EN

Instructions for use

HISTO SPOT® HLA AB Screen/ID Kits

Test kits for the identification of anti-HLA antibodies on a multiplex immunodiagnostic basis

Electronic instructions for use see www.bag-diagnostics.com

IVD CE

REF 728100: HISTO SPOT® HLA AB ID Class I (48 tests)

REF 728101: HISTO SPOT® HLA AB ID Class II (48 tests)

REF 728102: HISTO SPOT® HLA AB Screen/ID Class I (480 tests)

REF 728103: HISTO SPOT® HLA AB Screen/ID Class II (480 tests)

REF 728198: HISTO SPOT® AB Reagent Kit (96 tests)

Version: 11 / 2022

Issue: 2022-05

Changes to version 10 / 2020 highlighted in orange

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
A BAG Group company

T. +49 (0) 6404/925-100
F. +49 (0) 6404/925-460
M. info@bag-diagnostics.com
W. www.bag-diagnostics.com

Ordering:
T. +49 (0) 6404 / 925 - 450
F. +49 (0) 6404 / 925 - 460
M. order@bag-diagnostics.com

Customer Service:
T. +49 (0) 6404 / 925 - 125
F. +49 (0) 6404 / 925 - 421
M. service@bag-diagnostics.com

INHALT

1. INTENDED USE 2
2. PRODUCT DESCRIPTION 2
3. TEST PRINCIPLE 2
4. MATERIAL 3
4.1 Reagents provided with the HISTO SPOT® HLA AB Screen/ID kits specific for HLA class I and class II 3
4.1.1 HISTO SPOT® AB ID Class I kit 3
4.1.2 HISTO SPOT® AB ID Class II kit 3
4.1.3 HISTO SPOT® AB Screen / ID Class I kit 4
4.1.4 HISTO SPOT® AB Screen / ID Class II kit 4
4.2 Reagents provided with the HISTO SPOT® AB Reagent kit 4
4.3 Reagents and equipment required but not provided 4
5. STORAGE AND STABILITY 5
6. TEST PROCEDURE 5
6.1 Safety conditions and special remarks 5
6.2 Sample preparation 6
6.3 Automated assay on the MR.SPOT® / MR.SPOT® 2.0 processor 6
6.3.1 Reagent preparation 6
6.3.2 Sample / Control Dilution 7
6.3.3 Setup of the MR.SPOT® / MR.SPOT® 2.0 processor 8
6.3.4 Transfer of results to a PC for interpretation 8
6.3.5 Interpretation of results 8
7. WARNINGS AND PRECAUTIONS 10
8. SPECIFIC PERFORMANCE CHARACTERISTICS 11
8.1 Analytical sensitivity 11
8.2 Diagnostic sensitivity 11
8.3 Diagnostic specificity 11
8.4 Repeatability 12
9. LIMITATIONS OF THE METHOD 12
10. INTERNAL QUALITY CONTROL 13
11. TROUBLESHOOTING 13
12. TRADEMARKS USED IN THIS DOCUMENT/PRODUCT 13
13. EXPLANATION OF SYMBOLS USED ON LABELING 14

1. INTENDED USE

The intended use of the HISTO SPOT® HLA AB Screen/ID kits is

- the screening and identification of anti-HLA antibodies in planned organ transplantation
- the monitoring of donor specific anti-HLA antibodies after organ transplantation
- the detection of possible anti-HLA antibodies before platelet transfusions in refractory patients

The kits are intended to be used by health care professionals with experience in HLA antibody diagnostics in:

- transplantation centers
- hospital laboratories

Anti-HLA antibody testing for transplantation purposes must follow guidelines issued by professional societies like the European Federation for Immunogenetics (EFI), the American Society for Histocompatibility and Immunogenetics (ASHI) or national societies like the Deutsche Gesellschaft für Immungenetik (DGI).

2. PRODUCT DESCRIPTION

The HISTO SPOT® HLA AB kits are in vitro diagnostic medical devices for identification of anti-HLA antibodies on a multiplex immunodiagnostic basis and provides high resolution antibody (Ab) identification results.

