RTLC Daily Check Source Strip

Datasheet

Source standard is a 10cm x 2cm laminated strip of printer paper. Laminate thickness and composition ensure that β particles are emitted. The ¹³⁷Cs spots are placed on the strip at 1cm, 5cm, and 7cm distance from one side of the strip (see Figure 1). The spots of radioactivity are within the red dots at the centers of the three trefoil icons shown in the picture.



Figure 1. Picture of RTLC Daily Check Source Strip. Distances of red dots (point sources of activity) are 1cm, 5cm, and 7cm (+/- 0.05cm) from the right side of the strip of paper.

Activity amounts of spots are in ratios of 2.5:95.0:2.5 in order to mimic FDG quality control tests for production purposes. ¹³⁷Cs β - and γ -emissions allow for convenient, efficient, and accurate verification of any RTLC instrument for spatial, constancy, and accuracy parameters. Total activity of the strips ranges from ~0.247 µCi (9kBq) to ~10 µCi (370 kBq). These activities are chosen to provide good statistical analytics in short instrument operation intervals, but also remain as low as possible to facilitate shipping of item.

Note: Activity of strip is highly dependent on instrument on which it will be used and shipping destination. If you are interested in purchasing a strip and or possible activities available, please contact Cyclomedical International Inc. at <u>RTLCorder@cyclomedical.com</u>.

Sample data and analytics:

Sample data and analytics for a prototype RTLC Daily Check Source Strip were taken on a Carroll & Ramsey EZScan at Wisconsin Medical Cyclotron in West Allis, Wi. A sample chromatogram of the source strip can be seen in Figure 2.

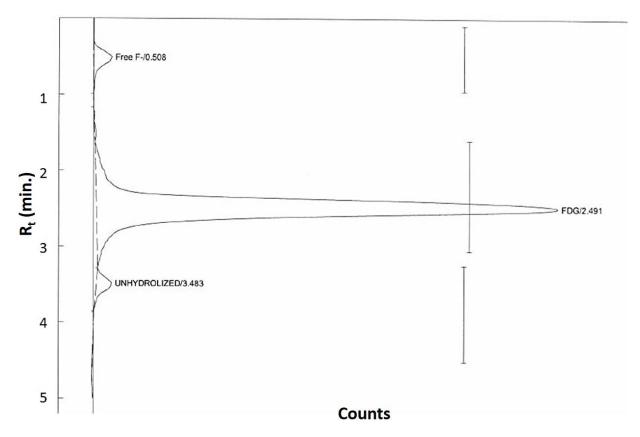


Figure 2. RTLC chromatogram of RTLC Daily Check Source Strip. The chromatogram was taken on a Carroll & Ramsey EZScan chromatograph. The bed speed of the device is ~2cm/min. The resultant location of the peaks are 1.016 cm, 4.982 cm, and 6.966 cm.

The instrument was checked for precision by running the strip ten times and constancy by running the strip 3 times each on three consecutive days. The resulting data showed that the EZScan had relative standard deviations for retention time, area, and % area of 0.4% - 2.8%, 1.7% - 6.5%, and 0.2% - 6.1%, respectively. Also, the percent activity of total activity for each of the three peaks were measured as 3.5%, 93.9%, and 2.6%, respectively. See Figure 3 for a spreadsheet of RTLC precision data. Constancy result indicated that the EZScan ranged from 1.6% - 4.5% based on the expected value peak areas on a daily basis. See Figure 4 for a spreadsheet of RTLC constancy data.

