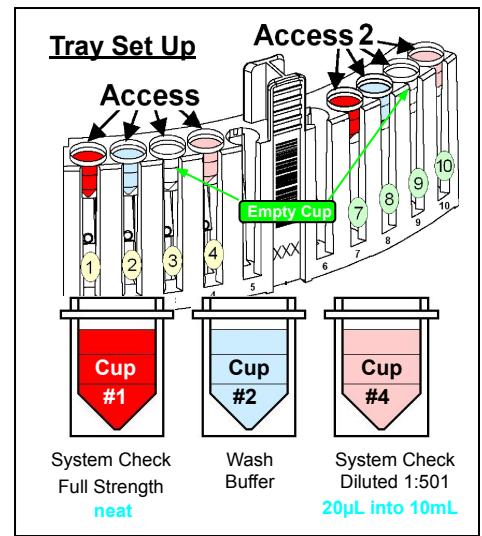


Systems Check

During the Systems Check procedure, the Main Pipettor aspirates and delivers reagents from sample cups to reaction vessels. A wash sequence is performed on two of the test areas. Substrate is delivered to the reaction vessel which acts on the reagent to produce photons. The photon excitement level is measured by the Luminometer resulting in information presented in relative light units (RLUs). The integrity of fluid aspiration and delivery systems is revealed during the systems check procedure. The four test, Washed, Clean, Substrate and Unwashed, aid in identifying instrument issues.



System Check Report

Wash Efficiency = 0.34 PPM

Test	Mean	SD	%CV	Ratio
Washed	12484	994.65	7.97	1.01
Clean	7614	58.70	0.77	
Substrate	7866	165.06	2.10	
Unwashed	9128497	63994.62	0.70	

Test	RLUs	Dark Counts	Drift Corr
Washed	12267	5	0.990
Washed	14931	5	0.990
Washed	13083	5	0.990
Washed	12663	5	0.990
Washed	12013	5	0.990
Washed	12441	5	0.990
Washed	12437	5	0.990
Washed	11269	5	0.990
Washed	11791	5	0.990
Washed	11940	5	0.990
Clean	7576	5	0.990
Clean	7707	5	0.990
Clean	7634	5	0.990
Clean	7586	5	0.990
Clean	7564	5	0.993
Substrate	7907	5	0.993
Substrate	7872	5	0.993
Substrate	7812	5	0.993
Substrate	7933	5	0.993
Substrate	7776	5	0.993
Substrate	7830	5	0.993
Substrate	7786	5	0.993
Substrate	7741	5	0.993
Substrate	7876	5	0.993
Substrate	8190	5	0.993
Unwashed	9112210	5	0.993
Unwashed	9162830	5	0.993
Unwashed	9083970	5	0.993
Unwashed	9137240	5	0.993
Unwashed	9022350	5	0.993
Unwashed	9118650	5	0.993
Unwashed	9047800	5	0.993
Unwashed	9194120	5	1.000
Unwashed	9195810	5	1.000
Unwashed	9209990	5	1.000

Wash Buffer Dispense & Aspirate: QS=350 µL, D2 & D3 =500 µL
 Substrate Dispense: 200 µL

Washed Check



Main Pipettor: 150µL from sample cup #1
 Pipettor draws 165µL and delivers 150µL

Wash & Aspirate 3x
 Substrate: 200µL
 Read: RLUs 5,000 - 1.25 x Substrate Mean
 CV ≤ 5%

Washed Check Mean > Substrate Check Mean

Clean Check



Main Pipettor: 150µL from sample cup #2
 Pipettor draws 165µL and delivers 150µL

Wash & Aspirate 3x
 Substrate: 200µL
 Read: RLUs
 No CV specification

Clean Check Mean < Washed Check Mean
 Clean Check Mean < Substrate Check Mean

Substrate Check



Substrate: 200µL
 Read: RLUs 5,000 - 8,700
 CV ≤ 3.5%

Ratio = $\frac{\text{Hi}}{\text{Mean}}$

Substrate Ratio

Highest RLU from the 1st four substrate reads is divided by the mean of the last 6 substrate reads. This ratio should be ≤ 1.1

Unwashed Check



Main Pipettor: 50µL from sample cup #4
 Pipettor draws 55µL and delivers 50µL
 Substrate: 200µL
 Read: RLUs 4 million - 10million (approximate)
 CV ≤ 1.2%

Wash Efficiency -1...+1 PPM

Dark Counts: Typically <50

Areas not tested in this procedure include; pipetting from reagent packs, **ultrasonics** for particle mixing, particle pipetting, small volume pipetting, sample dilutions and assay incubation.

System Check Interpretation Sheet for Field Service Engineers

Instrument Functions	Washed	Clean	Substrate	Unwashed
Main Pipettor				
aspirate reagents	NO	NO	NO	NO
mixes particles	NO	NO	NO	NO
level sense	YES	YES	NO	YES
aspirate sample	YES	YES	NO	YES
Incubation	NO	NO	NO	NO
Washing				
dispense	YES	YES	NO	NO
aspirate	YES	YES	NO	NO
mixing	YES	YES	YES	YES
particle resuspension	NO	NO	NO	NO
Substrate	YES	YES	YES	YES
Read	YES	YES	YES	YES
Equivalent Test	LumWash	LumWash	LumBlank	LumiAP
RLU Mean Range	5,000 to 1.25 x Substrate Mean	< Substrate < Washed	5,000–8,700	4-10 Million
% CV Specifications	<5%		<3.5%	≤1.2%
Ratio			<1.1	
Wash Efficiency: -1...+1 PPM				
Step 1: Substrate = substrate dispense & luminometer (air leak, substrate seals, luminometer)				
Step 2: Unwashed = main pipettor (precision pump seals, dirty probe, alignments)				
Step 3: Washed = washing system (mixing?, dirty aspirate probes, dispense or aspirate buffer?)				
Step 4: Ratio = aspiration system				