

Quality Assurance Quick Guide for Field Studies

		PURPOSE	INTENDED USE	RESULTS
PRIOR TO FIELD STUDY ACTIVITIES	Quality Assurance (QA)	Affirm the test performs as intended, in a controlled setting, prior to use in studies	<ul style="list-style-type: none"> Used by single most skilled user or lab technician QA run on each lot before other RDT use One panel used per lot of $\leq 10,000$ RDTs. Test 8 replicates of each sample in the panel 	<ul style="list-style-type: none"> Record results on the Quality Assurance Data Panel Form Report results to study leadership and copy PATH Notify study leadership and PATH immediately if results are not as expected
	Training	Teach and inform individual test users how to properly conduct the test	<ul style="list-style-type: none"> For new users who are being trained Each panel can be used by up to 4 trainees 	<ul style="list-style-type: none"> Record results on the Training Panel Data Recording Sheet
	Proficiency	Provide assurance that the test user can correctly conduct the test and interpret results	<ul style="list-style-type: none"> For trained users to demonstrate proficiency prior to use in field Users are blinded to sample status Each panel can be used by up to 4 trainees 	<ul style="list-style-type: none"> Record results on the Proficiency Panel Data Recording Sheet Trainer reviews results to determine if trainee is proficient. If not, additional training needed
DURING FIELD STUDY	Daily Quality Control (QC)	Affirm that the test is working properly at the point of use	<ul style="list-style-type: none"> Used daily Negative and positive controls Each control tube can be used up to 3 times (3 days) 	<ul style="list-style-type: none"> Record results on the Daily Quality Control Data Form and monitor that results are as expected Notify study leadership and PATH immediately if results are not as expected