

HighLighter Core Plus Kit

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Intended Use: For InVitro Diagnostic Use

The HighLighter Core Plus Kit with all content reagents are RFID tagged and assigned for IHC staining for HighLighter™ Automated Slide Stainer and intended to use for qualitative immunohistochemistry. This autostainer is compact, benchtop, 36-slide system and fully automated from baking to counterstain stain step.

**Principles of
the Procedure:**

The principle of the procedure is that Linker 1 introduces HRP into the system. Linker 2 is to introduce the biotin into the system. Tracer introduces streptavidin and additional HRP into the system. SITVue /DAB HighLighter Core Plus Detection System is an enzyme-mediated reaction that utilizes horseradish peroxidase (HRP) to catalyze the deposition of two separate Linkers applied sequentially onto tissue sections or cell preparation. The deposited Linkers can be detected with a streptavidin-peroxidase conjugate followed by a reaction with a peroxidase substrate/chromogen solution such as diaminobenzidine (DAB). SITVue /DAB Detection System results in a significant increase in sensitivity compared to standard IHC detection methods, while maintaining similar specificity.

Kit Contents

Labels	Cap Sticker	Vol (72 Tests)
DP1(Dewax solution-1)	DP1	11 mL (2 vials)
DP2(Dewax solution-2)	DP2	11 mL (2 vials)
CA2(RTU Citrate buffer,pH6.0)	CA2	15 mL (2 vials)
EA1(RTU Tris EDTA buffer,pH9.0)	EA1	15 mL (2 vials)
Tissue Primer	TP	11 mL (2 vials)
Linker 1	LNK-1	11mL (1 vial)
Linker 2	LNK-2	11mL (1 vial)
Tracer	TRC	11mL (1 vial)
DAB-Auto buffer	DAB-B	10mL (1 vial)
DAB-Auto Chromogen	DAB-C	10 mL (1 vial)
Blue Hematoxylin	HEMA	11mL (1 vial)

**Storage and
Handling**

Store at 2°-8°C away from light. Do not use product after the expiration date printed on vial. If reagents are stored under conditions other than those specified here, they must be verified by the user. Diluted reagents should be used promptly.

Stability

12-36 months (see expiration date on reagent bottles)

Composition

The reagents are provided in ready-to-use form.



Material Required But Not Provided Some of the reagents and materials required for IHC are not provided, Permanent Mounting Medium Coverslips are available from Diagnostic BioSystems. Please refer to the Diagnostic BioSystems website at www.dbiosys.com.

Precautions This product is a single-use, non-sterile, in vitro diagnostic device.

- i) DAB has been classified as a suspected carcinogen and can cause skin irritation upon contact. Wear appropriate personal protective apparel. Avoid contact with clothes and exposed skin. In case of accidental skin exposure, flush with water immediately. Consult a physician if required.
- ii) Interpretation of the results is the sole responsibility of the user.

Troubleshooting If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem is suspected, contact Diagnostic BioSystems Technical Support at (925) 484-3350, extension 2 or techsupport@dbiosys.com.

Recommended Staining Protocol

Please read the Operator's Manual for the HighLighter™ Staining System for instructions on operating the instrument. IHC procedure for the HighLighter™ Staining System

Step	Reagent Name	Time (hh:mm:ss)	Temperature (°C)
1.	Deparaffinization DP1	00:06:30	65
	Deparaffinization DP2	00:06:30	65
2.	Antigen retrieval solution*	00:27:00	95-101*
3.	Tissue Primer	00:05:00	25
4.	Antibody	00:10:00*	25
5.	Linker 1	00:05:00	25
6.	Linker 2	00:05:00	25
7.	Tracer	00:05:00	25
8.	DAB-Auto on board	00:05:00	25
9.	Blue Hematoxylin	00:02:00	25

Antigen retrieval solution, antibody incubation time and temperature are specific to an antibody. Please refer to the antibody datasheet. 1X Immuno Wash Buffer is used on the instrument for wash steps. The wash steps are already included in the system protocol.

The investigator needs to optimize the dilution and incubation times for third party primary antibodies. Each immunostaining run should include known positive and negative controls to assure proper functioning of the staining system and aid in valid interpretation of the results.

Typical controls:

Positive Control: A tissue known to contain the desired antigen, which has yielded positive staining in the past.

Negative Controls: Negative tissue controls are used to reveal non-specific binding and false positive results. Negative controls should not express the target antigen.



Reagent Controls

- A. Substitute normal non-immune serum from the same host animal as the primary antibody (e.g. if using mouse monoclonal primary antibodies, use mouse non-immune serum).
- B. Substitute matching host species isotype control for primary antibody
- C. Use antigen-adsorbed primary antibody (i.e. antibody reagent which has been adsorbed with the target antigen to remove specific antibody)

Tissue control – A tissue known to not contain the desired antigen.