The HISTO SPOT® HLA AB screening and identification kits contain testwells with immobilized HLA Class I or Class II antigens for the detection of specific anti-HLA antibodies, the sample buffer, a negative control and a positive control. The HISTO SPOT® AB Reagent kit contains the reagents required for incubation and detection of bound antibodies and can be used in combination with all HISTO SPOT® HLA AB screening and identification kits. The test is performed with a microarray processor. The MR.SPOT / MR.SPOT 2.0 processor is validated for automatic processing of the HISTO SPOT kits. Between 1 and 96 tests can be processed simultaneously. The interpretation of the results is done with the HISTO MATCH HLA AB module software.

3. TEST PRINCIPLE

The test includes four basic steps:

- sample preparation

- incubation

- detection

- data interpretation

The HISTO SPOT® HLA AB Screen/ID test is a miniaturized and multiplexed solid phase enzyme linked immunosorbent assay. Each well of the microtiter plates is printed with various recombinant ~~or native~~ HLA antigens. Each antigen is printed on the bottom of the well to have an independent spot.

After dilution, the sera are transferred in the testwells containing an array of immobilized HLA antigens. In the subsequent incubation time anti-HLA antibodies present in the serum bind to their specific antigens. In a first wash step non-specific antibodies are removed. Following this wash step, a specific peroxidase -labelled antibody directed against human IgG (conjugate) is added in the wells to bind to the present antibody-antigen complexes in the subsequent incubation time. Afterwards wash buffer is added to the wells to remove unbound conjugate. Then a TMB substrate is added to each well. If peroxidase is present an enzyme-substrate reaction takes place which causes a blue colouring of the spots. The dots in the bottom of each test well are photographed by the camera of the microarray processor and the image is transferred into the HISTO MATCH HLA AB module software installed on the PC of the user. The image analysis program of the HISTO MATCH HLA AB module software determines the intensity of each spot in the array and compares it to the intensity of the background. From this data the positive and negative reactions are calculated. The pattern matching program of the HISTO MATCH HLA AB module software identifies the HLA antibodies of the sample against the HLA antigens of the pattern in the array.

4. MATERIAL

4.1 Reagents provided with the HISTO SPOT® HLA AB Screen/ID kits specific for HLA class I and class II

All batch files and instructions for use are provided on the CDs with the kits and can be downloaded from the website: https://www.bag-diagnostics.com/en/downloads.html

4.1.1 HISTO SPOT® AB ID Class I kit

Testwells Abs | Class I	8-well strips, individually packed, each strip containing 8 tests, contains immobilized HLA Class I antigens
SAMBUF **Class I**	Sample Buffer, ready to use, contains < 0.05% Proclin® 300 (pink liquid)
CONTROL | +	Positive control, concentrated solution, to be diluted (red cap)
CONTROL | -	Negative control, ready to use, contains 0.04% Proclin® (yellow cap)

With each kit there is a CD containing the instructions for use and the batch file that has to be stored within the database of the interpretation software.

4.1.2 HISTO SPOT® AB ID Class II kit

Testwells Abs | Class II	8-well strips, individually packed, each strip containing 8 tests, contains immobilized HLA Class II antigens
SAMBUF **Class II**	Sample Buffer, ready to use, contains < 0.05% Proclin® 300 (orange liquid)
AD | 1	Additive for the Sample Buffer, to be diluted 1:100 in sample buffer
CONTROL | +	Positive control, concentrated solution, to be diluted (blue cap)
CONTROL | -	Negative control, ready to use, contains 0.04% Proclin® (white cap)

With each kit there is a CD containing the instructions for use and the batch file that has to be stored within the database of the interpretation software.

4.1.3 HISTO SPOT® AB Screen / ID Class I kit

Testwells Abs | Class I	96-well plates, individually packed, each plate containing 96 tests, contains immobilized HLA Class I antigens
SAMBUF **Class I**	Sample Buffer, ready to use, contains < 0.05% Proclin® 300 (pink liquid)
CONTROL | +	Positive control, concentrated solution, to be diluted (red cap)
CONTROL | -	Negative control, ready to use contains 0.04% Proclin® (yellow cap)

With each kit there is a CD containing the instructions for use and the batch file that has to be stored within the database of the interpretation software.

