

First-Gen



Second-Gen

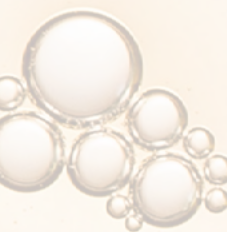


**NEXT-GEN**

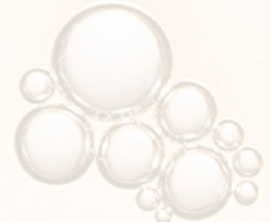
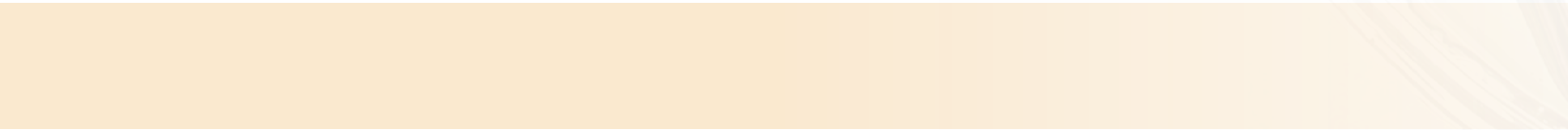


## *Mapping Your Journey*

From LAL Reagents to  
PyroSmart NextGen<sup>®</sup>  
Recombinant Cascade Reagent



