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Date: 2024-05-06

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Field Safety Notice
HISTO SPOT® AB Reagent Kit

Dear customers,

we regret to inform you that there is a mistake in the batch file of the HISTO SPOT® HLA AB ID Class I Kit. The nomenclature of the antigens is not compatible with the interpretation in the latest HISTO MATCH version 4.3.1 software. Interpretation is not possible for worklist with results generated with the batch file ABS I 154-17. The batch file has been corrected and uploaded to the download section of our website ([BAG Diagnostics - Downloads - Home \(bag-diagnostics.com\)](https://www.bag-diagnostics.com/Downloads-Home))

Please don't use the batch file on the CDs provided with the kit.

Information on Affected Devices	
1.	Commercial name(s) HISTO SPOT® HLA AB ID Class I
2.	Intended purpose of device(s) Screening and identification of HLA antibodies in planned organ transplantation, for monitoring of donor specific anti-HLA antibodies (DSA) after organ transplantation and in platelet transfusion recipients if there is platelet transfusion refractoriness
3.	Affected serial or lot number range REF 728100 HISTO SPOT® HLA AB ID Class I Lot: C103-23072001

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Type of Action to mitigate the risk

- | | |
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| 1. | <p>Action To Be Taken by the User</p> <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </div> <p><input checked="" type="checkbox"/> On-site device modification/inspection</p> <p><input type="checkbox"/> Follow patient management recommendations</p> <p><input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)</p> <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Other <input type="checkbox"/> None </div> <ul style="list-style-type: none"> - Do not use the batch file on the CD - Use the corrected batch file provided on the website or sent by email |
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