

CERTIFICATE OF ANALYSIS

Product No.: 12131
Name: PM 4A MicroArray™
Lot No.: 3806131
Expiration Date: 13 JUN 2026

Quality Profile

Results

Control well check:	Passes test
Performance check: (± 10% of average historic values)	Passes test
Contamination check:	Passes test


Storage Recommendations

Store between 2 °C and 8 °C

Intended Use

Not for human *in vitro* diagnostic use

For Research Use Only


Quality Assurance


Date

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CA12131 RevB
Effective Date: 10/20/2023

	Manufacturing Procedure	Document # MF12131
	PM4A MicroPlate – Run Size ~2,000	Revision: B1 Issue Date: 03/03/2021 Effective Date: 03/03/2021

Lot Number:	3106131
Technician Name / Date:	13 June 2024 JT

- 6.23. Provide MF12131 and QSD80.009 to QC.
- 6.24. File MF12131.F1 in Document Control.
- 6.25. QC will:
 - 6.25.1. Test the MicroPlate according to QC12131, Quality Control Testing of PM4A MicroPlate.
 - 6.25.2. Provide all completed paperwork to QA for approval.
- 6.26. The QA Manager will:
 - 6.26.1. Review, sign, and date all paperwork where specified.

Production Manager:	
Date:	06/14/24

7.0 References

- 7.1. LVR13106 PM-M6 MicroPlate Label Verification Record
- 7.2. MF13106.F1 PM-M6 Substrate Sheets
- 7.3. QC13106 Quality Control Testing of PM-M6 MicroPlate
- 7.4. QSD03.018 Traceability and Lot Number
- 7.5. QSD03.032 Good Documentation Practices
- 7.6. QSD61.001 Autoclaving Glassware
- 7.7. QSD61.002 Pre-Production Cleaning and Autoclaving, MicroPlate Filling Machine
- 7.8. QSD61.014 Post-Production Cleaning, MicroPlate Filling Machine
- 7.9. QSD62.001 Guidelines for the Preparation of Manufacturing Stock Solutions
- 7.10. QSD71.001 Filling MicroPlates Using the Sandy Springs Filling Machine
- 7.11. QSD71.003 Setting Out MicroPlate Lids Prior to Lidding Process
- 7.12. QSD72.001, Sealing MicroPlates into Pouches Using the Hayssen Form/Fill/Seal Machine
- 7.13. QSD72.002 Drying MicroPlates in the Dry Room
- 7.14. QSD72.003 Assembling Lids on Dried MicroPlates
- 7.15. QSD72.004 Completion of the Plate Production Log Sheet
- 7.16. QSD73.004 Management of Controlled Substances
- 7.17. QSD80.009 Plate Production Log Sheet

8.0 Risk Management

Hazard	Risk Management
N/A	N/A

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	PM4A MicroPlate – Run Size ~2,000	

Lot Number:	380621
Technician Name / Date:	13 June 2024 JS

9.0 Document History

DCR#:	Rev.	Effective Date	Summary of Changes
371	A	22Dec2001	Initial release.
20-013	B	21Dec2020	Update to current format, reorganize content to current practice, change from 1,000 run to 2,000 plate run and adjusted volumes, clarify preparation/cleaning steps, add Biolog no. to each substrate
21-002	B1	03Mar2021	Correct spelling errors.