# *Mapping Your Journey*

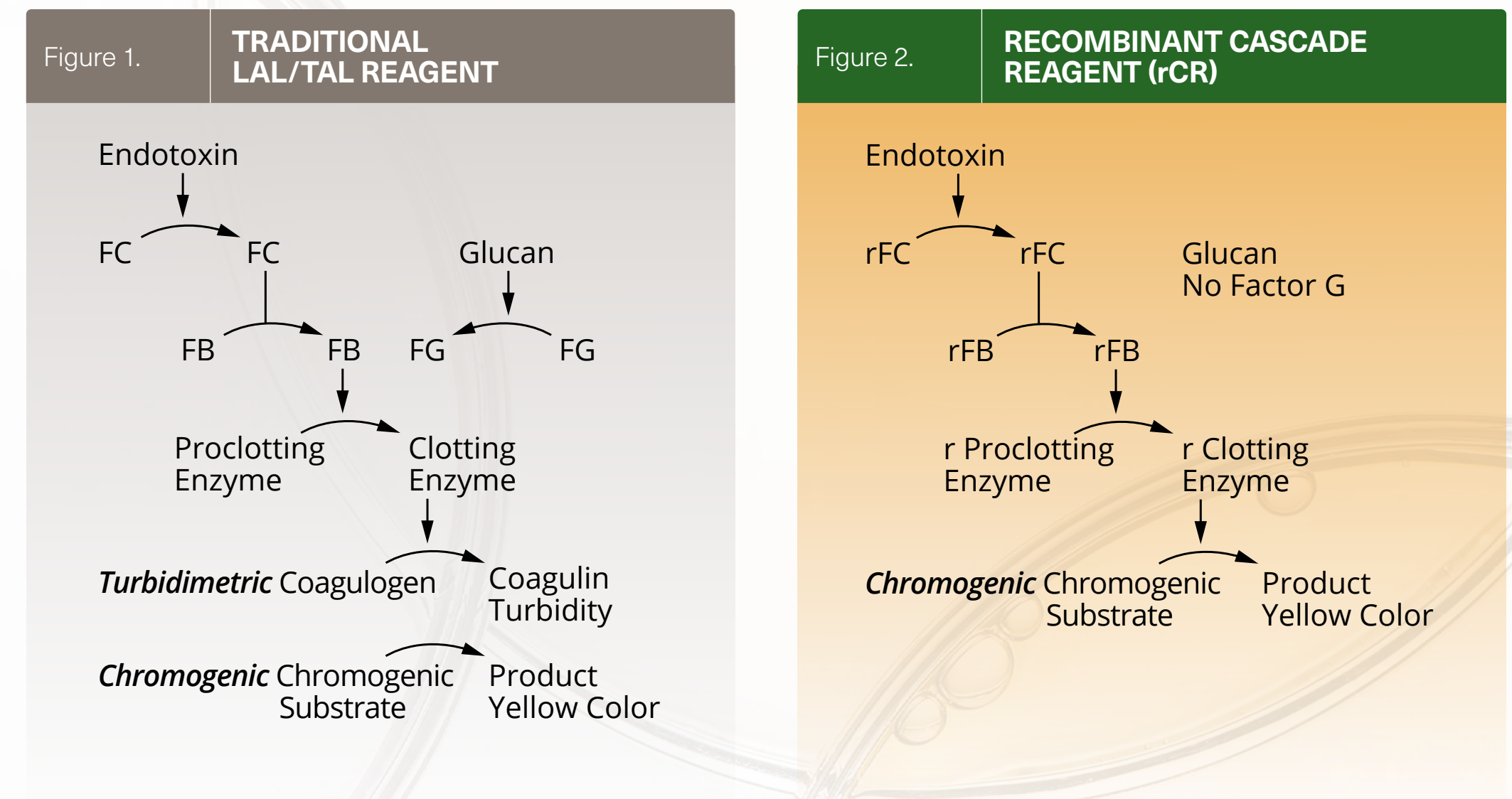


WHAT IS BET & rBET?

**BET Is a Proven Test,  
With 50 Years of Real-World Performance.**

The Bacterial Endotoxins Test (BET) is a release test for detection and quantitation of bacterial endotoxins in parenteral drug products and medical devices. Limulus Amebocyte Lysate (LAL) reagents have been used since the 1970s to perform the BET assay. ACC's Pyrotell® gel-clot reagent was the first LAL reagent to receive an FDA license, allowing for a qualitative method to detect endotoxins. This was followed by photometric methods (turbidimetric and chromogenic), which could be used for the quantitative measure of endotoxins. All these methods rely on the same mechanism of action — the LAL cascade (see Fig. 1).

Building on this success, the PyroSmart® reagent (based on genetic sequence of the Japanese horseshoe crab *Tachypleus tridentatus*, TAL) was developed and characterized as the first recombinant cascade reagent (rCR)<sup>1,2,3,4</sup>. Later on, to accommodate the fact that the majority of global customers used LAL reagents, not TAL, for endotoxin testing, PyroSmart NextGen® was developed to incorporate recombinant proteins based on the genetic sequence of *Limulus polyphemus*. Figure 2 shows the recombinant cascade.



**DETECTION METHOD**

**Absorbance.** The enzymatic cascade produces a colored compound from a chromogenic substrate.

WHY TRANSITION FROM LAL TO rBET?

**Transitioning to rBET is Directly Tracked by the Sustainability Scorecard for Endotoxin Testing.<sup>5</sup>**

**1**

**2**

**3**



PREP

PLAN

PROCEED

WHY RECOMBINANT CASCADE REAGENT (rCR)?

**rCR Represents a Stepwise Improvement Over Recombinant Factor C (rFC) Reagents.**

**1**

**2**

**3**



WHAT IS PYROSMART NEXTGEN®?

**PSNG is a Superior rBET Reagent.**

**PyroSmart®**  
NEXT GEN Recombinant Cascade  
Reagent (rCR)

**1**

**2**

**3**

Web Links:

[PSNG Instructions For Use](#)

WHAT IS PYROSMART NEXTGEN®?

PSNG is a Superior rBET Reagent.

