

URIT-8210 Delivery Inspection Record

Order No.:

No.	821080001	Temperature	20°C	Humidity	72%
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1. Appearance check

Item	Qualified(Y/N)	Item	Qualified(Y/N)
shell	Y	Components installation	Y
Glue fixing	Y	Moving parts	Y

2. Instrument parameter

Item	Qualified(Y/N)	Item	Qualified(Y/N)
Power input	Y	Parameter setup reading	Y
Optic center	Y	Position of reagent probe	Y
Position of sample probe	Y	Position of stirrer	Y
Position of washing mechanism	Y	Temperature of reaction tray and reagent tray	Y
Liquid path	Y	A/D signal and blank reading	Y

3. Electrical safety check

Item	Mark	Allowable voltage limit of attachable components		Ground impedance	Dielectric strength	Continuous leakage current		Qualified (Y/N)
		Normal condition	Single fault condition			Normal condition	Single fault condition	
Requirements	Label paste correctly	Normal condition	Single fault condition	$\leq 0.1\Omega$	1390V/60sNo flash –over or voltage breakdown	Normal condition	Single fault condition	Y
results	correct	$\leq 33Vr.m.s$ or $70Vd.c$	$\leq 55Vr.m.s$ or $140Vd.c$	0.05Ω	Y	$\leq 5mA$	$\leq 10mA$	Y
		$26Vr.m.s$	$39Vr.m.s$			$1mA$	$3mA$	

4 Performance check

4.1 Stray light absorbance

Time	1	2	3	4	5	Average ≥ 4.0	Qualified(Y/N)
Result	5.3012	5.3692	5.1057	5.3659	5.3074	5.2917	Y
Remark							

4.2 Absorbance stability (340 nm: A= 0.5122)

	Time (s)	absorbance	Time (s)	absorbance	Time (s)	absorbance	Time (s)	absorbance	Time (s)	absorbance	Time (s)	Absorbance
	Result	30	0.4950	330	0.4960	630	0.4959	930	0.4945	1230	0.4961	1530
60		0.4957	360	0.4959	660	0.4953	960	0.4947	1260	0.4960	1560	0.5145
90		0.4941	390	0.4955	690	0.4954	990	0.4946	1290	0.4957	1590	0.5147
120		0.4932	420	0.4957	720	0.4957	1020	0.4952	1320	0.4952	1620	0.5142
150		0.4937	450	0.4951	750	0.4959	1050	0.4956	1350	0.4958	1650	0.5146
180		0.4942	480	0.4957	780	0.4958	1080	0.4951	1380	0.4949	1680	0.5108
210		0.4957	510	0.4961	810	0.4948	1110	0.4957	1410	0.4942	1710	0.5121
240		0.4952	540	0.4962	840	0.4942	1140	0.4956	1440	0.4958	1740	0.5116
270		0.4961	570	0.4961	870	0.4936	1170	0.4963	1470	0.4953	1770	0.5106
300		0.4966	600	0.4969	900	0.4937	1200	0.4963	1500	0.4959	1800	0.5147
Stability	$\Delta A \leq 0.01$						$\Delta A = 0.0047$					

Remark		Qualified (Y/N)	Y
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4.3 Absorbance stability (660 nm; A=0.4981)

Result	Time (s)	absorbance	Time (s)	absorbance	Time (s)	absorbance	Time (s)	absorbance	Time (s)	absorbance	Time (s)	Absorbance
	30	0.5084	330	0.5083	630	0.5084	930	0.5087	1230	0.5085	1530	0.5011
	60	0.5085	360	0.5087	660	0.5087	960	0.5087	1260	0.5087	1560	0.5120
	90	0.5086	390	0.5089	690	0.5086	990	0.5086	1290	0.5086	1590	0.5004
	120	0.5088	420	0.5088	720	0.5087	1020	0.5085	1320	0.5087	1620	0.5102
	150	0.5084	450	0.5089	750	0.5085	1050	0.5085	1350	0.5088	1650	0.5011
	180	0.5082	480	0.5088	780	0.5084	1080	0.5087	1380	0.5086	1680	0.5126
	210	0.5081	510	0.5089	810	0.5087	1110	0.5084	1410	0.5089	1710	0.5111
	240	0.5081	540	0.5087	840	0.5086	1140	0.5085	1440	0.5085	1740	0.5092
	270	0.5079	570	0.5086	870	0.5087	1170	0.5088	1470	0.5087	1770	0.5078
300	0.5081	600	0.5085	900	0.5086	1200	0.5087	1500	0.5089	1800	0.5071	
Stability	$\Delta A \leq 0.01$						$\Delta A = 0.0041$					
Remark							Qualified (Y/N)			Y		

4.4 Absorbance repeatability (A= 1.0731)

Result	No.	Result	No.	Result	No.	Result	No.	Result
	1	1.0801	6	1.0667	11	1.0639	16	1.0781
	2	1.0738	7	1.0689	12	1.0795	17	1.0769
	3	1.0689	8	1.0743	13	1.0665	18	1.0812
	4	1.0747	9	1.0857	14	1.0678	19	1.0668
	5	1.0824	10	1.0855	15	1.0695	20	1.0659
Repeatability	CV \leq 1.0%							
	0.58%							
Remark					Qualified (Y/N)		Y	

