

### Testing 200ml and 300ml IV-Bags with VeriPac Vacuum Decay Technology

		200	ml	300ml		
		leak size [µm]	Number	leak size [µm]	fNumber	
	NC	N/A	30	N/A	30	
		20	9	20	9	
	PC	/	/	15	2	
		/	/	10	2	

Table 1: Summary of tested samples

### **POSITIVE CONTROLS**



From left to right: 200ml capillary PC, 200ml laser drilled disk PC, 300ml capillary PC, 300ml laser drilled disk PC

#### **VERIPAC VACUUM DECAY TEST SYSTEM SETUP**



Test setup with VeriPac, Test Chamber and Microcallibrator

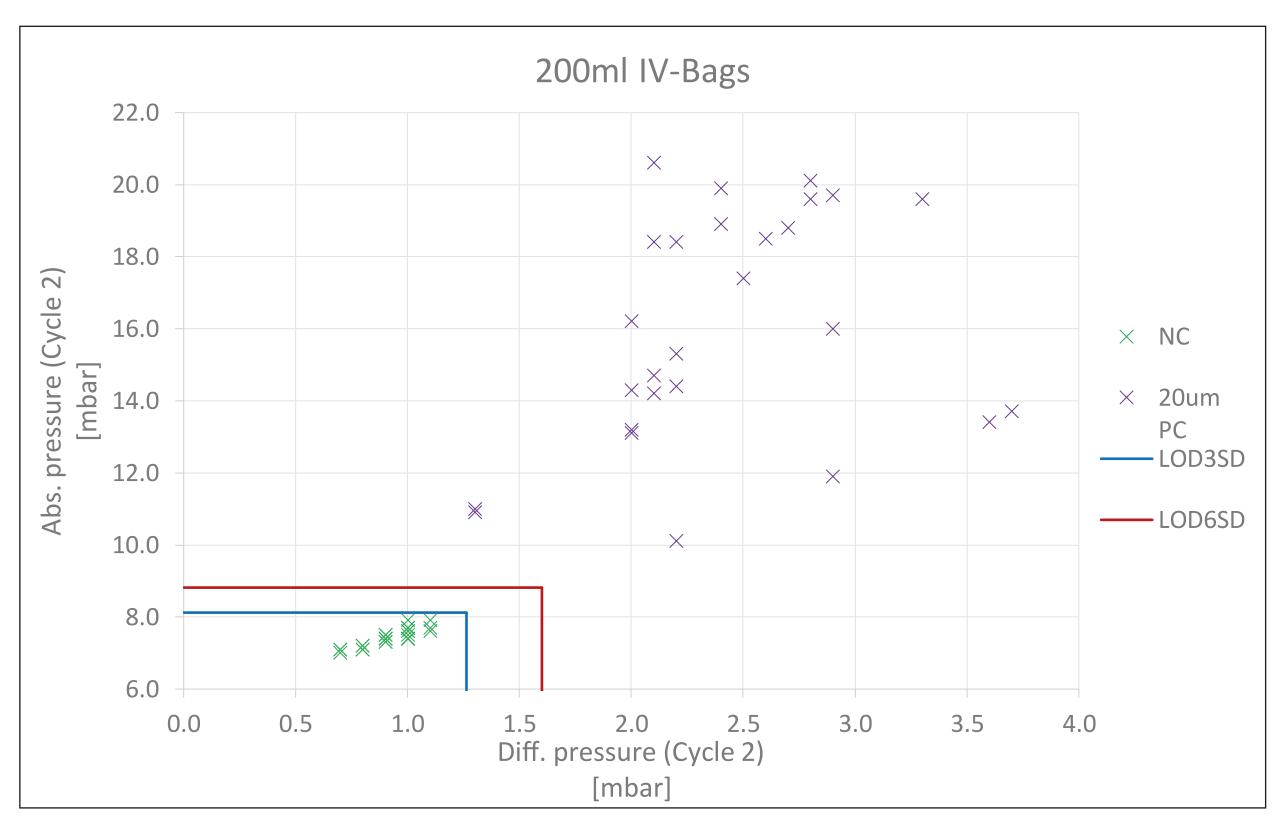


Example of 300ml (left) and 200ml (right) NC samples.