4.1.4 HISTO SPOT® AB Screen / ID Class II kit

Testwells Abs | Class II	96-well plates, individually packed, each plate containing 96 tests, contains immobilized HLA Class II antigens
SAMBUF **Class II**	Sample Buffer, ready to use, contains < 0.05% Proclin® 300 (orange liquid)
AD | 1	Additive for the Sample Buffer, to be diluted 1:100 in sample buffer
CONTROL | +	Positive control, concentrated solution, to be diluted (blue cap)
CONTROL | -	Negative control, ready to use contains 0.04% Proclin® (white cap)

With each kit there is a CD containing the instructions for use and the batch file that has to be stored within the database of the interpretation software.

4.2 Reagents provided with the HISTO SPOT® AB Reagent kit

The reagents contained in one kit are sufficient for 96 tests. Each reagent set contains:

~~**SAMBUF**~~	~~Sample Buffer, ready to use, contains 0.05% Proclin® 300~~
WASHBUF	Wash Buffer, ready to use, contains < 0.05% Proclin® 300
CONJ | AB	Conjugate, Anti-human IgG conjugate with horseradish peroxydase, contains < 0.05% Proclin® 300
CONJBUF	Conjugate diluent Buffer, ready to use, contains < 0.05% Proclin® 300
SUBS | AB	Substrate, ready to use, (**3,3′,5,5′-Tetramethylbenzidine**)

With each kit there is a CD containing the instructions for use.

4.3 Reagents and equipment required but not provided

- Validated microarray processor
- HISTO MATCH software, REF 726102
- Pipetting tips for the microarray processor
- Sample plate: Skirted PCR plates with lids or adhesive film
- Deionized water
- Variable pipettes (range 0.5 – 1000 µl) and disposable tips

Validated microarray processors	Validated pipetting tips	Validated sample plates and closing systems
MR.SPOT® Prozessor REF 726100 Comp. BAG Diagnostics	HISTO SPOT® Pipetting Tips 1000 µl REF 726099 200 µl REF 726097 Comp. BAG Diagnostics	FrameStar® Break-A-Way PCR Plate REF 726220 HISTO SPOT® PCR Caps REF 726090 HISTO SPOT®PCR Foils REF 726089 Comp. BAG Diagnostics
MR.SPOT® 2.0 Prozessor REF 726110 Comp. BAG-Diagnostics		

5. STORAGE AND STABILITY

All reagents and kit components have to be stored at 2...8ºC.

The expiry date is indicated on the label of each reagent and is valid for the originally sealed reagents. The expiry date indicated on the outer box label refers to the reagent with the shortest stability contained in the kit.

Assay performance is dependent on reagents stability. They must not be used after their expiration date.

In use stability: Testwells stored in open foil pouches **must be used within 7 days after opening**. Opened reagents must be used within 1 months after opening.

The conjugate dilution must always be **prepared afresh** for each test run.

If the protective packaging is damaged, please contact the customer service.

6. TEST PROCEDURE

6.1 Safety conditions and special remarks

The HISTO SPOT® HLA AB test should be performed by well trained and authorized laboratory technicians. The HISTO SPOT® HLA AB kits can only be used in combination with the HISTO SPOT® AB Reagent kit, a validated microarray processor (MR.SPOT® / MR.SPOT® 2.0 processor) and the HISTO MATCH HLA AB module software.

The results from these tests must not be used as the sole determinant for making clinical decisions.

Special safety conditions must be noted in order to avoid contamination and thus false reaction:

- Wear gloves during work (powder-free, if possible).
- Use new tips with each pipeting step (with integrated filter).
- Use devices and other materials only at the respective places and do not exchange them.

All the reagents and troughs used for the assay must be those indicated for the HISTO SPOT® HLA AB test. The reagents and troughs indicated for SSO DNA testing must be excluded from the processor when a HISTO SPOT® HLA AB test is running.

6.2 Sample preparation

Serum samples must be used. Samples collected with anti-coagulant can not be used.

EDTA treatment of the serum is consistent with the assay. Samples heat inactivated and samples with microbial contamination may give nonspecific reactions and should not be used. Lipaemic or hemolyzed samples should be avoided.

Serum can be stored at -20°C prior testing. Avoid repeated freezing and thawing of the samples.

Take samples out of the freezer and allow them to warm to room temperature. Samples must be clarified by centrifugation (from 1 to 5 min, from 2500 to 10 000 g) prior to testing.

If there is a fatty layer on the serum after centrifugation this has to be removed or the clearer part of the sample has to be withdrawn and used for the testing.

