431	57	13%
HCW#11	252	28	11%
Total	683	85	12%

Site 5:

	Number	#Invalid	% Rate
HCW#12	225	27	12%
HCW#13	377	24	6%
Total	602	51	8%

Dar es Salaam

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Total	602	51	8%

Site 4:

	Number	#Invalid	% Rate
HCW#10	431	57	13%
HCW#11	252	28	11%
Total	683	85	12%

Invalid Test Rates of Pima CD4 Test: Pima Analyer

Site 1:

PIMA-D-001			PIMA-D-002		
Number	#Invalid	% Rate	Number	#Invalid	% Rate
288	18	6%	308	13	4%

Site 2:

PIMA-D-003			PIMA-D-004		
Number	#Invalid	% Rate	Number	#Invalid	% Rate
264	24	9%	269	28	10%

Site 3:

PIMA-D-005			PIMA-D-006			PIMA-D-007			PIMA-D-008		
Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
322	28	9%	166	14	8%	310	20	6%	301	28	9%

Site 4:

PIMA-D-009			PIMA-D-0010			PIMA-D-0011		
Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
254	28	11%	180	18	10%	249	39	16%

Site 5:

PIMA-D-0012			PIMA-D-0013			PIMA-D-0014		
Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
202	26	13%	246	11	4%	154	14	9%

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Number	#Invalid	% Rate	Number	#Invalid	% Rate
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Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
254	28	11%	180	18	10%	249	39	16%

Site 5:

PIMA-D-0012			PIMA-D-0013			PIMA-D-0014		
Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
202	26	13%	246	11	4%	154	14	9%

Invalid Test Rates of Pima CD4 Test: HCW & Pima Analyer

Site 1:

	PIMA-D-001			PIMA-D-002		
	Number	#Invalid	% Rate	Number	#Invalid	% Rate
HCW#1	170	14	8%	237	11	5%
HCW#2	96	2	2%	37	0	0%
HCW#3	22	2	9%	34	2	6%

Site 2:

	PIMA-D-003			PIMA-D-004		
	Number	#Invalid	% Rate	Number	#Invalid	% Rate
HCW#4	21	1	5%	164	11	7%
HCW#5	76	4	5%	105	17	16%
HCW#6	102	9	9%			
HCW#7	65	10	15%			

Site 3:

	PIMA-D-005			PIMA-D-006			PIMA-D-007			PIMA-D-008		
	Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
HCW#8	105	14	13%	107	13	12%	146	13	9%	142	22	15%
HCW#9	217	14	6%	59	1	2%	164	7	4%	159	6	4%

Site 4:

	PIMA-D-009			PIMA-D-0010			PIMA-D-0011		
	Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
HCW#10	2	0	0%	180	18	10%	249	39	16%
HCW#11	252	28	11%						

Site 5:

	PIMA-D-0012			PIMA-D-0013			PIMA-D-0014		
	Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
HCW#12	191	25	13%	17	1	6%	17	1	6%
HCW#13	11	1	9%	229	10	4%	137	13	9%

Invalid Test Rates of Pima CD4 Test: HCW & Pima Analyer

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HCW#8	105	14	13%	107	13	12%	146	13	9%	142	22	15%
HCW#9	217	14	6%	59	1	2%	164	7	4%	159	6	4%

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	PIMA-D-009			PIMA-D-0010			PIMA-D-0011		
	Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
HCW#10	2	0	0%	180	18	10%	249	39	16%
HCW#11	252	28	11%						

Site 5:

	PIMA-D-0012			PIMA-D-0013			PIMA-D-0014		
	Number	#Invalid	% Rate	Number	#Invalid	% Rate	Number	#Invalid	% Rate
HCW#12	191	25	13%	17	1	6%	17	1	6%
HCW#13	11	1	9%	229	10	4%	137	13	9%

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HCW#8	105	14	13%	107	13	12%	146	13	9%	142	22	15%
HCW#9	217	14	6%	59	1	2%	164	7	4%	159	6	4%

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	PIMA-D-005			PIMA-D-006			PIMA-D-007			PIMA-D-008		
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HCW#8	105	14	13%	107	13	12%	146	13	9%	142	22	15%
HCW#9	217	14	6%	59	1	2%	164	7	4%	159	6	4%

HCW#8 = 12%

HCW#9 = 5%

QA Monitoring Pima CD4: Invalid Test Rates

- ❑ POCT Quality Assurance activities are important to ensure accurate and reliable results
- ❑ POCT QA activities involves the HCW and QA monitoring team
- ❑ Monitoring Invalid Test Rates is one QA activity for Pima CD4
- ❑ Pima CD4 Invalid tests due to:
 - Failures of Pima Analyzer or cartridges → Replace or service
 - Suboptimal specimen → Training / Supervision
 - Incorrect testing procedure → Training / QI activity
- ❑ In our study, site with higher Invalid Pima Test Rest could be attributed to individual HCWs → Correction Action

Nichole Arnett, CDC

Sehin Birhanu, CDC

Karen Chang, CDC-Tanzania

Mary Schmitz, CDC-Tanzania

Katie Tucker, CDC

Omotayo Bolu, CDC

John Nkengasong, CDC

Luciana Kohatsu, CDC

Fausta Mosha, Tanzania MoHSW

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention

Exporting of Pima Results for Monitoring

Facility A



POC Analyzers

Black boxes collect store and forward testing data to the server through the GPRS network



Monitoring Site

Queries over GSM/Internet



Web applications built to query “black boxes” for data collected from lab analyzers

Information on quantity of tests done, quality of test and maintenance information collected

The screenshot shows a Windows Explorer window with the address bar set to '2-Sinza Pima Data > Sinza Pima Exports 2011'. The window displays a list of files with the following columns: Name, Date modified, Type, and Size.

Name	Date modified	Type	Size
AssayID_2 (PIMA CD4)	12/5/2011 11:01 PM	Microsoft Excel SL...	106 KB
AssayID_2 (PIMA CD4)-001406	12/5/2011 11:01 PM	Microsoft Excel SL...	127 KB
AssayID_3 (PIMA BEADS)-001368	12/6/2011 7:40 AM	Microsoft Excel SL...	20 KB
AssayID_3 (PIMA BEADS)-001406	12/6/2011 7:40 AM	Microsoft Excel SL...	17 KB