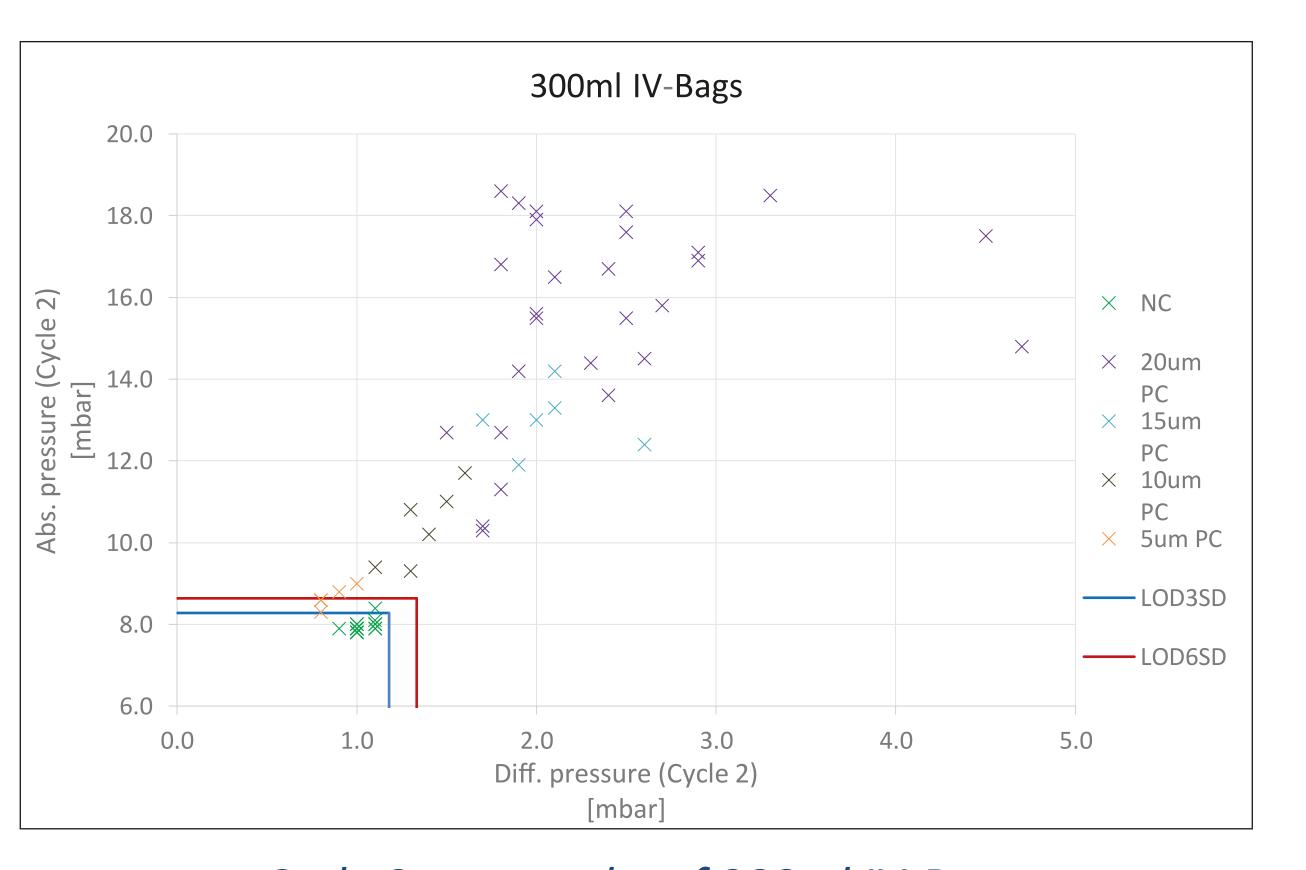
### **RESULTS**

	200ml IV-Bags				300ml IV-Bags						
	Cycle 1		Cycle 2		Cycle 1		Cycle 2				
	Abs. pres.	Diff. pres.	Abs. pres.	Diff. pres.	Abs. pres.	Diff. pres.	Abs. pres.	Diff. pres.			
	[mbar]	[mbar]	[mbar]	[mbar]	[mbar]	[mbar]	[mbar]	[mbar]			
AVG	297.01	3.48	7.43	0.93	265.80	3.61	7.92	1.03			
SD	5.39	0.41	0.23	0.11	9.38	0.52	0.12	0.05			
LOD <sub>3SD</sub>	313.19	4.70	8.12	1.26	293.94	5.18	8.28	1.18			
LOD <sub>6SD</sub>	329.37	5.92	8.82	1.60	322.09	6.74	8.64	1.33			