Vortex the clarified sample before dilution.

6.3 Automated assay on the MR.SPOT® / MR.SPOT® 2.0 processor

6.3.1 Reagent preparation

- Take HISTO SPOT® AB reagents and HISTO SPOT® HLA AB testwells out of the fridge and allow them to warm to room temperature.
- Homogenize the reagents **SAMBUF** and **CONJBUF** by shaking before use.
- Vortex the **CONTROL | -** before use.
- The additive for the sample buffer **AD | 1** has to be diluted 1:100 in sample buffer for class II **SAMBUF** **Class II** prior to testing. Volumes depend on the number of samples to be tested, e.g. for 1 ml of diluent buffer add 10 µL of **AD | 1** in 1 ml of **SAMBUF** **Class II**
- The dilution of **AD | 1** must always be prepared afresh for each test run.
- **Salt crystals** may be observed in the Wash Buffer (**WASHBUF**). **Before using warm the Wash Buffer 15 minutes at 30°C to dissolve.** Warm the whole content of the bottle, not an aliquot. Check by eyes if there are no residual crystals remaining, warm it again if it is the case.
- The conjugate has to be diluted 1:100 in Conjugate diluent Buffer **CONJBUF** prior to testing.
- The conjugate dilution must always be prepared afresh for each test run.
- The conjugate has to be vortexed and spun down each time before the dilution step!

The required volumes of the reagents will vary depending on the number of strips to be tested. The MR.SPOT® / MR.SPOT® 2.0 processor displays the required volumes for the chosen number of strips. Fill the required volumes of the reagents into the corresponding labelled reservoirs.

Reagents used for a run can not be reused for a second run. After each run, all the reagents should be discarded.

6.3.2 Sample / Control Dilution

It is possible to incubate simultaneously **Testwells Abs | Class I** and **Testwells Abs | Class II** in the same RUN but with caution on the volumes, different sample buffers and the arrangement of the different sera in the plate.

Sample dilution:

HLA AB Class I:

- add 10 µl of the serum and 90 µl of **SAMBUF Class II** into the sample plate.

HLA AB Class II:

- dilute the additive for the sample buffer **AD | 1** 1:100 in sample buffer for class II **SAMBUF Class II**. Volumes depend on the number of samples to be tested, e.g. for 1 ml of diluent buffer add 10 µl of **AD | 1** in 1 ml of **SAMBUF Class II**.
  The dilution of **AD | 1** must always be prepared afresh for each test run
- add 2 µl of the serum and 160 µl of diluent buffer from the previous step into the sample plate.

Mix at least 5 times or vortex and centrifuge the closed sample plate after dilution.

Dilution of the controls:

For each run and each assay (Class I and Class II) a positive control and a negative control should be included.

- Pre-dilution of the positive control (1:50):

add 1 µl of **CONTROL | +** in 50 µl of **SAMBUF Class I** or **SAMBUF Class II**, vortex

- Dilution of the controls

The controls are diluted in the same way as the serum samples:

HLA AB Class I:

add 10 µl of the **CONTROL | -** NC01 / diluted **CONTROL | +** PC01 and
90 µl of **SAMBUF Class I** into into the sample plate.

HLA AB Class II:

add 2 µl of the **CONTROL | -** NC02 / diluted **CONTROL | +** PC02 and
160 µl of diluent buffer into the sample plate.

Mix at least 5 times or vortex and centrifuge the sample plate after dilution.

The serum sample dilutions given above (1:10 for class I and 1:80 for class II) have been validated and give optimal results with most of the tested samples. If the sera show very weak or very strong reactions other dilutions might be better. If the results are unclear it is recommended to titrate the sera.

Place the sample plate with the diluted sera and controls in the sample plate holder in the MR.SPOT® / MR.SPOT® 2.0 processor. Be careful to do this with the correct orientation of the sample plate.

Place the testwells into the reaction plate holder of the MR.SPOT® / MR.SPOT® 2.0 processor.

Note the correct arrangement of the testwells according to the worklist layout.

Please make sure that there is no dirt or plastic particles in the reaction plate holder.

The testwells can be separated in single wells according to figure 1, if less than eight tests should be run. If you are using separated wells be careful that they are sitting properly in the reaction plate holder and are not twisted against each other. Clear dummy wells have to be added to reach test numbers of multiples of four.

