

PEM  
Protein Expression Medium  
For PER.C6(R) cells  
– L-Glutamine

**Lot Number:** 2753803  
**Item Number:** 12661  
**Expiration Date:** 2024-07  
**Storage Temp:** 2 to 8C  
**Storage Instructions:** Store in the dark

For Research Use or Further Manufacturing. Not for diagnostic use or direct administration into humans or animals.

TEST	TEST ID	SPECIFICATION	RESULT	UNITS
<b>Endotoxin Testing</b>	ENDO0007	<=1.20	<0.10	EU/mL
<b>Osmolality</b>	OSMO0002	260 - 290	273	mOsm/kg
<b>PEM Performance Assay</b>	PEM0001	Acceptable	Acceptable	
<b>pH</b>	PH0003	7.0 - 7.4	7.3	
<b>Sterility Testing</b>	STERI0007	Negative	Negative	

Read SDS

PER.C6(R) is a registered trademark of Crucell Holland B.V.

Notice: Effective 29JAN2018, the intended use for this product has changed per ECR1040213. If you have questions regarding this change, please contact Thermo Fisher Scientific Technical Support at 1-800-955-6288 in North America or techsupport@thermofisher.com globally.



Quality Systems Department

Date: 22-Aug-2023

## References

- ENDO0007: Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- OSMO0002: Thermo Fisher Scientific Specifications.
- PEM0001: Thermo Fisher Scientific Specifications, PER.C6.EpCAM cells adapted to PEM. Each lot of medium is tested for its ability to support growth of cells in a two passage assay consisting of a low cell density culture in the first passage and a high cell density culture in the second. Test and Control medium conditions are inoculated at  $0.3 \times 10^6$  viable cells/ml in the second passage, incubated for 5 days and evaluated for cell population doublings compared to the approved control. An acceptable result is for the test medium to perform  $\geq 85\%$  of control on day 5 of the second passage.
- PH0003: Thermo Fisher Scientific Specifications.
- STERI0007: Current Edition of USP, Thermo Fisher Scientific Modified.