Statistical footprint from negative controls for 200ml and 300ml bags



Cycle 2 test results of 200ml IV-Bags (Negative Controls & Positive Controls)



Cycle 2 test results of 300ml IV-Bags (Negative Controls & Positive Controls)

## Container Closure Integrity Testing

# MicroCurrent HVLD Technology Testing AVT80 108 mg/0.68 mL in 1.0 mL syringes with a fill volume of ca. 0.71 mL with E-Scan® 615

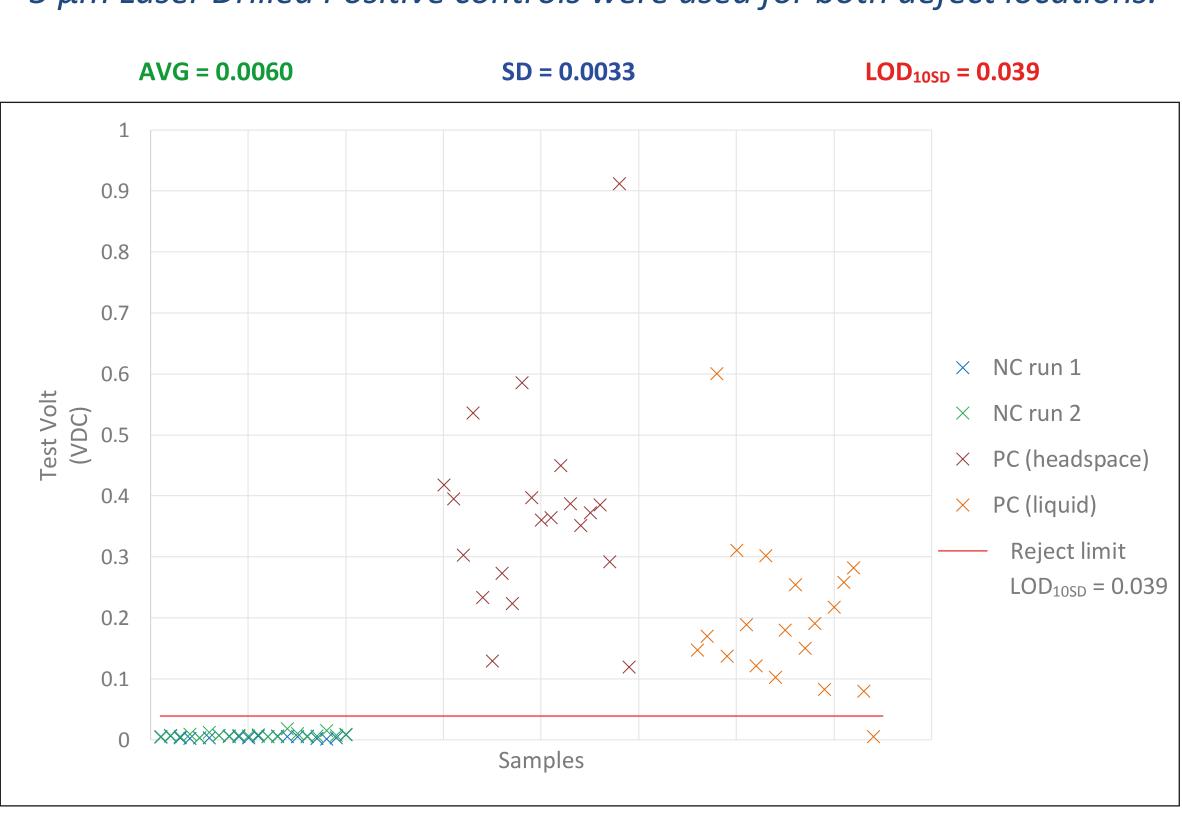
## HVLD<sup>MC</sup>: E-SCAN® 615 INITIAL SETUP PARAMETERS