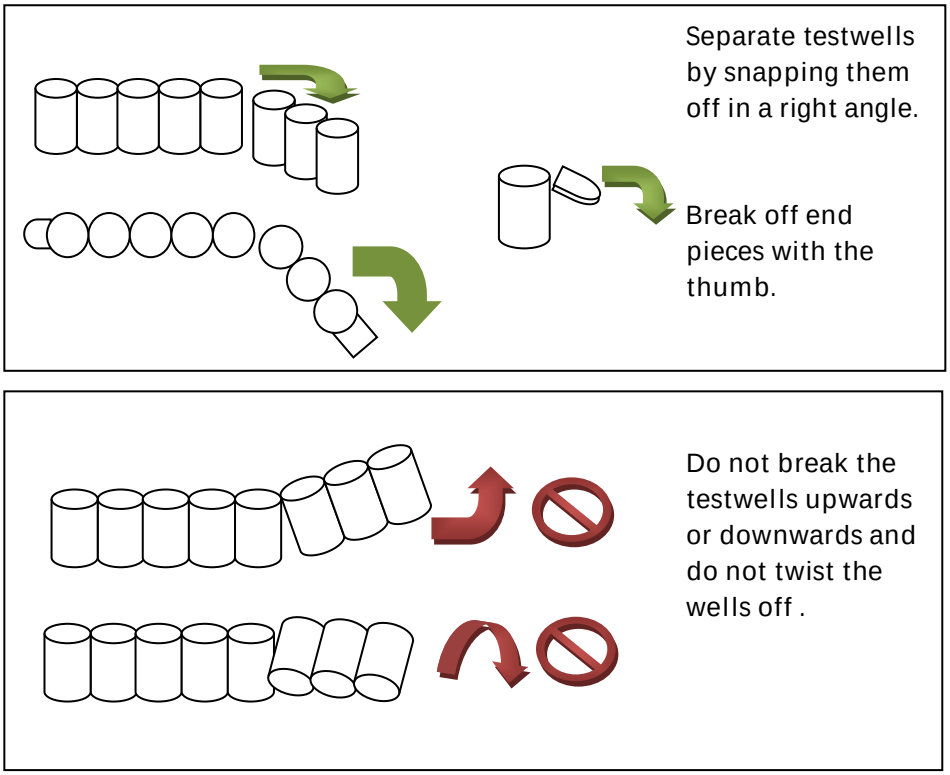

Fig. 1: Separating single testwells

6.3.3 Setup of the MR.SPOT® / MR.SPOT® 2.0 processor

Switch on the MR.SPOT®/ MR.SPOT® 2.0 processor. The start up screen will appear. Follow the process as indicated on the screen. Details are described in the User Manual for the MR.SPOT®/ MR.SPOT® 2.0 processor.

The temperature in the processor must not exceed 30°C.

6.3.4 Transfer of results to a PC for interpretation

Transfer the data to the HISTO MATCH HLA AB module software via network or USB stick as described in the manual for the HISTO MATCH software.

6.3.5 Interpretation of results

Please make sure you are using the latest version of the HISTO MATCH HLA ABS module which is version 4.2.1. For details of the interpretation please read the instructions for use for the HISTO MATCH software.

Open the HISTO MATCH HLA AB module software (if this is not already installed please contact your local distributor or our customer service at complaint@bag-diagnostics.com) and interpret the data as described in the manual for the HISTO MATCH software.

The images should look like the example shown in figure 2. Figure 3 gives a schematic illustration of the result and the functions of the different spots.

