

Microblot Array kits Checklist

Dear Customer:

For the training of the MBA kits, you should consider the following information in order to help you and your staff prepare the laboratory and materials in advance to get the most our of the training.

Training- Microblot Array kits:

- The duration of the training will take 1 day.
- The training involves theoretical and practical classes, distributed as specified in the corresponding agenda.
- The participants are limited to a maximum of 10 people for the practical part, and only 2 will execute the protocol procedures. For theoretical classes there is no limit on participants.
- For the training, it is possible to process a minimal number of 8 samples (or 7 samples + Positive Control) and a maximum of 24 samples.

The information about input material, reagents, accessory equipment and consumables necessary for training in the preparation of samples with the MBA kit and it subsequent reading in the MBA Reader system are listed below:

1. Input material:

The following human body fluids can be used as samples for testing: serum and plasma. Samples with bacterial, hemolytic or chilosan contamination and anticoagulants contained in the plasma (except citrate) may affect the test result.

A sampling tube for coagulable blood is recommended for serum collection. A citrated plasma collection bag is recommended for plasma collection. The use of other types of plasma (EDTA, heparin) is possible, but not recommended, since anticoagulants can affect the test result.

Follow the manufacturer's instructions when using commercial or other specially modified samples.

Clinical samples taken within the framework of standardized medical procedures in standardized test tubes are ready for immediate use (no centrifuging or other separations are necessary).

Processed serum/ plasma samples can be stored at 2–8 $^{\circ}$ C for up to 7 days. For long term storage, the samples should be kept frozen below –20 $^{\circ}$ C. Is recommended to avoid multiple freeze/thaw cycles.

It is highly recommended to use fresh samples previously typed by other methodology (i.e Indirect immuno-fluorescence microscopy, ELISA), for the training. If this is the case, please provide the following information:

- Type of Methodology
- Sample type and sample age
- Brand and Name of the kit used
- Instruction of Use of the kit used
- Results obtained

2. Required reagents included in the MBA kit:

The kits allows to perform up to 48 or 96 tests (depending on the kit). It is important to keep all kit's component stored at its recommended storage conditions between 2°C and 8°C.

Please check down in the list below the components that the laboratory has (Y) or does not have (N):

Catalog number	Description	<u>Y</u>	<u>N</u>
	Microplate		
	Positive Control		
	Conjugate		
	Substrate		
	Universal Solution		
	Calibration Card		
	Instruction for Use or e-Instruction for Use		

3. Reagents and Consumables required but not included in the kit:

Please check down in the list below the components that the laboratory has (Y) or does not have (N):

Reagent	<u>Provider</u>	<u>Catalog</u>	<u>Y</u>	<u>N</u>
Distilled water	Third party			
20uL sterile single use Tips	Third party			
200 uL sterile single use Tips	Third party			
1000 uL sterile single use Tips	Third party			
Disposable gloves, powder-free	Third party			
Lab Tissue	Third party			

4. Accesory equipment

Please check down in the list below the components that the laboratory has (Y) or does not have (N):

Equipment	<u>Provider</u>	Catalog	<u>Y</u>	<u>N</u>
2-20uL volume range Single Channel Pipette	Third party			
20-200uL volume range Single Channel Pipette	Third party			
100-1000uL volume range Single Channel Pipette	Third party			
20-200uL volume range Multi Channel Pipette	Third party			
Aspirator or ELISA plate Washer (optional)	Third party			
Vortex/ shaker	Third party			
Wash tray or reservoir	Third party			
Timer	Third party			
Microblot- Array Reader system including: - Microblot-Array Reader - PC ACER all in one (84714100) - TestLine Analytics software - MBA dryer (8514198000) - Barcode reader Kleeya/MBA (90275000) - Opaque and transparent calibration plates	TestLine Clinical Diagnostics s.r.o	ARCXIX096		
Internet connection for Array C Reader	Third Party	N/A		

The listed products are responsibility of the customer. The protocol has been optimized and validated using the elements listed. Performance is not guaranteed when using alternative supplies and equipment.

If there is any enquiry regarding the requested components for the training, please do not hesitate to contact the support team:

Marta Seifertová (Application Specialist): seifertova@testlinecd.com

Peter Döhmer (Technical and Product Specialist): dohmer@testlinecd.com

It is mandatory to send this document when all the working material requested is available at the laboratory, and before the training.

THE LABORATORY WILL ASSUME FULL RESPONSIBILITY FOR THE TRUTHFULNESS IN THE COMPLIANCE OF ALL THE PRE-REQUIREMENTS NOTED IN THIS CHECKLIST.

IRREGULARITIES, MISSING PROCEDURES OR REAGENTS THAT COMPROMISE THE TRAINING WILL RESULT IN THE CANCELLATION OF THE TRAINING.

The person designated here below as "contact" will be responsible for:

- The availability of reagents in the laboratory during training.
- Communicate to the participants of the day and time the training will be given.
- Communicate to the laboratory the training conditions described above.
- Provide the samples that will be processed during training

CONTACT SIGNATURE OF CONFORMITY

Name ans Surname	Signature
Telephone	Email
Date	Place