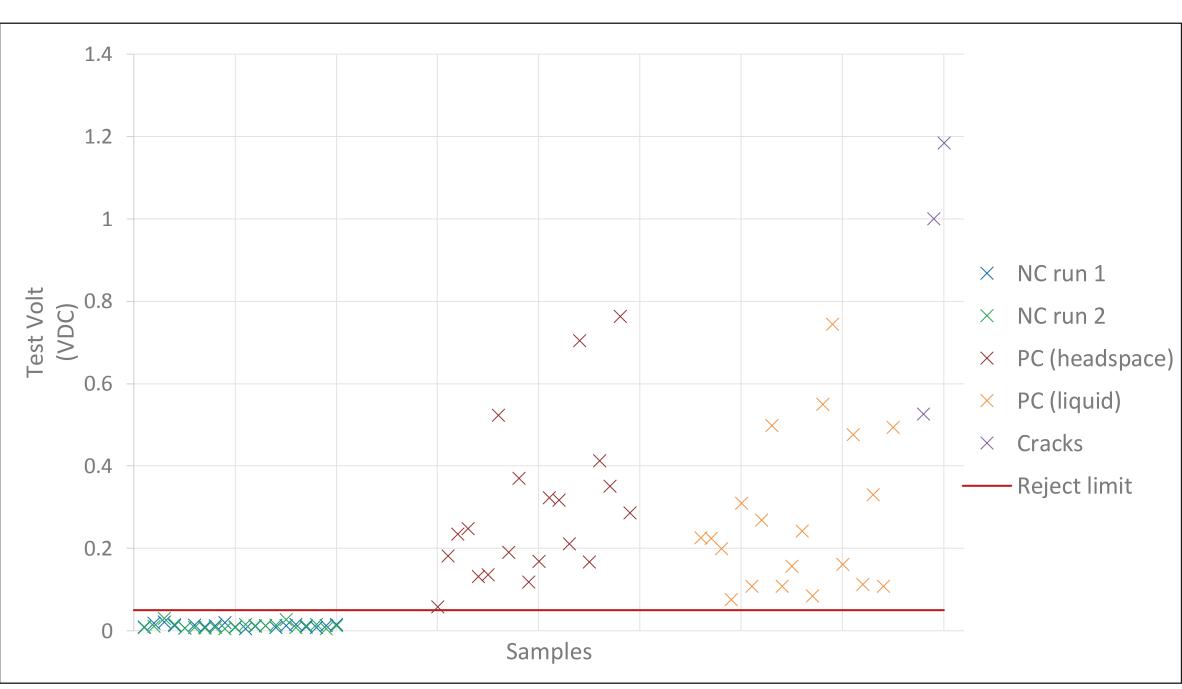


### **RESULTS**

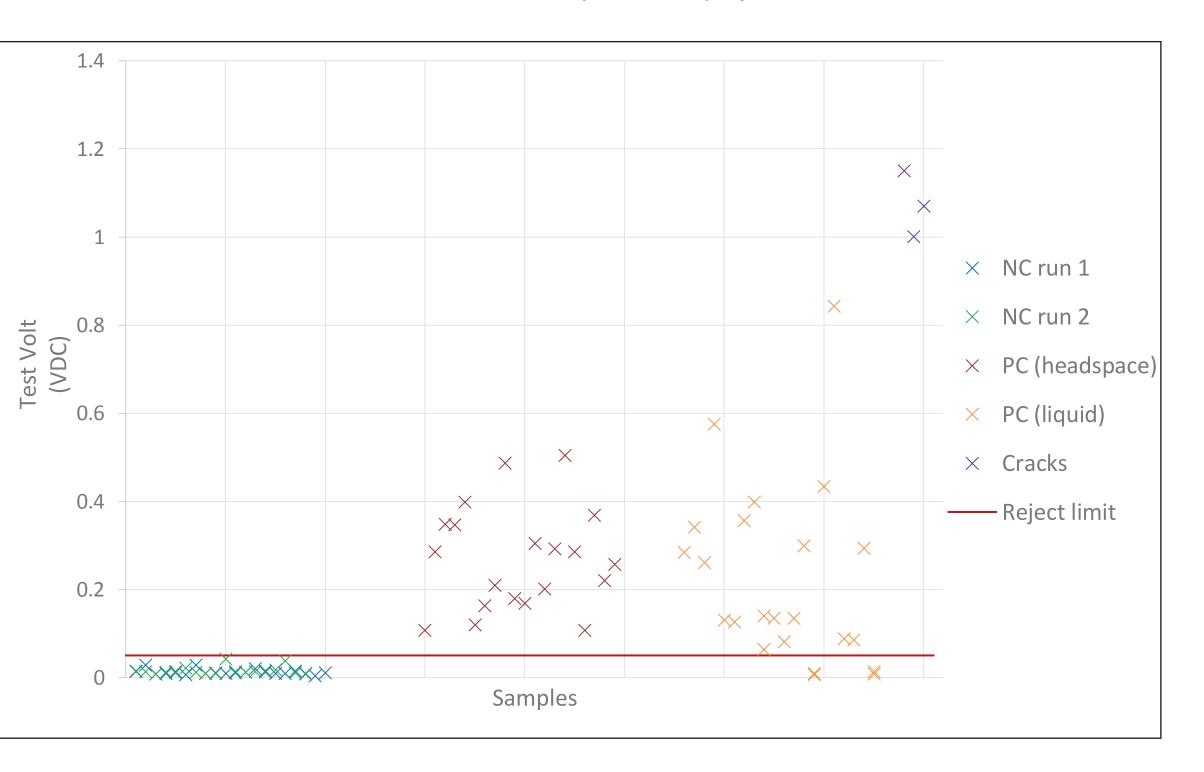
For this study, 2 runs of tests of 20 negative control samples were made with 1 run of all 40 positive controls

5 μm Laser Drilled Positive controls were used for both defect locations.





Results Week 1: All test results from tests performed on 2024-03-20

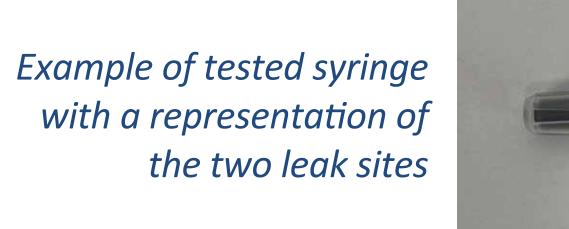


Results Week 3: All test results from tests performed on 2024-04-03.