		Cyclomedical I Cesium-137 RTLC S								
	· · · · · · · · · · · · · · · · · · ·	2 May, 2016 Wisco		108 C						
Component	Retention Time (min) Rete	ention Distance (cm)	Area	Area %	Dev. From Desired (cm)					
Free Fluoride	0.5080	1.02616	53.4125	3.4814	0.02616					
	0.5410	1.09282	61.0130	3.8519	0.09282					
	0.5500	1.11100	51.8965	3.3200	0.11100					
	0.5410	1.09282	54.5895	3.4998	0.09282					
	0.5500	1.11100	55.2775	3.5501	0.11100					
	0.5410	1.09282	57.4450	3.6732	0.09282					
	0.5330	1.07666	60.6065	3.8384	0.07666					
1	0.5410	1.09282	50.8600	3.2481	0.09282					
	0.5410	1.09282	55.1330	3.3727	0.09282					
	0.5080	1.02616	51.2497	3.3203	0.02616					
Ave.	0.5354	1.08151	55.1483	3.5156	0.08151					
Stand. Dev.	0.0152	0.0308	3.6050	0.2142	0.03079					
Rel. Stan.Dev	2.847	2.847	6.5370	6.094						
Component	Retention Time (min) Rete	antion Distance (cm)	Area	Area %	Dev. From Desired (cm)					
FDG	2 4830	5.01566	1442.8190	94.0417	0.01566					
100	2.4910	5.03182	1483.0450	93.6273	0.03182					
	2.4910	5.03182	1469.4775	94.0063	0.03182					
	2.5000	5.05000	1463.8715	93.8516	0.05000					
	2.4910	5.03182	1459.9510	93.7631	0.03182					
	2.4910	5.03182	1463.1530	93.5587	0.03182					
	2.4910	5.03182	1479.6820	93.7131	0.03182					
	2.5000	5.05000	1473.2400	94.0863	0.05182					
	2.5080	5.06616	1533.2162	93.7923	0.06616					
	2.4910	5.03182	1451.8260	94.0579	0.03182					
Ave.	le constant	5.03727	1472.0281	93.8498	0.03727					
Stand, Dev.		0.0142	24.6855	0.1898	0.03727					
Rel. Stan.Dev		0.281	1.6770	0.202	0.01410					
				12 (22)						
and other a survey and the survey	Retention Time (min) Rete		Area	Area %	Dev. From Desired (cm)					
Unhydrolized	3.5160	7.10232	38.0015	2.4769	0.10232					
	3.5080	7.08616	39.9297	2.5208	0.08616					
	3.4830	7.03566	41.7960	2.6738	0.03566					
	3.4910	7.05182	41.3120	2.6486	0.05182					
	3.5250	7.12050	41.8357	2.6868	0.12050					
	3.4830	7.03566	43.2895	2.7681	0.03566					
	3.4910	7.05182	38.6605	2.4485	0.05182					
	3.4830	7.03566	41.7390	2.6656	0.03566					
	3.5000	7.07000	46.3440	2.8350	0.07000					
	3.4830	7.03566	40.4695	2.6219	0.03566					
Ave.		7.06253	41.3377	2.6346	0.06253					
Stand. Dev.		0.0310	2.3694	0.1229	0.03105					
Rel. Stan.Dev	0.440	0.440	5.7318	4.666						

Figure 3. EZScan Precision data using RTLC Daily Check Source Strip.

