

## Certificate of Analysis

### General Product Information

Product Name: **Rb a Hu CD117, c-Kit**

Code Number: **A450229-2**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **11813687**

Expiration date: **2026FEB28**

### Specifications

Test	Specification	Result
Immunohistochemistry Specific Stain	Membrane and/or cytoplasmic staining of gastrointestinal stromal tumors	Pass
Immunohistochemistry Equivalent	Intensity of specific and background staining must be equivalent to corresponding control lot $\pm$ 0.5 grade	Pass
Immunohistochemistry Specific Stain	GIST specimen 2.0 - 4.0 membrane and/or cytoplasmic staining	Pass
Immunohistochemistry Background	$\leq 1.0$ background staining	Pass
Immunohistochemistry Specific Stain	Negative area/tissue must have no specific staining and non-specific staining $\leq 1.0$	Pass

QC approval	<u>Eric Smith</u>	Date	<u>2025MAR10</u>
QA approval	<u>Hector Cristobal</u>	Date	<u>2025MAR11</u>

## Certificate of Analysis

### General Product Information

Product Name: **Mo a Hu CD22/FITC, Clone 4KB128**

Code Number: **F7060**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41710386**

Expiration date: **2027MAR31**

### Specifications

Test	Specification	Result
Flow Cytometry	Whole lysed human blood. Staining intensity and % positive cells of the batch must comply to a reference batch.	Pass

QC approval	<u>Majbritt Krog</u>	Date	<u>2023JUN16</u>
QA approval	<u>Anette Bruun Hansen</u>	Date	<u>2024APR26</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Polyclonal Rabbit Anti-Human IgA, Ready-to-Use (Dako Omnis)**

Code Number: **GA510**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41691097D**      Expiration date: **2025DEC31**

### Specifications

Test	Specification	Result
Accuracy/Sensitivity	Lot tested on positive control slide, shall confirm specific staining. When using negative control reagent instead of lot, result shall be negative.	Pass
Reproducibility	The same specific staining shall be seen on three positive control slides.	Pass

QC approval	<u>Michael Carlsson</u>	Date	<u>2022MAR15</u>
QA approval	<u>Lisbet Drewsen</u>	Date	<u>2024OCT07</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Polyclonal Rabbit Anti-Human IgG, Ready-to-Use (Dako Omnis)**

Code Number: **GA512**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41791594**      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>Lene Tidemand</u>	Date	<u>2024NOV28</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024DEC20</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Polyclonal Rabbit Anti-Human IgM, Ready-to-Use (Dako Omnis)**

Code Number: **GA513**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41741882**      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>Lene Tidemand</u>	Date	<u>2024JUL24</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024AUG14</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human CD246, ALK Protein, Clone ALK1, Ready-to-Use (Dako Omnis)**

Code Number: **GA641**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41805218**      Expiration date: **2026NOV30**

### 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>2025JAN22</u>
QA approval	<u>Maria Nielsen</u>	Date	<u>2025FEB07</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human CD7, Clone CBC.37, Ready-to-Use (Dako Omnis)**

Code Number: **GA643**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41767384**      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>Janni Buch</u>	Date	<u>2024OCT02</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Monoclonal Mouse X-H CD5 Clone 4C7, RTU, (Link)**

Code Number: **IR08261-2**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **11711303**      Expiration date: **2026MAR31**

### 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>Maria Jeronimo</u>	Date	<u>2024MAY07</u>
QA approval	<u>Jeff Taylor</u>	Date	<u>2024MAY13</u>



## Certificate of Analysis

### 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 Polyclonal Rabbit Anti-Human Myeloperoxidase, Ready-to-Use (Link)**

Code Number: **IR511**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41765776A**      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>Lene Tidemand</u>	Date	<u>2024SEP19</u>
QA approval	<u>Maria Nielsen</u>	Date	<u>2025JAN22</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human CD20cy, Clone L26, Ready-to-Use (Link)**

Code Number: **IR604**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41710831**      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>Merete Johnsoen</u>	Date	<u>2024APR18</u>
QA approval	<u>Anette Bruun Hansen</u>	Date	<u>2024MAY23</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human BCL2 Oncoprotein, Clone 124, Ready-to-Use (Link)**

Code Number: **IR614**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41715518**      Expiration date: **2026APR30**

### 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>Lene Tidemand</u>	Date	<u>2024MAY15</u>
QA approval	<u>Lisbet Drewsen</u>	Date	<u>2024JUN06</u>

## Certificate of Analysis

### General Product Information

Product Name: **FLEX Monoclonal Mouse Anti-Human BCL6 Protein, Clone PG-B6p, Ready-to-Use (Link)**

Code Number: **IR625**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41529549**      Expiration date: **2024NOV30**

### 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>Lene Tidemand</u>	Date	<u>2022DEC15</u>
QA approval	<u>Maria Nielsen</u>	Date	<u>2023JAN31</u>

## Certificate of Analysis

### 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>

## Certificate of Analysis

### 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>

## Certificate of Analysis

### 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>



## Certificate of Analysis

### 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 ( $\pm 0.1$ ) @ 25°C	Pass
Conductivity	150 mS/cm ( $\pm 3.0$ ) @ 25°C	Pass

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

## Certificate of Analysis

### 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 CD61, Platelet Glycoprotein IIIa, Clone Y2/51**

Code Number: **M0753**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41760220**      Expiration date: **2027AUG21**

### 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>2022AUG11</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024SEP09</u>

## Certificate of Analysis

### General Product Information

Product Name: **Monoclonal Mouse Anti-Human Leukaemia, Hairy Cell, Clone DBA.44**

Code Number: **M0880**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41686150**      Expiration date: **2026JAN08**

### 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>2022JUN03</u>
QA approval	<u>Janni Buch</u>	Date	<u>2024JAN24</u>

## Certificate of Analysis

### General Product Information

Product Name: **Monoclonal Mouse Anti-Human CD34 Class II, Clone QBEnd 10**

Code Number: **M7165**

Storage data: **See Product label**

### Lot Specific Data

Lot Number: **41793322**      Expiration date: **2026FEB26**

### 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>Eva Holm</u>	Date	<u>2022JUN21</u>
QA approval	<u>Janni Buch</u>	Date	<u>2025JAN31</u>