PSNG IS AN rCR OF SUPERB ANALYTICAL PERFORMANCE



Table 1: PSNG Primary Validation Data for Microplate Readers<sup>15</sup>

Analytical Characteristics	Results				Acceptance Criteria
	Rate Assay Mode		Onset Assay Mode		
<b>1. Linearity (absolute value, correlation coefficient)</b>	<b>0.00625-0.1 EU/mL</b> Minimum 0.998 Maximum 1.000		<b>0.005-50 EU/mL</b> Minimum 0.996 Maximum 0.999		r  ≥ 0.980
<b>2. Accuracy (recovery)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	50-200%
	0.00625	84-125	0.005	71-88	
	0.0125	98-109	0.05	87-138	
	0.025	94-105	0.5	75-140	
	0.05	93-101	5.0	106-118	
	0.10	100-102	50	75-95	
<b>3. Precision</b>					
<b>3.1 Repeatability (CV)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	CV ≤ 25% 0.00625 EU/mL CV ≤ 20% 0.0125-0.10 EU/mL
	0.00625	7-21	0.005	8-30	
	0.0125	5-16	0.05	6-25	
	0.025	6-12	0.5	7-23	CV ≤ 35% 0.005 EU/mL
	0.05	3-14	5.0	4-12	CV ≤ 30% 0.05-50 EU/mL
	0.10	3-18	50	5-16	
<b>3.2 Intermediate Precision (95% CI for CV)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	CV ≤ 25% 0.00625 EU/mL CV ≤ 20% 0.0125-0.10 EU/mL
	0.00625	15-19	0.005	20-24	
	0.0125	9-11	0.05	12-15	
	0.025	8-10	0.5	16-19	CV ≤ 35% 0.005 EU/mL
	0.05	7-9	5.0	7-9	CV ≤ 30% 0.05-50 EU/mL
	0.10	7-9	50	10-12	
<b>3.3 Reproducibility (95% CI for CV)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	CV ≤ 25% 0.00625 EU/mL CV ≤ 20% 0.0125-0.10 EU/mL
	0.00625	15-17	0.005	19-22	
	0.0125	9-11	0.05	12-14	
	0.025	8-10	0.5	15-17	CV ≤ 35% 0.005 EU/mL
	0.05	7-8	5.0	7-9	CV ≤ 30% 0.05-50 EU/mL
	0.10	7-8	50	10-12	
<b>4. Range</b>	0.00625-0.1 EU/mL		0.005-50 EU/mL		Precision, accuracy and linearity at suitable level
<b>5. Quantitation Limit</b>	Not Assessed		At 0.005 EU/mL Accuracy: 71-88% Repeatability: 6-30%		The lowest concentration of Et that can be quantitatively determined with suitable precision and accuracy
<b>6. Specificity (Reactivity with Beta Glucan)</b>	<b>Results from regression analysis (95% CI)</b> Intercept: -0.901-0.150 Slope: 0.909-1.020		<b>Results from regression analysis (95% CI)</b> Intercept: 5.923-113.0 Slope: 0.924-1.006		Not reactive to Beta Glucan

Table 2: PSNG Primary Validation Data for Tube Readers<sup>16</sup>

Analytical Characteristics	Results		Acceptance Criteria
	Onset Assay Mode		
<b>1. Linearity (absolute value, correlation coefficient)</b>	<b>0.001-1 EU/mL</b> Minimum 0.997 Maximum 0.999		r  ≥ 0.980
<b>2. Accuracy (recovery)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	50-200%
	0.001	84-101	
	0.01	99-119	
	0.1	111-129	
	1.0	83-94	
<b>3. Precision</b>			
<b>3.1 Repeatability (CV)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	CV ≤ 35% 0.001 EU/mL CV ≤ 30% 0.01-1 EU/mL
	0.001	7-32	
	0.01	5-14	
	0.1	3-30	
	1.0	3-7	
<b>3.2 Intermediate Precision (95% CI for CV)</b>	<b>EU/mL</b>	<b>Min-Max (%)</b>	CV ≤ 35% 0.001 EU/mL CV ≤ 30% 0.01-1 EU/mL
	0.001	15-18	
	0.01	8-9	
	0.1	11-13	
	1.0	5-7	
<b>4. Range</b>	0.001-1 EU/mL		Precision, accuracy and linearity at suitable level
<b>5. Quantitation Limit</b>	<b>At 0.001 EU/mL</b> Accuracy: 84-101% Repeatability: 7-32%		The lowest concentration of Et that can be quantitatively determined with suitable precision and accuracy

Note: Reproducibility (multiple locations) and specificity were analyzed, and the results met the acceptance criteria in a previous study not included here.