_				12. State 1 - St	100 (100 (100 (100 (100 (100 (100 (100	Cesium-137 RTLC Stri		
	4			clotron	n Medical Cy	2 May, 2016 Wisconsi		
-			Date	Area %	Area	Retention Distance (cm)	Retention Time (min)	Component
			2-May-16	3.475	59,451	1.077	0.533	Free Fluoride
			2-May-16	3,419	59.135	1.093	0.541	
Deviation	Expected	Ave. Area 59.335	2-May-16	3.438	59.421	1.061	0.525	
			3-May-16	3.556	58.957	1.061	0.525	
	1		3-May-16	3.207	52.474	1.010	0.500	
Deviation	Expected 59.33172	Ave. Area 56.675	3-May-16	3.518	58.596	1.077	0.533	
	10000000000000		4-May-16	3.603	60.972	1.042	0.516	
			4-May-16	3.447	58.635	1.093	0.541	
Deviation	Expected 59.32797	Ave. Area 59.510	4-May-16	3.493	58.924	1.061	0.525	
			2-May-16	93.721	1603.391	5.066	2.508	FDG
			2-May-16	93.712	1620.705	5.050	2.500	
Deviation	Expected	Ave. Area 1614.847	2-May-16	93.763	1620.445	5.016	2.483	
			3-May-16	93.484	1549.961	5.016	2.483	
			3-May-16	94.108	1539.959	5.016	2.483	
Deviation	Expected	Ave. Area	3-May-16	93.442	1556.374	5.016	2.483	
4.09	1614.74458	1548.765						
			4-May-16	93.589	1583.784	5.000	2.475	
			4-May-16	93.751	1594.586	5.032	2.491	
Deviation	Expected 1614.64251	Ave. Area 1585.665	4-May-16	93.572	1578.626	5.016	2.483	
			2-May-16	2.804	47.972	7.121	3.525	Unhydrolized
			2-May-16	2.869	49.623	7.137	3.533	
Deviation	Expected	Ave. Area 48.657	2-May-16	2.799	48.375	7.036	3.483	
			3-May-16	2.960	49.080	7.052	3.491	
			3-May-16	2.686	43.945	7.001	3.466	
Deviation 1.58%	Expected 48.65352	Ave. Area 47.884	3-May-16	3.040	50.627	7.020	3.475	
			4-May-16	2.808	47.521	7.070	3.500	
			4-May-16	2.802	47.655	7.086	3.508	
Deviation	Expected 48.65045	Ave. Area 48.235	4-May-16	2.936	49.531	7.086	3.508	

Figure 4. EZScan constancy results using RTLC Daily Check Source Strip.

The results from the EZSCan indicate that the instrument is functioning well and well within acceptable limits for daily FDG quality control testing. However, the strip does inform us that retention times of greater than 2.4 min (distance > 0.5 cm) are more reliable than retention times less than 2.4 min (distance < 0.5 cm) due to better relative standard deviations. Also, the instrument is more accurate for measurements activities above 1 μ Ci (37 kBq) as compare to those below 1 μ Ci (37 kBq).

Of note, by using the method dictated by the local SOPs, the instrument was shown to have an offset of approximately 1mm (Figure 5). The figure shows that all calculated distances are short of the expected/desired distances by approximately 1mm. Although 1mm is not large enough to fail instrument qualification or process validation, in this case, the strip could be used to minimize this systematic error and thereby optimize the use of this instrument.

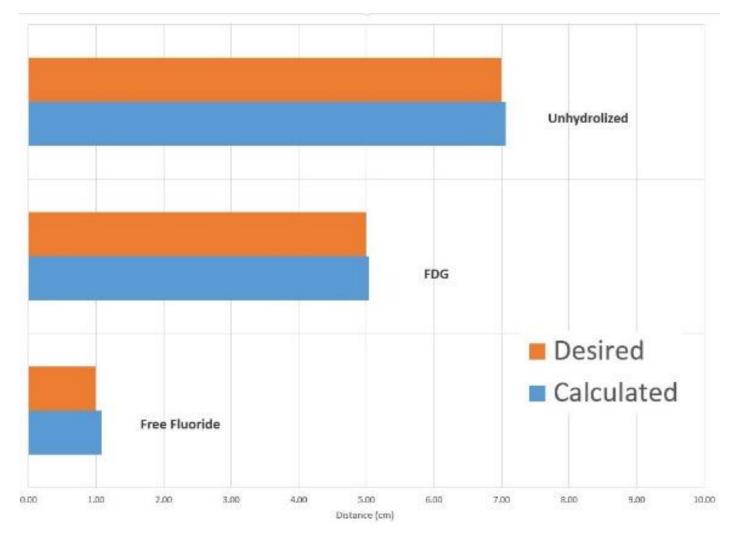


Figure 5. Chart of EZScan Desired vs. Calculated spot distances