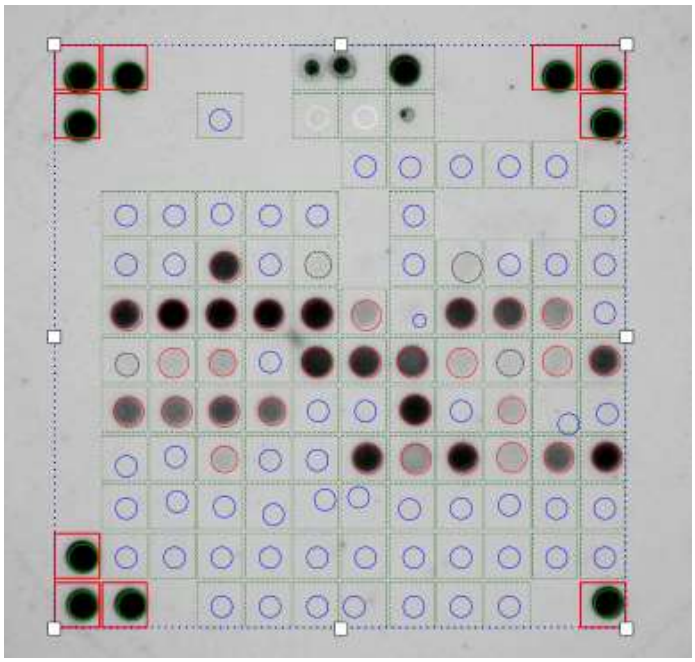

Figure 2: Example for a sample containing anti-HLA Class I antibodies.

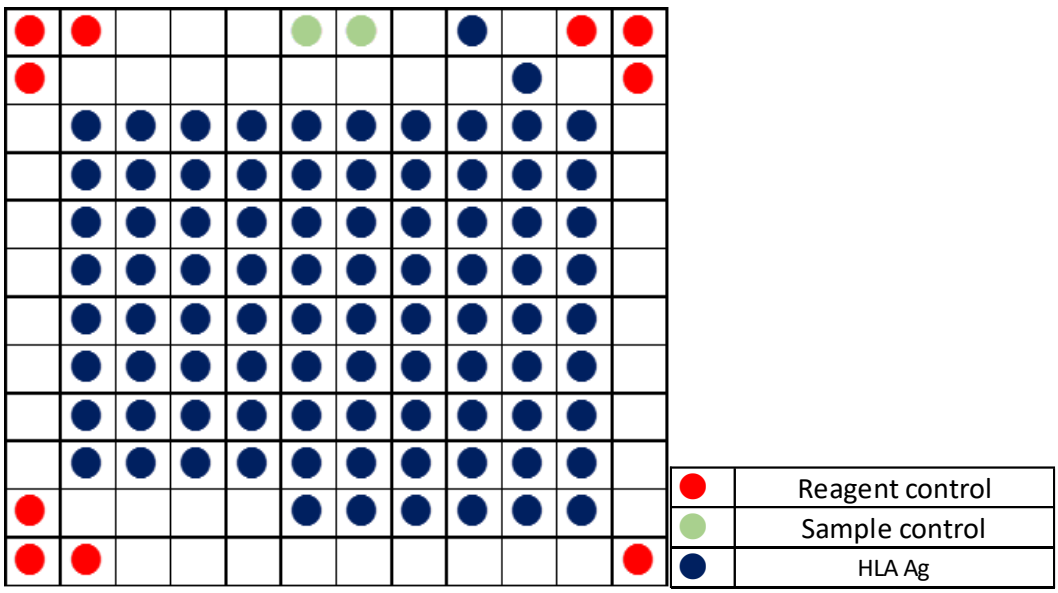

Figure 3: Schematic representation of the HISTO SPOT® HLA AB ID Class I

The interpretation of the spots performed by the software must be checked visually by the operator.
The automatic interpretation is meant as a tool to aid the user and must be validated by checking the image and the plausibility before assigning any result.
In the case of non-valid results due to e.g. dust or smear the operator can move the spot area in the grid or disable the spot (please see the instructions for use for the HISTO MATCH HLA AB module for details).

If a patient serum reacts positive with more than 80% of the antigens on the testwell on the microarray, the results are considered uninterpretable as these positivities can be considered as non-specific. A new test must be performed at a higher dilution (e.g. **1:20 for Class I** and **1:200 for Class II)** to avoid non-specific interaction and put in evidence the specific interaction.

The positive control sera should show the following expected positives reactions:

Class I: positive with all class I antigens (specific for public epitopes)

Class II: positive with all DP, all DR and the DQ2 antigens (specific for public epitopes)

7. WARNINGS AND PRECAUTIONS

The HISTO SPOT® HLA AB kits are designed for in vitro diagnostic use and should be used by properly trained, qualified staff. All work should be performed using Good Laboratory Practices.

Biological material used, e.g. sera, should be handled as potentially infectious. When handling biological material appropriate safety precautions are recommended (do not pipet by mouth; wear disposable gloves while handling biological material and performing the test; disinfect hands after finishing the test). Biological material should be inactivated before disposal (e.g. in an autoclave). Disposables should be autoclaved or incinerated after use.

Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a suitable standard disinfectant or 70% alcohol.

Material used to clean spills, including gloves, should be inactivated before disposal (e.g. in an autoclave).

SAMBUF, **WASHBUF**, **CONJBUF**, **CONJ| AB** and **CONTROL | -** contain ProClin®300 in a very low concentration of ≤ 0.05% as preservative, nevertheless avoid contact with the skin and mucous membranes.

Do not expose **SUBS | AB** to metals, oxidising agents. **SUBS | AB** may possess skin sensitizing and slightly water polluting properties.

All work with reagents should be handled with the appropriate precautions. Wear eye protection, laboratory coats and disposable gloves when handling the reagents. Avoid contact of these materials with the skin, eyes or mucous membranes. If contact does occur, immediately wash with large amounts of water. Burns can occur if left untreated.

If spills of reagents occur, dilute with water before wiping dry.

Disposal of all samples, unused reagents and waste should be in accordance with country, federal, state and local regulations.

Avoid microbial contamination of reagents when removing aliquots from reagent bottles. The use of sterile disposable pipettes and pipette tips is recommended. Do not use reagents with evidence of turbidity or microbial contamination.

To avoid bacterial growth in the tubing, the MR.SPOT® / MR.SPOT®2.0 processor must be disinfected monthly with a suitable disinfectant following the procedure indicated in the manual.

Material Safety Data Sheets (MSDS) are available to download at www.bag-diagnostics.com .

8. SPECIFIC PERFORMANCE CHARACTERISTICS

8.1 Analytical sensitivity

Class I: All antigens are detected with the positive control (W6/32 monoclonal antibody) at a concentration of 0.3 ng/ml and above.

Class II: All antigens expected positive for the positive control (monoclonal antibody F3.3) are detected at a concentration of 0.3 ng/ml and above (except for the antigen DPA1*02:02-DPB1*15:01 which can be detected at 1 ng/µl and above).

8.2 Diagnostic sensitivity

Class I:

96% detection of the positive consensus specificities assigned by more than 95% of the participating centers of the external proficiency testing (EPT from Eurotransplant, Netherlands) with a Luminex Single antigen assay for 59 positive sera with 1873 reported consensus specificities.

Class II:

92% detection of the positive consensus specificities assigned by more of 95% of the participating centers (EPT from Netherlands, SFHI from France) of the external proficiency testing with a Luminex Single antigen assay for 92 sera with 1239 reported consensus specificities.

100% detection of the specificities of 4 monoclonal antibodies with 9 reported CDC specificities.

8.3 Diagnostic specificity

Class I:

92% of the negative consensus specificities assigned by more of 95% of the participating labs for the external proficiency testing (EPT from Eurotransplant,Netherlands) with a Luminex Single antigen assay are negative with the HISTO SPOT® HLA AB Class I kits for 59 sera and a total of 2377 reported negative consensus specificities.

Class II:

97% detection of the negative consensus specificities assigned by more than 95% of the participating centers (EPT from Netherlands, SFHI from France) of the external proficiency testing with a Luminex Single antigen assay are negative with the HISTO SPOT® HLA AB Class II kits for 92 sera with 3669 reported consensus specificities.

~~8.4 Repeatability~~

~~Class I:The global coefficient of variation (CV) of the mean signal intensity (MCI) obtained with 8 replicates of the positive control at three different concentrations was between 1% and 3%. The global CV obtained for 8 replicates of 6 patient sera was between 6% and 9%.~~

~~Class II: The global coefficient of variation (CV) of the mean signal intensity (MCI) obtained with 6 replicates of the positive control at two different concentrations was between 4% and 6%.~~

9. LIMITATIONS OF THE METHOD

Extreme care should be taken to prevent bacterial contamination of the kit reagents and other laboratory materials and equipment.

Erroneous results can occur if inadequate reagents, temperature, incubation period or washing are used. Therefore, the HISTO SPOT® HLA AB tests should only be used in combination with a validated microarray processor (MR.SPOT® / MR.SPOT® 2.0 processor) to ensure correct temperatures and incubation times.

All instruments (e.g. pipettes, MR.SPOT® / MR.SPOT® 2.0 processor) must be calibrated according to the manufacturers instructions.