WHAT IS PYROSMART NEXTGEN®?

**PSNG is a Superior rBET Reagent.**

PSNG IS AN rCR WITH A HIGH DEGREE OF REPRODUCIBILITY

Table 3: Onset times of commercial lots obtained under release testing between December 2020 and December 2024 (adopted from Certificates of Compliance)<sup>17</sup>

PSNG Lot Number	Onset times (seconds) for RSE concentrations (EU/mL)					Descriptors (Linear Regression Analysis)	
	50	5	0.5	0.05	0.005	Slope	Y-intercept
PNG0001	283	461	765	1320	2510	-0.235	2.833
PNG0002	289	463	761	1317	2475	-0.232	2.830
PNG0004	288	457	753	1318	2412	-0.230	2.830
PNG0005	284	456	755	1310	2482	-0.234	2.830
PNG0006	280	449	740	1309	2467	-0.236	2.820
PNG0007	254	424	713	1272	2507	-0.246	2.800
PNG0008	275	446	744	1305	2534	-0.239	2.820
PNG0009	293	466	762	1325	2591	-0.235	2.840
PNG0010	307	482	788	1382	2516	-0.228	2.850
PNG0011	300	482	771	1319	2315	-0.221	2.840
PNG0012	261	430	721	1269	2437	-0.241	2.810
PNG0013	284	458	740	1285	2268	-0.225	2.820
PNG0014	281	452	735	1285	2414	-0.232	2.820
PNG0015	247	410	693	1237	2391	-0.245	2.790
PNG0016	275	444	736	1305	2446	-0.237	2.820
PNG0017	255	427	727	1296	2467	-0.245	2.810
PNG0018	271	442	741	1314	2489	-0.240	2.820
PNG0020	283	463	778	1,414	2,650	-0.243	2.840
PNG0021	284	460	787	1,436	2,734	-0.246	2.850
PNG0022	227	399	725	1,362	2,769	-0.289	2.770
PNG0023	308	491	826	1,513	2,877	-0.243	2.870
PNG0024	291	469	785	1,394	2,386	-0.230	2.840
<b>CV%*</b>	<b>7%</b>	<b>5%</b>	<b>4%</b>	<b>4.7%</b>	<b>5.8%</b>	<b>5.5%</b>	<b>0.76%</b>

\*Industry-wide specification for Correlation of Variation (CV)% calculated based on onset times is < 10% for intra-assay replicates. There is no specification for inter-assay CV%.



WHY USE PYROSMART NEXTGEN®?

**PSNG Sets the Standard for Quality.**

**PyroSmart®**  
NEXT GEN Recombinant Cascade  
Reagent (rCR)

**1**

**2**

**3**

NEWS: Bayer's low dose MRI contrast Ambelvist™ (gadoquatrane) now granted market authorization in Japan. It is approved to be tested by PSNG in addition to LAL. PSNG use was granted for Ambelvist in 6 more countries to date (US, Canada, UK, Switzerland, Singapore and Australia).<sup>23</sup>

WHY USE PYROSMART NEXTGEN®?

