

Certificate of Analysis

General Product Information

Product Name: **FLEX Mono MxH CD15, Clone Carb-3 RTU, Link China**

Code Number: **IR06261-2CN**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **11775395C** Expiration date: **2026SEP30**

Specifications

Test	Specification	Result
Appearance	Clear, colorless liquid	Pass
Immunohistochemistry Specific Stain	HE: 3.0 to 4.0 specific staining LE: 0.5 to 3.0 specific staining	Pass
Immunohistochemistry Background	≤1.0 background staining	Pass
Immunohistochemistry Equivalent	Intensity of specific and background staining of test lot must be equivalent to corresponding control lot ± 0.25 grade	Pass
Immunohistochemistry Comparable	Staining pattern of test lot must be consistent with the antibody used and comparable to control slide	Pass

QC approval	<u>Eric Smith</u>	Date	<u>2025MAR04</u>
QA approval	<u>Jeff Taylor</u>	Date	<u>2025MAR05</u>

Certificate of Analysis

General Product Information

Product Name: **FLEX Monoclonal Mouse X-H CD1a Clone 010, RTU, (Link), CN**

Code Number: **IR06961-2CN**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **11794330A** Expiration date: **2026JUN30**

Specifications

Test	Specification	Result
Appearance	Clear, colorless liquid	Pass
Immunohistochemistry Specific Stain	HE: 2.5 to 4.0 specific staining LE: 1.0 to 2.5 specific staining	Pass
Immunohistochemistry Background	≤1.0 background staining	Pass
Immunohistochemistry Equivalent	Intensity of specific and background staining of test lot must be equivalent to corresponding control lot ± 0.25 grade	Pass
Immunohistochemistry Comparable	Staining pattern of test lot must be consistent with the antibody used and comparable to control slide	Pass

QC approval	<u>Maria Jeronimo</u>	Date	<u>2025FEB21</u>
QA approval	<u>Jeff Taylor</u>	Date	<u>2025FEB21</u>

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General Product Information

Product Name: **FLEX Polyclonal Rabbit Anti-Human CD3, Ready-to-Use (Link)**

Code Number: **IR503**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41793148** Expiration date: **2026AUG31**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Merete Johnsoen</u>	Date	<u>2024OCT02</u>
QA approval	<u>Janne Bayer</u>	Date	<u>2024DEC04</u>

Certificate of Analysis

General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human CD21, Clone 1F8, Ready-to-Use (Link)**

Code Number: **IR608**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41774434** Expiration date: **2026SEP30**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Merete Johnsoen</u>	Date	<u>2024OCT18</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024NOV04</u>

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General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human CD8, Clone C8/144B, Ready-to-Use (Link)**

Code Number: **IR623**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41718521** Expiration date: **2026MAR31**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Heidi Joergensen</u>	Date	<u>2024MAY02</u>
QA approval	<u>Maria Nielsen</u>	Date	<u>2024MAY24</u>

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General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human CD138, Clone MI15, Ready-to-Use (Link)**

Code Number: **IR642**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41752866** Expiration date: **2026AUG31**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Heidi Joergensen</u>	Date	<u>2024SEP19</u>
QA approval	<u>Maria Nielsen</u>	Date	<u>2024OCT01</u>

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General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human CD4, Clone 4B12, Ready-to-Use (Link)**

Code Number: **IR649**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41773478A** Expiration date: **2026OCT31**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Merete Johnsoen</u>	Date	<u>2024NOV14</u>
QA approval	<u>Janni Buch</u>	Date	<u>2025JAN29</u>

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General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human B-Cell-Specific Activator Protein, Clone DAK-Pax5, Ready-to-Use (Link)**

Code Number: **IR650**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41745073A** Expiration date: **2026JUL31**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Merete Johnsoen</u>	Date	<u>2024AUG07</u>
QA approval	<u>Lisbet Drewsen</u>	Date	<u>2025JAN02</u>

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General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human Beta-Catenin, Clone β -Catenin-1, Ready-to-Use (Link)**

Code Number: **IR702**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41749786** Expiration date: **2026JUN30**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Merete Johnsoen</u>	Date	<u>2024AUG23</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024SEP12</u>

