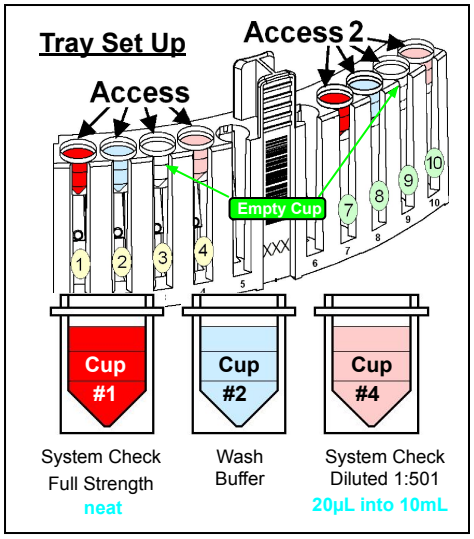
Systems Check

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	
Clean	7614	58.70	0.77	
Substrate	7866	165.06	2.10	1.01
Unwashed	9128497	63994.62	0.70	

Test		RLUs	Dark Counts	Drift Corr
Washed	mean=12,484	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	mean=7,614	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	mean=7,866	7907	5	0.993
Substrate		7872	5	0.993
Substrate		7812	5	0.993
Substrate		7933 ← Hi	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	mean=9,128,497	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%

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

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