**PSNG Sets the Standard for Quality.**



PSNG DETECTS THE ENDOGENOUS ENDOTOXINS AT COMPARABLE LEVELS TO LAL

Table 4: Multicenter inter-laboratory study of comparability between rBET to LAL reagents: Samples containing endogenous endotoxins tested by different reagents (expressed as Relative Recovery with the Acceptable Range of 50 –200%<sup>19</sup>)

Sample	Comparability Study for Deionized Water Samples								
	Endotoxin Concentration (EU/mL)						Relative Recovery (%)		
	PSNG (rCR)	Reagent A (rFC)	Reagent B (rFC)	Chromogenic (LAL)	Turbidimetric (LAL)	Mean (LAL)	PSNG (rCR)	Reagent A (rFC)	Reagent B (rFC)
DI water #1	8.965	3.490	2.108	7.059	6.067	<b>6.563</b>	137	53	32
DI water #2	1.354	0.504	1.034	1.182	1.813	<b>1.498</b>	90	34	69
DI water #3	5.260	1.530	1.317	4.610	6.603	<b>5.607</b>	94	27	23
DI water #4	1.190	0.407	0.722	0.991	1.119	<b>1.055</b>	113	39	68
DI water #5	0.063	0.044	0.055	0.065	0.041	<b>0.053</b>	119	83	104
DI water #6	0.238	0.040	0.083	0.278	0.125	<b>0.202</b>	118	20	41
DI water #7	0.037	0.013	0.012	0.038	0.047	<b>0.043</b>	86	30	28
DI water #8	1.718	0.400	0.547	1.570	1.399	<b>1.485</b>	116	27	37
DI water #9	1.423	0.364	0.383	1.122	1.691	<b>1.407</b>	101	26	27
<b>Culture Supernatant E. coli O113:H10</b>	<b>65,400</b>	<b>72,600</b>	<b>120,000</b>	<b>52,700</b>	<b>67,700</b>	<b>60,200</b>	<b>109</b>	<b>121</b>	<b>199</b>

Additional studies on comparability of PSNG to LAL can be accessed in the following publications.<sup>16, 20, 21, 22</sup>

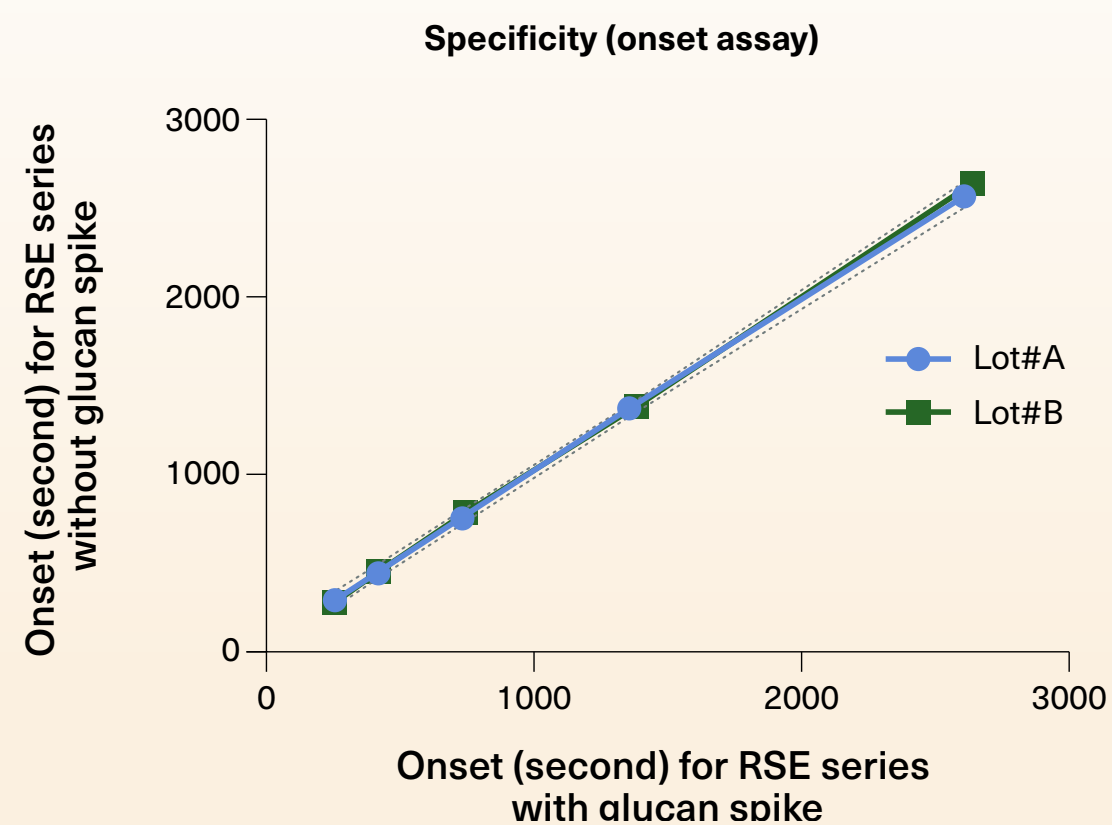
WHY USE PYROSMART NEXTGEN®?