Certificate of Analysis

General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human CD10, Clone DAK-CD10, Ready-to-Use (Link)**

Code Number: **IR786**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41790703** Expiration date: **2025SEP30**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Merete Johnsoen</u>	Date	<u>2024OCT18</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024DEC20</u>

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General Product Information

Product Name: **EnVision FLEX+, Mouse, High pH (Link)**

Code Number: **K8002**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41803698** Expiration date: **2025NOV12**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Line Hansen</u>	Date	<u>2025JAN17</u>
QA approval	<u>Maria Nielsen</u>	Date	<u>2025FEB27</u>

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General Product Information

Product Name: **EnVision FLEX Target Retrieval Solution Low pH (50x)**

Code Number: **K8005**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41793185** Expiration date: **2025NOV19**

Specifications

Test	Specification	Result
pH measurement	pH: 5,50 – 5,60	Pass

QC approval	<u>Annette Wisler</u>	Date	<u>2024NOV20</u>
QA approval	<u>Janni Buch</u>	Date	<u>2025JAN27</u>

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General Product Information

Product Name: **EnVision FLEX Antibody Diluent**

Code Number: **K8006**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41788283** Expiration date: **2026MAR27**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>MICHAEL KONGSGAARD</u>	Date	<u>2020DEC07</u>
QA approval	<u>Janne Bayer</u>	Date	<u>2024DEC18</u>

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General Product Information

Product Name: **EnVision FLEX Wash Buffer (20x)**

Code Number: **K8007**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **11806788**

Expiration date: **2026FEB28**

Specifications

Test	Specification	Result
Appearance	The solution is clear with no undissolved raw materials by visual inspection	Pass
pH	7.7 (± 0.1) @ 25°C	Pass
Conductivity	150 mS/cm (± 3.0) @ 25°C	Pass

QC approval	<u>Jon St.Onge</u>	Date	<u>2025MAR04</u>
QA approval	<u>Jeff Taylor</u>	Date	<u>2025MAR05</u>

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General Product Information

Product FLEX IHC Microscopes Slides

Code K8020

Presentation Material provided with K8020:

Coated microscope slides, 75 mm (W) x 25 mm (D) x 1 mm (H) with a white-painted label area. Provided as 5 boxes each containing 100 slides.

Storage Store at 15-30 °C.

Lot Specific Data


Lot Number: 20240706

Expiration date: 2026JUL06

Specifications

Test	Test Material	Specification
QA control	-	Certificate of Compliance is related to DMRI and IFU

Date: 2025FEB27


f. QC Approval

Certificate of Analysis

General Product Information

Product Name: **Monoclonal Mouse Anti-Human Epithelial Membrane Antigen, Clone E29**

Code Number: **M0613**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41790451** Expiration date: **2027NOV07**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Charlotte Kroell</u>	Date	<u>2023MAY25</u>
QA approval	<u>Janne Bayer</u>	Date	<u>2024NOV28</u>

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General Product Information

Product Name: **Mo a Hu CD45, LCA, cls 2B11 + PD7/26, CN**

Code Number: **M0701**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41700680A** Expiration date: **2027MAR08**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Merete Johnsoen</u>	Date	<u>2024MAR15</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024NOV22</u>

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General Product Information

Product Name: **Monoclonal Mouse Anti-Human CD30, Clone Ber-H2**

Code Number: **M0751**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41775232** Expiration date: **2027OCT15**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Charlotte Kroell</u>	Date	<u>2024FEB07</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024NOV06</u>

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General Product Information

Product Name: **Monoclonal Mouse Anti-Human CD20cy, Clone L26**

Code Number: **M0755**

Storage data: **See Product label**

Lot Specific Data

Lot Number: **41769962** Expiration date: **2027SEP20**

Specifications

Test	Specification	Result
Immunohistochemistry	Human Tissue section. Location of staining and staining intensity of the lot must comply to reference lot. This applies for both specific and unspecific staining.	Pass

QC approval	<u>Perihan Turan</u>	Date	<u>2021OCT28</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024OCT22</u>