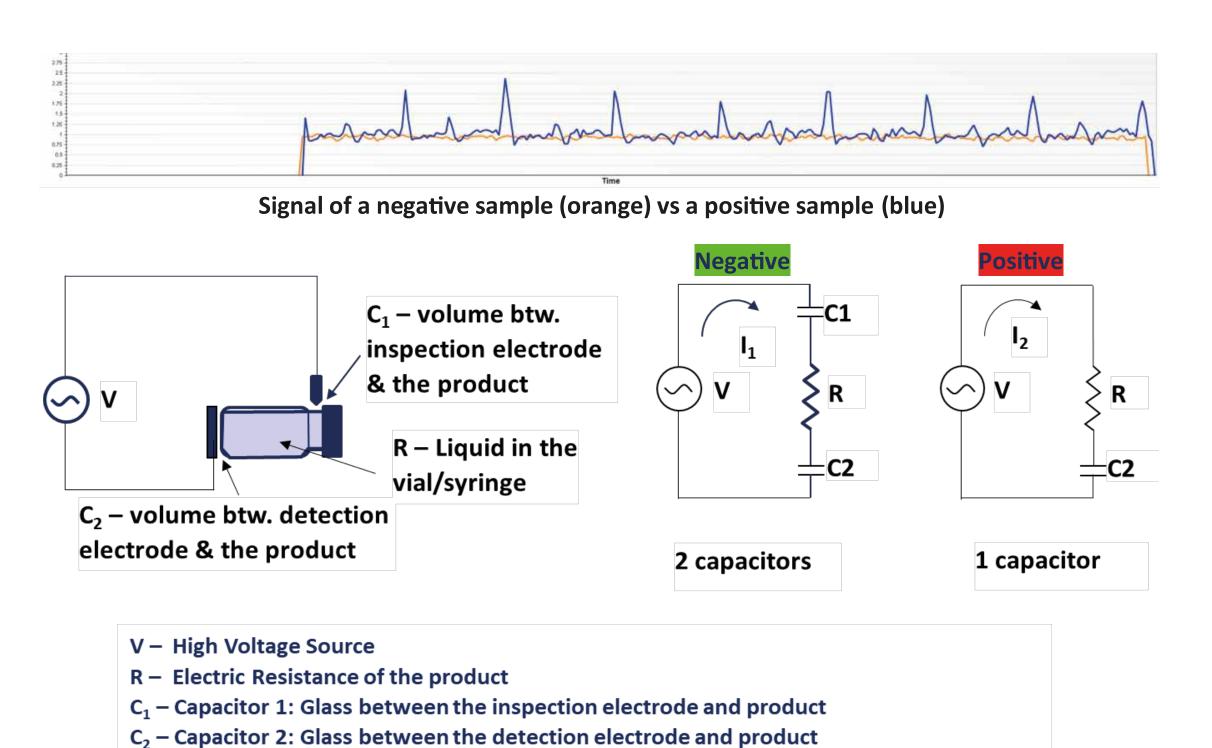
Top view of a sample in the holder.