PSNG Sets the Standard for Quality.

PSNG OFFERS SIGNIFICANT TECHNICAL ADVANCEMENTS



Fig. 3: Regression analysis of the reactivity of PSNG to endotoxin in the presence and absence of (1,3)-beta-glucan



No Cross-Reactivity with (1,3)-Beta Glucan<sup>15</sup>

The absence of reactivity with (1,3)-Beta-D-glucan is illustrated in this figure, which shows standard series of 50 to 0.005 EU/mL, each per one PyroSmart NextGen® lot. The excellent correlation between the curves demonstrates there was no interference caused by the added (1,3)-Beta-D-glucan spike (200 pg/mL) at either concentration.

Table 5: Typical expected onset times for LAL chromogenic and PSNG assay (in seconds) for a dynamic range of 50 to 0.005 EU/mL (microplate reader)

RSE Concentration (EU/ml)	Onset Times (seconds) for a typical LAL kinetic chromogenic assay at Onset OD 0.03	Onset Times (seconds) for a typical PyroSmart NextGen® assay at Onset OD 0.03
<b>Negative Controls</b>	<b>&gt;4500</b>	<b>&gt;3000</b>
0.005	3900	2510
0.05	2240	1320
0.5	1350	765
5	820	461
50	500	283

Fast Test to Results

PSNG achieves the same dynamic range in half the time of typical LAL assay. A proven reagent for high-throughput labs.

Table 6: Non-Interfering Dilution (NID) determined experimentally for a range of finished products, buffer and water when using LAL and rBET reagents<sup>15</sup>

Samples	MVD for LOD=0.005 EU/mL	Non-Interfering Dilution (NID)				
		PSNG (rCR)	Reagent A (rFC)	Reagent B (rFC)	Chromogenic (LAL)	Turbidimetric (LAL)
Sodium Citrate Injection for Transfusion	1,120	1	256	512	4	4
Vancomycin Hydrochloride Injection	5,000	64	128	32	32	128
Glucose Injection	100	8	8	4	8	4
Heparin Calcium	15,000	512	> 60,000	> 60,000	128	8
D-Mannitol Injection	100	2	2	1	4	2
Aciclovir 75 mg/vial	N/A	4	128	256	8	8
Insulin 8 mg/mL	N/A	1	16	64	2	1
PBS (Dulbecco)	N/A	1	1	2	1	1
WFI	50	1	1	1	1	1

Suitability for a Wide Range of Drug Products

PSNG is suitable for a wide range of products, often with NID lower than that of an LAL reagent. See references for more suitability data.<sup>2,15</sup>

HOW TO TRANSITION TO PYROSMART NEXTGEN®?

**Strategic Migration Simplifies the Road to rBET.**

**1**

**2**

**3**

Web & Email Links:

[techservice@acciusa.com](mailto:techservice@acciusa.com)

HOW CAN ACC HELP?

**ACC Offers the Right Services and Support to Help You Succeed.**

**1**

**2**

**3**

Web & Email Links:

Contact [techservice@acciusa.com](mailto:techservice@acciusa.com)  
for access to our gated resources.

