



Doc. nr. REA-S004-01-42-0553

Versie 2.0

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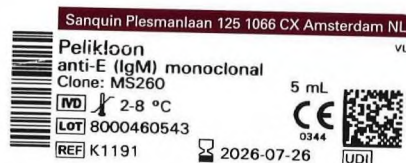
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Document eigenaar BBR

Titel Pelikloon anti-E (IgM) monoclonal release

K1191

Clone number MS260



| Analysis         | Requirement                                    | Result                                                                                       |
|------------------|------------------------------------------------|----------------------------------------------------------------------------------------------|
| Specificity      | Negative with cells negative for the E antigen | Conform requirements                                                                         |
| Avidity          | Ee                                             |                                                                                              |
|                  | Tube method $\geq 3+$                          | Conform requirements                                                                         |
|                  | Microplate method $\geq 3+$                    | Conform requirements                                                                         |
|                  | Cellbind Screen method $\geq 3+$               | Conform requirements                                                                         |
|                  | Cellbind Direct Type method $\geq 3+$          | Conform requirements                                                                         |
| Titer            | Ee                                             |                                                                                              |
|                  | Tube method $\geq 1:16$                        | Conform requirements                                                                         |
|                  | Microplate method $\geq 1:16$                  | Conform requirements                                                                         |
| Growthtest       | no growth                                      | Conform                                                                                      |
| External release | released by Notified Body                      | Released <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">Y/N</span> |

Date

: 26 April 2024

Approved by QA/QC

:

VERTROUWELIJK

Use copy according to REA-SOP-0002.

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