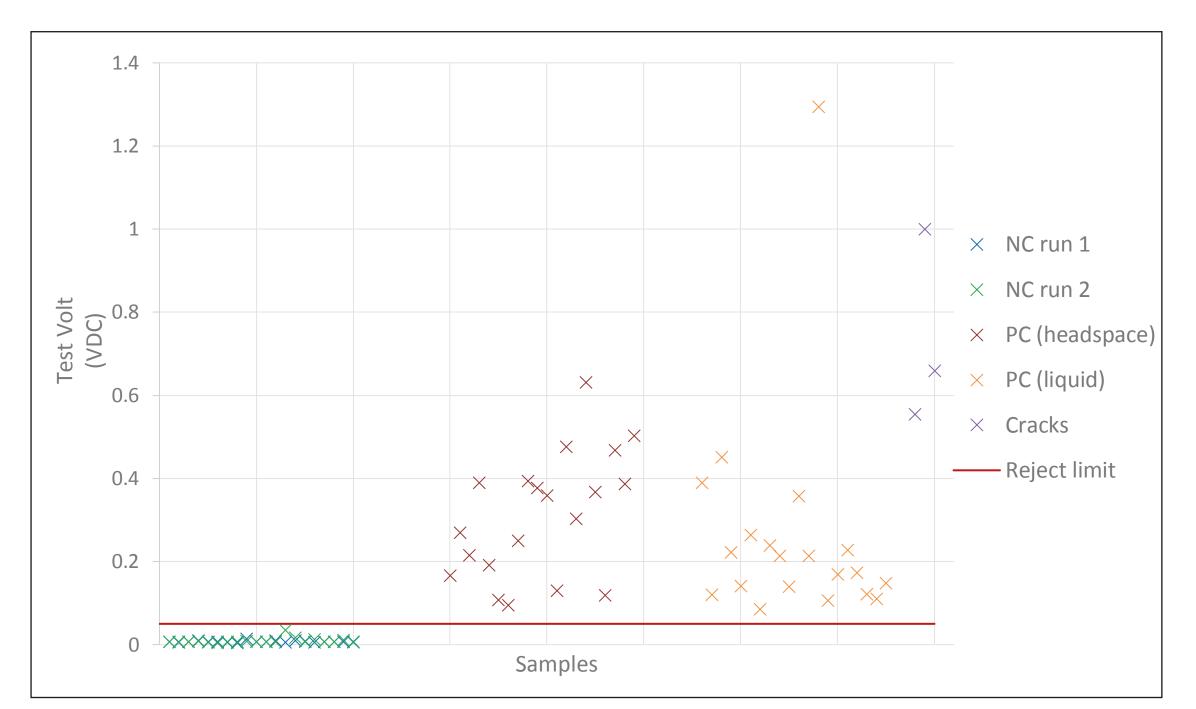


<sub>1</sub> – current produced when product container is sealed

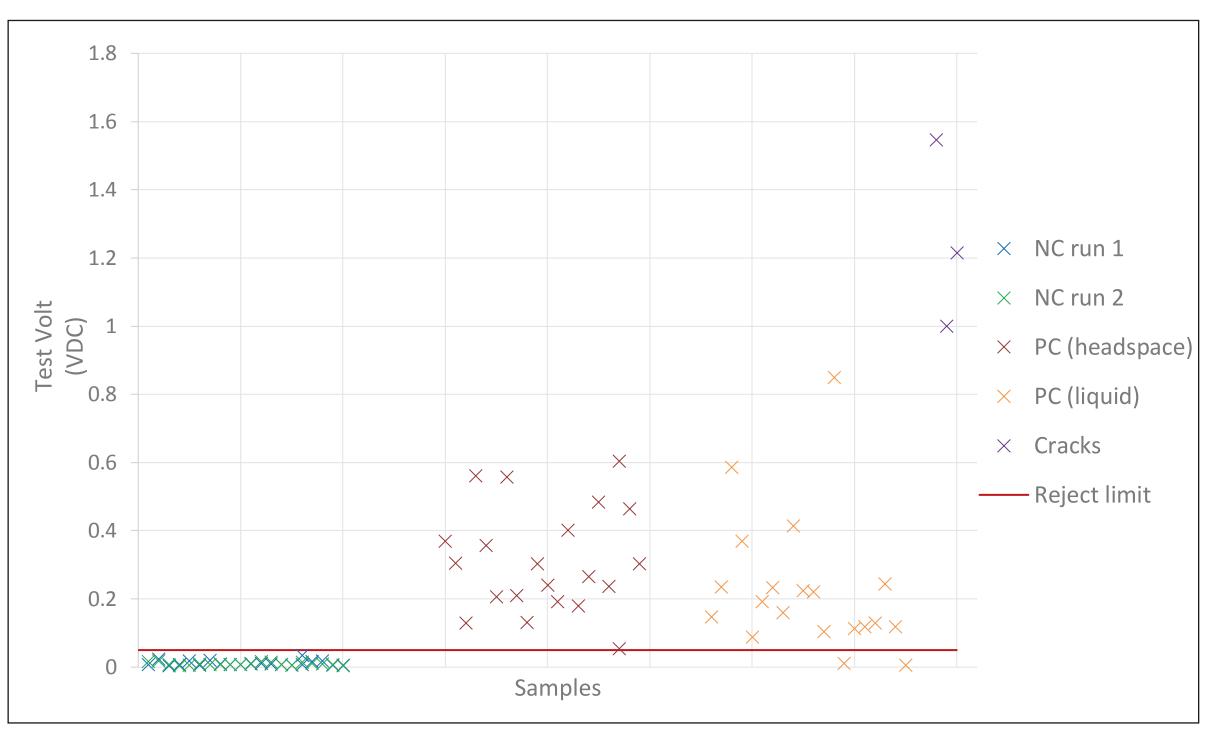
I<sub>2</sub> – current produced when product container is defective







Results Week 2: All test results from tests performed on 2024-03-28'



Results Week 4: All test results from tests performed on 2024-04-08.