4.5 clinical project precision

Result	Item	ALT		TP		UREA		
	Lot No. /reference		K:		K:		K:	
	1(11)	44.1	47	68.1	67.9	10.41	10.61	
	2(12)	46.5	45.6	66.8	68.1	10.34	10.57	
	3(13)	43	48.1	67	67	10.3	10.67	
	4(14)	46	47	68	66.5	10.41	10.81	
	5(15)	46	48.2	67.2	65.8	10.23	10.76	
	6(16)	45.7	47.5	67	68.1	10.12	10.71	
	7(17)	46.5	46	66.5	67.5	10.71	10.8	
	8(18)	46.2	46	67.5	66.8	10.64	10.79	
	9(19)	44.7	46.5	67	67.5	10.58	10.78	
	45.2	46.5	67	67.5	10.78	10.68		
CV value		CV \leq 5%		CV \leq 2.5%		CV \leq 2.5%		
Actual CV value		3.46%		1.58%		2.21%		
Sample lot No.					Qualified (Y/N)		Y	

5. Packing

Item	Qualified (Y/N)	Item	Qualified (Y/N)
Host packing	Y	Accessory packing	Y
Cabinet packing		Remark	

6. Result

Qualified/unqualified	Handle	Inspector	Review person	Date
<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	<input checked="" type="checkbox"/> storage <input type="checkbox"/> repair			

Main performance inspection (Random inspection)

1. Temperature accuracy and fluctuation

Requirement	Time	Temperature	Time	Temperature	Time	Temperature	Time	Temperature
Accuracy: setting temperature $\pm 0.3^{\circ}\text{C}$ Fluctuation: not exceed $\pm 0.1^{\circ}\text{C}$	1	37.0	6	37.1	11	37.0	16	37.0
	2	37.0	7	37.1	12	37.0	17	37.1
	3	37.1	8	37.1	13	37.0	18	37.1
	4	37.0	9	37.1	14	37.0	19	37.1
	5	37.0	10	37.1	15	37.0	20	37.0
Result	Accuracy				fluctuation			
	0.05				± 0.1			
Remark					Qualified (Y/N)		Y	

2. Carried pollution rate

	Time	Absorbance A	$A_{i4}-A_{i6}$	K_i	Carried pollution rate	Requirement	Qualified (Y/N)
	Carried pollution rate	1	6.0000	0.0138			
6.0000							
6.0000							
0.0381							
0.0113							
0.0043							
2		6.0000	0.0149	0.0002			
		6.0000					
		6.0000					
		0.0395					
		0.0098					
		0.0039					
3		6.0000	0.0215	0.0039			
		6.0000					
		6.0000					
		0.0384					
		0.0093					
		0.0041					
4		6.0000	0.0121	0.0041			
		6.0000					
		6.0000					
		0.0343					
		0.0103					
		0.0054					
5	6.0000	0.0129	0.0021				
	6.0000						
	6.0000						
	0.0323						
	0.0116						
	0.0049						

3. Linear range inspection(340nm):

Linear range	Relative bias in the range of 5% and not less than 3.2		Dilution ratio 4/10	Relative bias=3.07%			
			Dilution ratio 5/10	Relative bias=2.58%			
			Dilution ratio 6/10	Relative bias =2.39%			
			Dilution ratio 7/10	Relative bias =1.76%			
			Dilution ratio 8/10	Relative bias =1.08%			
			Dilution ratio 9/10	Relative bias =1.69%			
			Dilution ratio 10/10	Relative bias =2.54%			
Dilution ratio	Data					Average value	
	Data						
0	0.0137	0.0134	0.0156	0.0132	0.0147	0.0142	
1/10	0.3295	0.3293	0.3287	0.3294	0.3289	0.3291	
2/10	0.6849	0.6845	0.6843	0.6842	0.6843	0.6846	
3/10	0.9987	0.9987	0.9984	0.9983	0.9982	0.9985	
4/10	1.3025	1.3022	1.3023	1.3026	1.3022	1.3203	
5/10	1.6954	1.6948	1.6949	1.6951	1.6948	1.6951	
6/10	1.9716	1.9709	1.9714	1.9712	1.9711	1.9713	
7/10	2.2102	2.2111	2.2108	2.2112	2.2114	2.2108	
8/10	2.6017	2.6019	2.6016	2.6014	2.6010	2.6015	
9/10	2.9115	2.9116	2.9117	2.9114	2.9112	2.9114	
10/10	3.1985	3.1989	3.1983	3.1982	3.1985	3.1984	
Remark					Qualified (Y/N)	Y	

4. Linear range inspection(480nm):

Linear range	Relative bias in the range of 5% and not less than 3.2		Dilution ratio 4/10	Relative bias=2.68%			
			Dilution ratio 5/10	Relative bias=1.17%			
			Dilution ratio 6/10	Relative bias =1.46%			
			Dilution ratio 7/10	Relative bias =1.23%			
			Dilution ratio 8/10	Relative bias =-0.15%			
			Dilution ratio 9/10	Relative bias =0.71%			
			Dilution ratio 10/10	Relative bias = -3.41%			
Dilution ratio	Data					Average value	
	Data						
0	0.0031	0.0034	0.0035	0.0037	0.0038	0.0034	
1/10	0.3675	0.3671	0.3672	0.3671	0.3675	0.3673	
2/10	0.6742	0.6741	0.6745	0.6746	0.6745	0.6743	
3/10	0.9981	0.9987	0.9985	0.9981	0.9986	0.9984	
4/10	1.2541	1.2547	1.2579	1.2543	1.2542	1.2545	
5/10	1.5964	1.5962	1.5964	1.5967	1.59965	1.5964	
6/10	2.0011	2.0016	2.0015	2.0018	2.0016	2.0014	
7/10	2.2319	2.3216	2.3214	2.3217	2.3216	2.3217	
8/10	2.6162	2.6167	2.6165	2.6164	2.6163	2.6165	
9/10	2.9941	2.9947	2.9945	2.9943	2.9945	2.9944	
10/10	3.1254	3.1252	3.1257	3.1256	3.1254	3.1255	
Remark					Qualified (Y/N)	Y	

5. Result

Qualified/unqualified	Inspector	Review person	Date
<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified			

