

PATsmart™ REBEL® System

Quantitative Calibration & Performance Qualification

Version 1.2, MAY 2022

The Basics**Do not suffer in silence - when in doubt, reach out!**

Most commonly, the PATsmart™ REBEL® System reports a 'fail' as an indication the REBEL chip or reagents need to be replaced. Rest assured, the Repligen team is here to help review results.

Do not hesitate to replace the chip or reagents if you encounter an issue. We understand time is valuable. Replacements will be provided for any consumables used during troubleshooting under the guidance of Repligen.

Remember: Kits are intended to run 200 samples. You may have excess depending on use case.

Quantitative Calibration (QC or Quant Cal for short)

Must be performed for each new REBEL chip or fresh set of REBEL standards.

Most calibration failures are related to an issue with the chip spray or expired standards.

Performance Qualification (PQ)

Automated check standard interlaced after every 5 samples throughout a batch. Failures can result from a range of issues. Review the details of a PQ report on Page 2.

Quick Reference

- Are BGE & standards within expiration date?
- Are the standards within 2 weeks from first use?
- Is BGE within 4 weeks from date opened?
- Is the remaining BGE level >20%?
- Is the BGE line fed into the bottom of bottle to avoid air bubbles and free of kinks?
- Were samples clarified (filtration/centrifugation) before dilution to remove cells/debris?

If above are confirmed, replace chip and contact TechSupport@repligen.com with serial number.

Expert Tip!**Opening new reagents?**

Grab a pen and record the open date on the standards, BGE & diluent labels.

**REBEL Knowledge Base**

Example: Performance Qualification Report**PQ Test Parameters**

Four types of metrics are included in a PQ Report.

Internal Standards

Four (4) internal standards are introduced with the REBEL diluent during sample dilution and must be detected.

Migration Index

Relative migration time of three (3) analytes (Arg, Ser, Asp) are monitored to verify separation performance.

Resolution

Two pairs of similar analytes are confirmed to be resolved for quantitation (Ile/Leu and Gln/Glu).

Failures? This usually indicates chip spray failure or a separation issue due to the chip or BGE.

1. Check BGE expiration date and storage time in unit. Replace as needed.
2. Replace with a new chip and run a new Quant Cal.
3. If all 5 migration / resolution parameters fail, replace the chip and refresh BGE and standards. Contact Repligen.

Quantitation Quality

Number of analytes reported out of method specifications.

Failure? Indicative that the calibration has drifted out of range. Aging chips will begin reporting 5 or 6. If > 6, swap in a new chip and run a new Quant Cal.

IMPORTANT: REBEL chip and standards must be non-expired consumables from the same kit type (e.g. SMA V2).

Service Diagnostics

Method and ambient background are correlated to what the REBEL may detect in the local environment and are included as Service Diagnostics for visibility to the Repligen team.

Method background

Intrinsic baseline which typically changes on a slower time scale with factors like relative humidity.

Ambient background

Caused by volatile compounds in the immediate surroundings of the REBEL, this factor may be complex and transient. Nearby activities may contribute to background signal (e.g. construction, use of cleaning products or volatile solvents). In extreme cases, the REBEL is relocated for improved humidity control, lower background, or equipped with a custom filtered hood per Repligen guidance.

Bottom Line

Do not hesitate to try a new chip to minimize downtime and frustration. Dispose of any excess or expired consumables. Fresh reagents are best. If you have questions, observe a persistent error, or intermittent failures in PQ checks throughout a batch, simply reach out to the Repligen Devices service team at TechSupport@repligen.com for support!

Performance Qualification Report



Performance Qualification Report

Serial Number:

R198

Time Completed:

13:19 2021.10.19

Summary Result:

PASS

Test Parameter	Results	Value	Bounds
Internal Standards Found	PASS	4.00	[4.00 4.00]
Arg Migration Index	PASS	0.13	[0.11 0.16]
Ser Migration Index	PASS	0.52	[0.50 0.55]
Asp Migration Index	PASS	0.86	[0.83 0.88]
Ile/Leu Resolution	PASS	1.59	[1.10 inf]
Gln/Glu Resolution	PASS	0.85	[0.30 inf]
Quantitation Quality	PASS	1.00	[0.00 6.00]

Service Diagnostics

Parameter	Value
Method Background	4.86
Ambient Background	6.82

REPLIGEN

Page 1 of 3

TechSupport@repligen.com