Samples from patients with autoimmune disorders or receiving immunoglobulin therapy have not to be tested. Such samples may give false positive or false negative results.

If a patient serum reacts positive with more than 80% of the antigens on the testwell, a retest must be performed at a higher dilution, to avoid false positive interaction.

Some very low titer antibodies to HLA antigens may not be detected and may give false negative results.

The pretreatment of the sample that are not listed in the preparation section must be validated by the laboratory prior testing.

10. INTERNAL QUALITY CONTROL

Internal positive controls are contained in each testwells to ensure sucessful incubation and reagent dispensing.

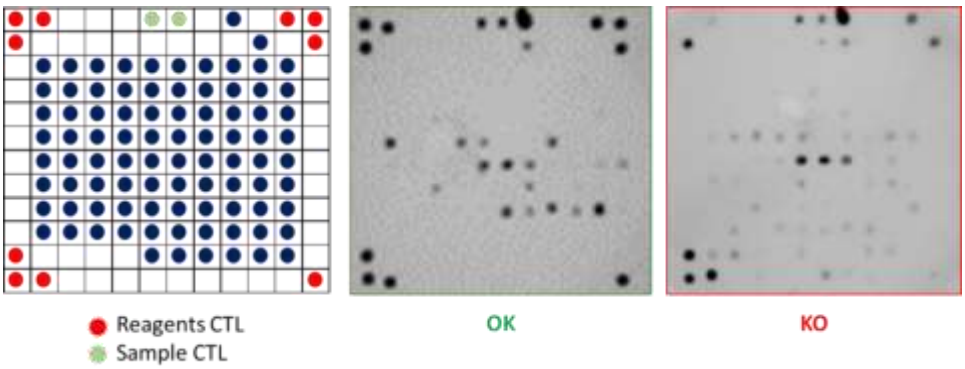

Figure 4: Control checking before the validation of the assay (CTL = Control)

The operator must check on the picture that all the CTL spots are positive before assigning a result. In case of low or no spots for IgG or anti-IgG CTL, the result cannot be interpreted.

11. TROUBLESHOOTING

Symptom	Possible problem(s)	Potential Solution(s)
Instrument malfunction	Numerous	Refer to MR.SPOT® / MR.SPOT® 2.0 manual
Error message at data transfer	Failure in data transfer	Manually transfer data using USB drive
No result	Failure to grid image	Perform manual gridding
No spots in the well	Failure to add a reagent	Repeat whole assay
No result / inconclusive result due to weak signals	Mistake in conjugate dilution Instrument malfunction	Repeat assay Check instrument

12. TRADEMARKS USED IN THIS DOCUMENT/PRODUCT

Proclin® is a trademark of Rohm and Haas company.

FrameStar® is covered by one or more of the following US patents or their foreign counterparts, owned by Eppendorf AG: US Patent Nos. 7, 347, 977 and 6, 340, 589. FrameStar® is a registered trademark owned by the company Azenta Life Sciences.

13. EXPLANATION OF SYMBOLS USED ON LABELING

	Storage temperature / Temperature limitation
	Use by
	Consult instructions for use
	Sufficient for n tests
	Manufacturer
CLASS I	HLA Class I
CLASS II	HLA Class II
CONJ | AB	Anti-human IgG conjugate (horseradish peroxydase)
CONJBUF	Conjugate diluent buffer
CONTROL | +	Positive control
CONTROL | -	Negative control
eIFU	Electonic instructions for use
HLA ANTIBODY ID	Intended use: anti-HLA antibody identification
IVD	For in vitro diagnostic use
LOT	Batch code
REF	Catalogue number
SAMBUF Class I	Sample buffer for class I
SAMBUF Class II	Sample buffer for class II
AD | 1	Additive for sample buffer for class II
SUBS | AB	Substrate
Testwells Abs | Class I	Testwells with printed HLA Class I Antigens
Testwells Abs | Class II	Testwells with printed HLA Class II Antigens
WASHBUF	Wash buffer
HISTO SPOT® HLA AB Information CD	CD, contains the Instructions for use and with the HISTO SPOT® HLA AB Screen/ID kits additionally the Batch File

Instructions for use in other languages see http://www.bag-diagnostics.com

or phone +49 (0)6404-925-125