

PreVAS Validation Update

May 2011

		Sterility	Endotoxin	Particulates	Mechanical	Extractables	Class VI	Package Integrity
RTS Needles	Small	✓	✓	✓		✓	✓	
	Large					✓	✓	
Gamma Needles	Small	✓	✓	✓		✓	✓	
	Large					✓	✓	
Pumps	6cc		✓	✓	✓	✓	✓	
	50cc					✓	✓	
Minimum System	6cc	✓	✓	✓				
	50cc		✓					
Maximum System	6cc	✓	✓	✓				
	50cc		✓					

Small Needles: 1.2 mm, 1.6 mm, 2.1 mm, 3.0 mm

Large Needles: 3.8 mm, 4.6 mm, 5.5 mm

Not Needed
Completed
Scheduled
Need to Re-Test