Web Links:

[Reagent transfer protocol \(G\\_0633\)](#)  
[Guide for reagent transfer protocols \(MKT23-022\)](#)



## HOW CAN ACC HELP?

### ACC Offers the Right Services and Support to Help You Succeed.

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#### Onsite Validation Support

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- (E) [techservice@acciusa.com](mailto:techservice@acciusa.com)

- Support For UK + European Customers

- (E) [technicalservices@acciuk.co.uk](mailto:technicalservices@acciuk.co.uk)

- **Contract Test Services**

- (T) (888) 232-5889

- (F) (508) 540-2019

- (E) [testservice@acciusa.com](mailto:testservice@acciusa.com)

## HOW CAN ACC HELP?

**See How ACC Has Helped Others Transition to rBET.**

*“BET testing using an alternative method with rBET was one of several sustainability projects at our Bayer site, and using the rCR, we were able to reliably detect the presence of naturally occurring endotoxin (NOE) contained in our products, compared to our established testing method. PyroSmart NextGen® met the acceptance criteria we set for our validation to our complete satisfaction. Plus, we can basically continue working as usual and don't have to make any additional investments in new equipment.”*

**Sandra Wieger**

Bayer AG, Bergkamen, Germany



*“The more I work with PSNG the more I like it! The faster reaction kinetics combined with the better interference profile enabled me to cut assay runtimes in half, and simplify sample treatment, which leadership absolutely loves.”*

**Anonymous**

US Based User

HOW CAN ACC HELP?

**ACC Offers the Right Services and Support to Help You Succeed.**

Table 7: Ordering Information

Equipment Type	Specification	Description/Catalog No.
<b>PyroSmart NextGen®</b>	Recombinant Cascade Reagent	PNG050-2
<b>Incubating absorbance platereader</b>	Capable of maintaining a temperature of 37°C while reading at 405nm	Agilent BioTek® ELx808™ or Epoch 2 Molecular Devices readers*
<b>Platereader software</b>	Allows for data reduction to Onset Time	Pyros® eXpress, Gen5™ or Softmax® Pro
<b>Control Standard Endotoxin (CSE)</b>	10ng/vial calibrated against RSE with PyroSmart NextGen®	ACC EC010-5
<b>Microplates 96-well</b>	Covered, non-coated, untreated microplates, free of interfering endotoxin, should not interfere with the test	ACC CA961-10
<b>LAL Reagent Water (LRW)</b>	Free of interfering endotoxins	e.g. ACC WP050-C*
<b>Depyrogenated Glass Dilution Tubes</b>	Free of interfering endotoxin, should not interfere with the test	ACC TB240-5, TB013-5 or TB016-C*
<b>Pipette tips</b>	Capable of delivering volumes of 5–20 µL, 20–100 µL and 100–1000 µL, Free of interfering endotoxin	ACC PPT25, ACC PPT10

Equipment Type	Specification	Description/Catalog No.
<b>Repeating pipette with compatible syringe barrels</b>	Auto-delivery of reagent aliquots	Eppendorf® Xstrem repeater with BioPur® combi-tip 2.5mL (EP0030089650)
<b>Multichannel pipette with BET compatible reservoirs</b>	Eight channel	Integra reservoir No. 4331
<b>A set of adjustable single-channel micropipettes</b>	Capable of delivering volumes of 5–20 µL, 20–100 µL and 100–1000 µL	Gilson®, Rainin® traditional or Eppendorf® model fit the tips below*
<b>Vortex mixer</b>		Any
<b>Timer</b>		Any
<b>Parafilm M®</b>	The side in contact with the paper backing is typically free of detectable endotoxin	American National Can™
<b>Tube rack</b>		Any
<b>Slanted plate stand</b>		Any

\*Or equivalent  
All trademarks are property of their respective owners.

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#### **COMPANY REGISTRATION NUMBER**

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